REACHLAW

STUDY ON

THE IMPACT OF **REACH AND CLP EUROPEAN CHEMICAL REGULATIONS** ON THE DEFENCE SECTOR

FINAL REPORT

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DISCLAIMER

This study was commissioned by the European Defence Agency. The study does not, however, express the Agency's official views.

While the study has been conducted in close collaboration with the EDA, which was supported at technical level by the EDA REACH Task Force (comprised of EDA participating Member States' Ministries of Defence REACH experts) and considering also input from the consultation of various stakeholders, the views expressed and all recommendations made are those of the authors, unless stakeholder opinions are explicitly quoted.

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With special regard to proposals submitted in the study, they do not imply that the stakeholders that are identified as proposal addressees are in any way committed to accept or act upon them, but merely to utilise them as basis for further consideration.

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[1] See list of consultees in Annex B.

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BACKGROUND AND OBJECTIVES

The REACH[2] and CLP[3] Regulations (and the processes involved e.g. authorisation, restrictions) may have a significant impact on European defence capabilities during the whole life cycle of defence equipment (design, manufacturing, in-service use and maintenance, disposal) and therefore on the European Defence Technological and Industrial Base (EDTIB). EU Ministries of Defence (MoDs) and their suppliers, namely defence industry, may not be able to implement all technological changes needed in order to be REACH compliant at a reasonable cost while maintaining the required performance level. In addition to REACH and CLP, other European Regulations on chemicals (e.g. BPR, ODS, POP[4]) also have an impact on European defence capabilities.

Among the aforementioned chemical Regulations, REACH, and the associated CLP Regulation, may have the greatest impact on defence capabilities, primarily due to the extended lifecycle of military equipment. A REACH Regulation review is planned by the European Commission (EC) to take place in 2017, to prepare the future of the Regulation beyond 2018.

Against this background, the European Defence Agency (EDA) commissioned REACHLaw Ltd. to conduct a *"Study on the Impact of REACH and CLP European Chemical Regulations on the Defence Sector"*.

[2] Registration, Evaluation, Authorisation and Restriction of Chemicals according to Regulation (EC) No 1907/2006.

[3] Classification, Labelling and Packaging according to Regulation (EC) No 1272/2008.

[4] Biocidal Products Regulation (Regulation (EC) No 528/2012); Ozone Depleting Substances (Regulation (EC) No 1005/2009); Persistent Organic Pollutants (Regulation (EC) No 850/2004).

The **objectives** of this study were:

1. Impact analysis of REACH and CLP on EU defence sector, both industry and governments;
2. Practical proposals on improvements for REACH and CLP and their current implementation regime, to serve as a basis for EDA, and its participating Member States' (pMS), input to the EC for the next REACH review and as suggestions for REACH evolutions beyond 2018;
3. Synthesis of information on impacts of other chemical regulations on EU Member States MoDs and the defence sector (especially BPR, ODS, POP), their interaction with REACH and CLP, and a strategy (draft as a minimum) with proposals for improvements.

It is important to see these study objectives in the light of the overarching goal to ensure the proper development of the EDTIB for the benefit of EU MoDs as EDA shareholders, as well as the preservation of capabilities, including sustainability of defence equipment maintenance processes performed by EU MoDs and related to equipment of EU or non-EU origin. Therefore, the analysis of impacts and proposals for their mitigation in relation to the defence industry is not to be seen in isolation as they are intrinsically linked to the role of the defence industry to support Member States in retaining existing and/or developing new, critical defence capabilities in the future.

This is in line with the current highest political discussions related to the EU Global Strategy and its implementation plan for defence and security as recently agreed by Member States at the level of the Council of the European Union[5] which among others called for measures to strengthen the EDTIB *"…..In line with the European Council Conclusions of December 2013 on security and defence, the Council reiterates the need to enhance the effectiveness of CSDP and the development and maintenance of Member States' capabilities,* ***supported by a more integrated, sustainable, innovative and competitive European Defence Technological and Industrial Base (EDTIB), which also contributes to jobs, growth and innovation across the EU and can enhance Europe's strategic autonomy, strengthening its ability to act with partners****. The Council recalls that these efforts should be inclusive, with equal opportunities for defence industry in the EU, balanced and in full compliance with EU law."*

METHODOLOGY

Targeted Stakeholders: With the support of the EDA and the EDA REACH Task Force experts, different key stakeholder groups were targeted in the study consultation, thus ensuring thorough coverage of the stakeholder issues:

- **All EU MoDs**;
- **Defence Industry**, including the ASD REACH Implementation Working Group, all EU National Defence Industry Associations (NDIAs), selected individual EU companies (comprising both large system integrators and SMEs) as well as major non-EU companies with EU operations;
- **The European Commission, European Chemicals Agency (ECHA) and REACH Member State Competent Authorities (MSCAs)**.

[5] COUNCIL CONCLUSIONS ON IMPLEMENTING THE EU GLOBAL STRATEGY IN THE AREA OF SECURITY AND DEFENCE, Foreign Affairs Council, 14 November 2016.

Stakeholders' Responses: In total, responses have been received from over 100 stakeholder organisations in 20 EU Member States and the United States (US), providing a solid evidence base for the study impact assessment which, in turn, gave rise to the improvement proposals.

Stakeholder Responses to the Study Consultation						
Defence Industry			Public bodies			Other (e.g. upstream suppliers, trade union)
EU Associations	EU companies	Non-EU companies	EU MoDs + EDA	REACH MSCAs	EC, ECHA	
4	27	5	13[6] + 1	17	2	33

KEY FINDINGS

The study has confirmed that the impact of REACH on the European defence sector is fundamentally determined by the combination of characteristics relating to the manufacture, import or through life use of their products, especially:

- Customers are mainly governments, i.e. the EU MoDs and Armed Forces;
- Products are a variety of highly complex and performance-driven defence systems (such as military aircraft, ships, tanks, munitions) and components (such as electronics and sensors);
- There are complex multi-tier, international product supply chains, that are often shared with other sectors that represent a larger market share (military as a niche use);
- Military equipment has very long and controlled lifecycles (typically for decades) for design, production and in-service phases, generating the need for Maintenance, Repair and Overhaul (MRO) activities;
- Typically a low volume use of chemicals because defence systems are produced in very small series and are sometimes tailor-made.

Against this background, the following key findings have been derived on the impact of REACH and CLP on EU defence sector based on the study consultation[7]:

[6] The MoDs that responded represent 90.5 % of the European defence expenditure, according to 2014 EDA defence data (https://www.eda.europa.eu/info-hub/defence-data-portal) and SIPRI database (https://www.sipri.org/sites/default/files/Milex-local-currency.pdf). In terms of defence industry annual turnover they represent 91.3 % of the European defence industry, according to EDA 2015 Study on Defence Industry Data Figures, Final Report. Greece is excluded from the defence industry turnover percentage, due to a lack of available data.

[7] **Important Note**: All percentages and comparative terms (e.g. majority of) mentioned in the key conclusions are **in reference to the overall number of stakeholders that responded to the study consultation**, and not the overall number of stakeholders that were targeted for consultation.

1. REACH authorisation timelines are strongly mismatched to the defence sector

There is a strong mismatch between the timelines of REACH authorisation (sunset dates of typically 3 years after Annex XIV inclusion and review periods for granted authorisations ranging from 4, 7 to 12 years) for Substances of Very High Concern (SVHCs) and the very long equipment lifecycles in the defence sector, which often requires the use of particular SVHC substances (up to several decades) for production and maintenance. This is causing defence companies in some instances, to implement quick substitutes of mostly lower technical performance (short term substitution) to avoid the double resource-intensive effort of authorisation and replacement, dependence on a shrinking number of suppliers and uncertainties associated with the possible need for several authorisation renewals even if prospects to obtain authorisation may be good, if the argumentation is robust. This negatively affects the defence companies' competitiveness and innovation potential.

2. Insufficient Research and Development (R&D) funding for SVHC substitution

There is insufficient R&D funding for substitution at all levels: industry, Member States and EU. R&D policy makers at national (Member State, defence industry) or EU level often consider REACH related substitution as a regulatory cost issue and not as innovative R&D. At the same time there is a strong willingness, both within industry and MoDs, to perform substitution R&D in a collaborative approach, at least at low Technology Readiness Levels (TRL).

A large majority of defence industry stakeholders (78.6%) have confirmed that substitution R&D activities have increased in their organisation or supply chain as a result of REACH. About half of MoDs (45.5%) are performing, financing or promoting R&D activities for SVHC substitution, including through the EDA and NATO. However, the budgets of both defence industry and MoDs have not increased and the R&D for substitution is performed to the detriment of other R&D activities.

Diminished innovative R&D could, therefore, potentially lead to a loss of future competitiveness. A large majority of the defence industry (70%) foresee a specific threat in this regard, while only 13% consider that REACH has already led to a gain on the company's global competitiveness.

3. REACH obsolescence causes risks to Security of Supply (SoS)

Obsolescence / SoS are a major concern for industry and MoDs, given the limited visibility towards chemicals and processes upstream in their very complex supply chains. The issue is expected to worsen with REACH Registration in 2018 (1 - <100 tonnes / year) and the further evolution of Annex XIV. Supply chain communication to anticipate such risks is very challenging due to complexity, confidentiality and intellectual property considerations and differences in information quality.

A significant majority (77.5%) of the defence industry have already been impacted by REACH related obsolescence (unavailability for supply of substances, mixtures or articles) from upstream suppliers. According to 69% of the defence industry this has also resulted in some own process/product obsolescence. While in the majority of such obsolescence cases this has not resulted in loss of business to date (73%), the required mitigation activities always come at a cost. This effect is further exacerbated by the cumulative nature of the obsolescence impact at the end user level.

In line with this finding, the majority of the MoDs responding believe that REACH is a challenge to maintain Security of Supply. Obsolescence is seen as the main REACH related challenge to Security of Supply. MoDs have already reported occurrences of shrinking supplier base, monopoly situations or

complete cessation of production by single source suppliers due to costly REACH compliance requirements (especially authorisation).

4. Unpredictability of REACH SVHC regulation

The unpredictability surrounding the regulatory fate of SVHCs (i.e. whether, when and in which process(es) it will be further regulated under REACH) creates substantial uncertainties and risks for the defence industry and – as a consequence – the MoDs as the customer. The visibility of the authorisation listing process is not in line with the defence industries' development cycle; difficulties arise in anticipating what action will be taken against a substance and when. Substance-level tracking is, consequently, difficult. There is the further risk that one SVHC is substituted with an alternative substance which could transpire to be equally as harmful and subsequently be targeted by REACH during the long product service life (regrettable substitution).

5. Possible EU policy conflicts with regard to SVHC regulation

REACH impacts the military uses of many inorganic substances, including those linked to Critical Raw Materials which, according to the EC's related policy, are very hard to substitute (e.g. beryllium, borates, cobalt salts). New Occupational Exposure Limits (OELs) under the EU workplace legislation (e.g. beryllium, hydrazine, refractory ceramic fibres) and Circular Economy are emerging as additional requirements, on top of existing ones (e.g. for lead and its compounds). The link between these EU laws and policies and REACH risk management options such as authorisation is not very clear today, leading to possible EU policy inconsistency. The case of chromates raises questions about the appropriateness of authorisation as a blanket risk management instrument for certain substances (like the above illustrative examples), which cannot be easily replaced; are broadly used in various sectors including high tech domains such as defence; and are also addressed by other EU policies.

6. Are MoDs/Armed Forces addressees of REACH? – Legal uncertainty

It is not clear today whether government bodies/MoDs/Armed Forces may themselves have direct obligations according to REACH. According to a legal analysis by representatives of the German MoD this is not the case. However, some MoDs have submitted pre-registrations and PPORD[8] notification to ECHA. In one case defence exemptions have been granted to the benefit of national Armed Forces. With a view to the upcoming final registration deadline, and possible further Annex XIV inclusions, this legal uncertainty should be addressed. The EC has been asked for and is in the process of developing an official answer as an important first step.

7. Article 33 compliance for complex defence equipment poses major challenges

Questions of proportionality were also raised unanimously with regard to REACH Article 33 (Duty to communicate information on substances in articles) compliance by producers of very complex articles such as military aircraft, ships or weapon systems, especially when imported from outside the EU and further re-supplied downstream.

According to the defence industry Article 33 Compliance is very difficult for complex defence products. The efforts required to comply with it are considered by the defence industry as an excessive burden with regard to the added value to safe use of the article, especially by importers. It

[8] Product and Process Orientated Research and Development.

is feared that the situation will further deteriorate soon due to the "Complex Article" judgment of the Court of Justice of the European Union (CJEU) of 10 September 2015 in case C-106/14 and the updated ECHA Guidance for Articles.[9]

Different views persist about the minimum information to be provided, especially whether it should normally include the component article where the reportable SVHC is located (view of most MoDs).

8. Military Application for Authorisation (AfA) not fully fit for purpose

Based on the defence industry survey and a dedicated analysis of applications for authorisation (AfAs) by the Contractor the defence sector has already been strongly affected by the AfA process, e.g. phthalates, lead sulfochromate yellow, lead chromate and severely for Cr(VI) compounds.

While the allowance of defence exemptions under REACH Article 2(3) is reserved for specific cases, and does not cover civil applications of dual use substances, the AfA for military uses is often seen by defence industry stakeholders, but also some MoDs as customers and supporting the AfA, as disproportionate and not fully fit for purpose.

Evidence of the large socio-economic benefit to European society and the control of the risks in using SVHC substances within the defence sector can be seen from past AfAs. Of the AfAs that supplied Socio-Economic Analysis information that were analysed as part of this study in which military uses are identified, a simple average cost benefit analysis ratio for military specific or dual use, downstream user applications is approximately 1.77 million : 1.[10] This raises questions of proportionality when having to go through such a burdensome process while the business case is generally clear, given the limited scope for substitution in defence equipment.

There is currently no dedicated defence sector-approach to authorisation. Non-air domains tend to be overlooked and a number of issues relating to military AfAs are unclear, such as the sufficiency of qualitative arguments (e.g. non-quantifiable impacts on the operational capabilities of the military and the ability to comply with international obligations as partner nations at EU level and wider field, e.g. with NATO) in lieu of economic quantification.

Authorisation costs, and through life maintenance activities using chemicals, are a particular concern, with the likely need for repeated renewals in high reliability sectors such as defence. Chemical supplier interest in supporting continued authorisation is also likely to diminish.

Decision uncertainty (review period/conditions) is a general concern, especially for upstream AfAs. However, generally, at the level of downstream user AfAs, ECHA considered that the applicants have been able to make their case.

9. Challenges for REACH defence exemption implementation across national borders

The so-called "defence exemption" in REACH Article 2(3) provides an important tool for EU Member States to mitigate negative impacts from the standard application of the REACH requirements in specific cases (only), in order to maintain a military capability. Most Member States consulted have

[9] The judgment clarified that the calculation of the 0.1% threshold in complex articles for the application of REACH Article 33 should be done based on each single constituent article (component article) instead of the complex article as a whole ("Once an article - Always an article"). The updated ECHA Guidance for Articles should reflect this judgment.

[10] The present ratio was derived from military specific or dual use, downstream user applications. This means that for every €1 society benefits from not using the SVHC substances it loses €1.77 million.

set up a system for granting defence exemptions, but only 6[11] of the 27 EDA participating Member States are known to have granted defence exemptions to date. Based on national implementation of the EDA Code of Conduct (CoC) 2015[12] by Member States, there is a gradual improvement in the overall harmonisation at European level with regard to defence exemptions. A major limitation of the REACH defence exemption is that it cannot cover the common civil applications of dual use substances. Also, national policies frequently foresee a conservative use of exemptions from health and environmental regulations.

Furthermore the REACH defence exemption process is often no option, or very difficult to manage, in cases in which defence industries in more than one Member State are involved in a transnational supply chain. This is especially true under the current, widely accepted restrictive (national only) interpretation of REACH Article 2(3). Given the challenges to apply REACH Article 2(3) across national borders, a clear majority of MoDs (73%) and defence industry (90%) responding would be in favour of an exclusion of defence from the REACH scope (fully or partly), whatever its form.

10. Emerging security issues: Unclear relationship with defence - Possible regulatory gap

It is not clear whether REACH Article 2(3) may apply in the interest of Security. Several MoDs have raised this question. There is an increasingly blurred borderline between "defence" and "security" given the current global situation, especially with respect to newly emerging potential security (asymmetric) threats in the interior of the EU/Member States, to which MoDs may be called to play a supporting role at national level.

11. High or hidden costs vs. limited health and environmental benefits of REACH to date

Costs of REACH may be significant for both the defence industry and MoDs (as customer and end user), but could not always be quantified beyond direct compliance costs, due in part to the difficulties in determining indirect REACH related costs (e.g. price increases related to substitution and overall lifecycle cost; complexity of military procurement programmes; shorter maintenance intervals due to lower performing substitutes). Whether measurable or not, they are ultimately borne by the MoDs and, hence, the tax payer. Compliance costs for REACH (e.g. Article 33 and authorisation applications) are often considered as disproportionately high by industry when compared to the benefit. The largest cost occurs for SVHC substitution R&D and requalification tasks. Further cost analysis by industry and MoDs would be required for better quantification of the impact.

On the *benefits* of REACH, the better knowledge about chemical hazards, data quality and supply chain communication were frequently acknowledged. Risk management measures at the workplace have also improved as a result of REACH with a majority of MoDs, but less than half of the defence industry. However, this was explained by the fact that in a large number of cases the already existing strict national measures predating REACH, such as workplace safety laws, are considered as

[11] Plus Norway, which participates as non-EU (EEA) Member State in EDA activities based on an Administrative Arrangement of 2006.

[12] https://www.eda.europa.eu/docs/default-source/documents/eda-code-of-conduct-on-reach-defence-exemptions.pdf. The EDA Code of Conduct 2015 states that the subscribing Member States fully support the objectives of REACH. If foresees a last-resort approach, according to which the granting of REACH defence exemptions should be considered only after the following alternative methods have been examined: Complying with the requirements of the REACH Regulation; substitution of hazardous substance(s) with more benign alternatives.

sufficient.[13] The actual benefits to human health and the environment have been relatively limited, in cases when the use of substances is typically in low volumes and already well controlled and presents a low risk to users. It is largely felt by the defence industry that because of the Risk Management Measures already implemented, and monitored nationally, coupled with highly trained professional workers, these benefits are not commensurate with the efforts and costs.

12. Cumulative impacts of REACH and CLP processes on the defence sector

As an end user sector, the defence industry is potentially affected by a high number of candidate list proposals. It "has all the issues" given also the plethora and sophistication of systems and components upon which defence relies, thus resulting in a multiplication of impacts. However, when comparing the different REACH processes, the largest impacts on the defence sector are caused by REACH authorisation (due to dependence on AfAs and resource-intensive substitution activities in parallel) and – for industry – REACH Article 33 compliance for very complex articles, while REACH registration is causing possible obsolescence and resulting in Security of Supply issues. Only the impact of REACH restrictions has been relatively limited and mostly indirect (commercial obsolescence, some issues for non-aerospace systems), because derogations are often foreseen for critical aerospace and defence applications (e.g. for cadmium and now also for decaBDE).

For CLP the labelling of ammunition (as "explosive articles"; currently no EU harmonised approach by EU MoDs) and the import of mixtures (lack of component info) have been identified as main issues.

13. Future impacts expected to be significantly higher

Some MoDs and defence industry expect the future impact of REACH to be significantly higher than the impact that has been realised so far, particularly if REACH (and CLP) implementation continues as is. The main reasons given include: REACH Registration in 2018 for the 1 to <100 tonnage band, REACH Article 33 compliance after the latest CJEU judgment, Cr(VI) authorisation decisions and sunset date in 2017, further additions to the candidate list and Annex XIV. The defence sector is already strongly impacted by the current authorisation list of only 31 SVHCs. The situation could become unmanageable if the addition of defence critical substances to Annex XIV would accelerate, causing a cumulative impact on the entire defence supply chain.

14. Relocation risks are a threat to Security of Supply; more leeway for non-EU companies

REACH challenges the competitive position (level playing field) of EU defence companies in export markets and causes industry to consider relocation to avoid the REACH constraints for SVHCs used in article production and manufacturing processes. This is especially true for component suppliers (e.g. connectors) and surface treatment shops. Such relocation risks are seen as a major risk to Security of Supply by most MoDs. This is because supply chains that reside outside the EU, resulting in the need for imports of products into the EU, are more difficult to control, manage and monitor (e.g. due to design restrictions as well as regulatory restrictions e.g. due to ITAR[14], if the production is moved to the US).

[13] EU MoDs state that they take Occupational Safety and Health (OSH) within their organisations very seriously – not only during missions but also for the day-to-day operations like maintenance of defence materiel.

[14] The International Traffic in Arms Regulations, see https://www.pmddtc.state.gov/regulations_laws/itar.html.

The impact for non-EU headquartered defence companies with operations in Europe is more or less similar to their EU competitors. However, the flexibility to move some hard-to-substitute processes or even the complete production out of the EU (e.g. to their home country) could be higher for non-EU companies. Some EU companies with existing operations outside EU may also have the option to relocate, but it is limited - for strategic and political reasons - to non-strategic components.

15. Inconsistent EU regulatory approach impacting defence

In addition to REACH and CLP, other EU regulations (e.g. BPR, ODS, POP) may each separately force substitution steps in rapid succession on military applications or upstream uses, leading to regrettable substitution – hence unnecessary cost and effort in wasted R&D activities – and possible EU policy inconsistency, as some cases suggest. Furthermore, there is an inconsistent approach among the different EU regulations on how defence issues are handled (exemptions, exclusions, disapplications, etc.). These should be addressed in a forward-looking way as, currently, limitations on the use of one set of problematic substances often simply lead to a substantial increase in the use of another set of problematic substances. Overall, the stakeholder input on non-REACH related issues has been limited. However, it has been sufficient to show that there is a need for further clarification and work on overall regulatory consistency.

16. Stakeholder calls for more EDA REACH/CLP support

Several MoDs and defence industry stakeholders have called for more EDA support on REACH/CLP or referred to the benefit of EDA's prior engagement (e.g. EDA/ECHA communication in 2015 has ensured decaBDE restriction tolerating use by civil aircraft has now been extended to military aircraft). Consultations with non-defence industry stakeholders also underlined the benefit of further clarifying the EDA's possible role with regard to REACH/CLP support in relation to the defence industry.

The cumulative impacts described above create a significant risk to maintaining cost effective military capabilities. The increased through life cost is unavoidable. Defence exemptions will not guarantee the availability of chemicals necessary to maintain defence equipment. The import of chemicals and articles also poses a risk due to insecurities that a global supply chain may bring. As a result, some MoDs strongly believe that REACH may impact the actual operability of the Armed Forces.

More specifically, they see a strong risk of EU defence system development and maintenance becoming unsustainable because of the timeframe difference between REACH cycles and defence product lifecycles. Furthermore, reducing the European Defence Technological and Industrial Base (EDTIB) in favour of more imported equipment and maintenance outside of the EU to avoid REACH constraints could jeopardise independence and reliance on the EU economy as vital pillars of EU MoDs' defence strategies.

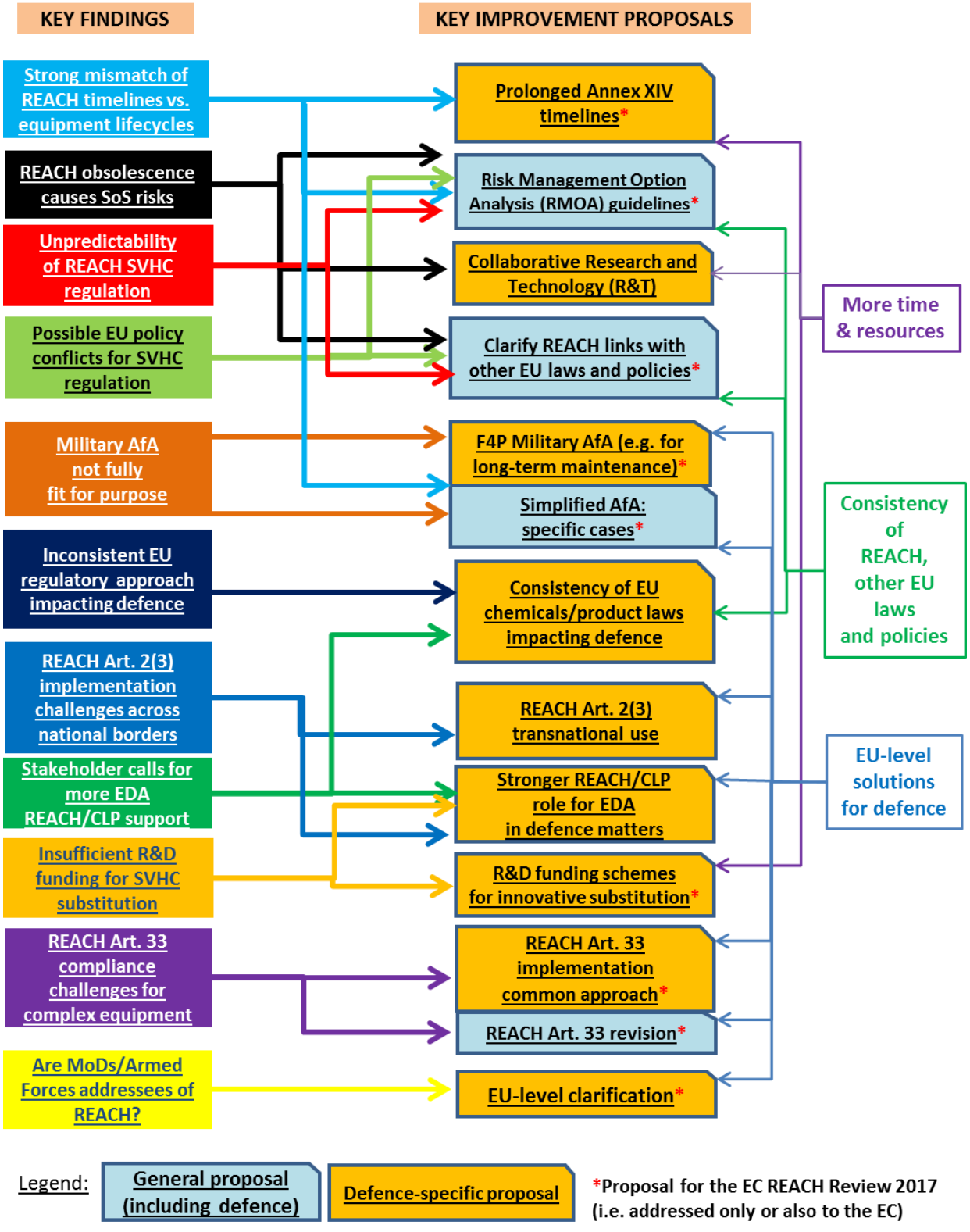
In a nutshell, the key findings from the REACH & CLP impact analysis are summarised in the table below.[15]

Actor		Defence industry	MoDs/Armed Forces
	Main concern due to REACH	Competitiveness	Guarantee of military capabilities
General impacts	Protection of human health and the environment	Some improvements confirmed by a minority, in addition to strict pre-REACH measures	Some improvements confirmed by a majority, in addition to strict pre-REACH measures
	Innovation potential (i.e. better performance)	Negatively affected: timeline mismatch; lack of R&D funding for SVHC substitution	Possible future negative impact on capability due to less performing substitutes
	Costs	Actor-specific: often considered as disproportionate, especially for REACH Article 33, authorisation compliance and substitution R&D work; hidden costs (to be clarified)	Mainly as customer (final payer of REACH costs). Some MoDs do substitution funding; possible shorter maintenance intervals due to substitutes and hidden costs (to be clarified)
	Obsolescence/SoS	Major issue, especially with regard to registration (2018 deadline) and authorisation	
	Certainty and predictability	Major issue, especially for REACH SVHC regulation and authorisation. Possible EU policy conflicts, e.g. with EU Workplace Legislation, Critical Raw Materials Policy and Circular Economy	
Process-specific impacts	Registration	Mostly indirect (obsolescence); some own registration needs (e.g. for ammunition)	As final customer and capability guarantor (MoDs for their Armed Forces); to be clarified: Are MoDs/Armed Forces REACH addressees?
	REACH Article 33	Major issue for complex defence materiel, especially imports; impact of "Complex Article" judgment (CJEU, C-106/14)	
	Authorisation	Major issue, especially for long-term maintenance; process not fully fit for purpose (no dedicated defence sector approach)	
	Restrictions	Limited impact due to derogations	
	CLP	Main issues: Labelling of ammunition ("explosive articles"); mixtures import (lack of info)	As final customer and capability guarantor; currently no harmonised approach to CLP
Impact mitigation	REACH Article 2(3) ("defence exemption")	Overall limited experience (Note: exemption is applied by Member States in "specific cases" only, to maintain a military capability)	Increased impact for procedures and harmonisation work (EDA CoC 2015); to be clarified: Article 2(3) transnational use; Are MoDs/Armed Forces REACH addressees?
	Relocation	Limited possibility for EU headquartered companies (non-strategic activities)	As final customer and capability guarantor: reduced control over imported products

[15] Note: This table strictly reflects a summarised version of the impacts (key findings 1-14) elaborated in the Study Report, on the basis of stakeholder responses to the study survey. As such, any impact on MoDs/Armed Forces reflected does not in any way pre-empt the outcome of the examination of the issue "Are MoDs/Armed Forces addressees of REACH?" mentioned previously under Key Finding 6, proposed to take place by EDA and Member States after the study is concluded, as described under Recommendations/EU-LEVEL SOLUTIONS FOR DEFENCE UNDER REACH/proposal e) below.

RECOMMENDATIONS

Based on the key findings from the impact analysis it was possible to derive the key recommendations for the improvement of REACH and its current implementation regime. The figure below illustrates their link schematically.



As shown in the figure, the key improvement proposals may be broadly grouped into **three main improvement areas**:

- **More time and resources**
- **Consistency of REACH, other EU laws and policies**
- **EU-level solutions for defence under REACH**

The key improvement proposals are detailed hereafter.[16]

MORE TIME AND RESOURCES

The mismatch of timelines and insufficient R&D funding are key findings of this study. The defence sector, having products with long lifecycles, stringent performance standards and high reliability requirements, needs more time and resources for innovative SVHC substitution, ideally through an approach to "innovate first – regulate later":

a) **R&D funding schemes for innovative substitution (EC, MoDs)**:*[17] Promote innovative substitution of SVHCs in defence applications through dedicated funding on an EU and national level.

b) **Collaborative Research and Technology (R&T) (EDA with MoDs)**: Promote innovative substitution of substances critical for defence which are impacted by REACH (SVHCs), through enhanced collaborative R&T projects within EDA Capability Technology Groups (CapTechs).

c) **Prolonged Annex XIV timelines (EC)**:* Clarify prerequisites for military use specific sunset dates in Annex XIV based on REACH Article 58(1)(c) ("production cycle specified for that use"), especially whether it may apply to maintenance activities.

CONSISTENCY OF REACH, OTHER EU LAWS AND POLICIES

It is important to see REACH and Risk Management Option Analysis (RMOA) in the context of other EU regulations and policies, in order for risk management approaches to be aligned and fitting in the global picture of the EU activities. To this end, a number of improvements are recommended in the interest of regulatory consistency, predictability and certainty.

a) **Risk Management Option Analysis (RMOA) guidelines (EC)**:* Adopt EU-level guidelines for a Risk Management Option Analysis, especially regarding technical and socio-economic issues to be considered, stakeholder participation, Risk Management Options (RMOs)/regulations, RMO selection criteria and deliverables, voluntary replacement and other "phased" approaches to enable fit-for-purpose REACH and related risk management. Enhanced assessment to conclude on candidate list for subsequent authorisation.

[16] The main addressee(s) is (are) given in brackets next to each proposal heareafter. However, it is **important to note** that there is often more than one addressee for a given proposal (or part of it). The complete list of addressees for each proposal/part is detailed in the Study Report.

[17] Proposals with an asterisk (*) are those for the EC REACH Review 2017, i.e. addressed to the EC, ECHA and/or the REACH MSCAs or necessitating their input for the proposal implementation.

b) **Consistency of EU chemicals/product laws impacting defence (EDA with MoDs)**: Consistent approach in EU legislation for chemicals and products to address defence specificities (exemptions/exclusions/etc.) and to avoid undesired regulatory outcomes impacting defence in multiregulation situations (e.g. regrettable substitution).

c) **Clarify REACH links with other EU laws and policies (EC)**:* Clarify REACH links and relationship with key relevant EU policies, especially EU Occupational Health and Safety (OSH) legislation (Occupational Exposure Limits), Critical Raw Materials policy and Circular Economy.

EU-LEVEL SOLUTIONS FOR DEFENCE UNDER REACH

REACH calls for EU-level solutions to ensure efficient implementation and a level playing field for industry. The defence sector, like many other sectors today, is highly reliant on cross-border activities. The EDA Code of Conduct (CoC) 2015 has been an important first step towards a harmonised approach to REACH implementation in this sector. The impact analysis has shown that further work is recommended to address key challenges for defence due to REACH – preferably on an EU level.

a) **Fit-for-purpose (F4P) military AfA (e.g. for long-term maintenance) (EDA with MoDs and defence industry, supported by the AfA Task Force)**:* Discuss a fit-for-purpose application for authorisation (template/modules) for military uses, taking into account their frequent dual use nature and identifying special cases, e.g. maintenance and ammunition.

b) **Simplified AfA: Specific cases (EC)**:* Explore further specific cases for simplified AfA, e.g. if compliance with a binding EU-wide Occupational Exposure Limit can be demonstrated.

c) **REACH Art. 33 implementation: Common approach (EDA with MoDs and defence industry)**:* Work together towards the practical implementation of REACH Article 33 communication, possibly through a sector-level approach, based on the latest ECHA Guidance for Articles and considering specific proposals made by some MoDs.

d) **REACH Art. 33 revision (EC)**:* *Should REACH be opened following the 2017 review*: Revise REACH Article 33 to address (very) complex articles, review its objective, usefulness (return of experience), requirements and feasibility.

e) **EU-level clarification: Are MoDs/Armed Forces addressees of REACH? (EC and EDA with MoDs)**:* Obtaining the EC legal view would be an important first step.

f) **REACH Art. 2(3) transnational use (EDA with MoDs)**: Legal clarification of REACH Article 2(3) is required on whether the exemptions *"from the REACH Regulation"* granted by individual Member States *"in the interests of defence"* apply automatically in other EU Member States (thus rendering the need for reciprocal acknowledgment redundant). Moreover, the possibilities of establishing a joint defence exemption process have to be examined. For the success of both the aforementioned cases, enhanced information exchange between Member States' interested parties (MoDs and defence industry) is of paramount importance.

g) **Stronger REACH/CLP role for EDA in defence matters (EDA with MoDs)**: EDA to assume stronger role for EU-level REACH & CLP support in defence matters.

In addition to the key proposals listed above, the following improvement proposals for different addressees complete the picture. They are not necessarily less important but some of them – other than proposals to the EC and ECHA - may address issues of a more limited scope.

ADDITIONAL IMPROVEMENT PROPOSALS FOR THE EC, ECHA AND MSCAs

a) **"Super" Downstream User (DU) platform (EC)**:* Establish a dedicated communication platform for "super" downstream users (such as the aerospace, defence and electronics industries) to discuss REACH, CLP and related regulatory issues.

b) **Substance tracking tool (ECHA)**:* Provide a practical tool for industry to facilitate monitoring of substances in the "pipeline" for regulatory risk management under REACH and CLP "from cradle to grave" (e.g. from RMOA to Annex XIV).

c) **EC REACH/CLP single web hub (EC)**:* A single webpage ("hub") and regular newsletter for easy access by industry to Commission activities on REACH and CLP.

d) **Authorisation exemption guidance (ECHA)**:* An ECHA Guidance / practical guide on exemptions from authorisation.

ADDITIONAL IMPROVEMENT PROPOSALS FOR EU MODS, EDA AND DEFENCE INDUSTRY

a) **Transparency of REACH Art. 2(3) procedures and decisions (EDA with MoDs)**: Publish national defence exemption application forms (in English), categorise REACH (and possibly CLP) defence exemptions and complete information on defence exemption procedures for remaining MoDs on the EDA REACH Portal.

b) **Collaboration within Member States on REACH/CLP defence matters (MoDs with MSCAs and National Enforcement Authorities)**: Strengthen collaboration among Member State administrations on defence and REACH/CLP.

c) **Align procurement contract terms with REACH (MoDs)**: Standardise to align with REACH.

d) **REACH cost analysis (MoDs, defence industry)**: Implement internal mechanisms to track REACH-related costs and (after 2018) analyse economic impact of REACH on EU MoDs and defence industry.

e) **Ammunition REACH status (EDA with MoDs)**: Finalise ongoing work.

f) **Ammunition CLP labelling (MoDs, EDA)**: National examination and position on the approach; further discussion on the overall picture, including on potential inconsistencies, aiming at a common understanding of MoDs on how to apply CLP to ammunition (or use of CLP defence exemption).

g) **EDA Code of Conduct (CoC) evolutions (EDA with MoDs)**: Discuss REACH/CLP update needs for EDA CoC 2015, especially with regard to EU-transnational use of REACH defence exemptions and addition of CLP.

h) **Exclusion for defence (MoDs, in consultation with their MSCAs and defence industries):** Examine the necessity to include an exclusion (from the REACH Regulation) for defence – whatever its form – in the legal text, *should REACH be opened following the 2017 review*.

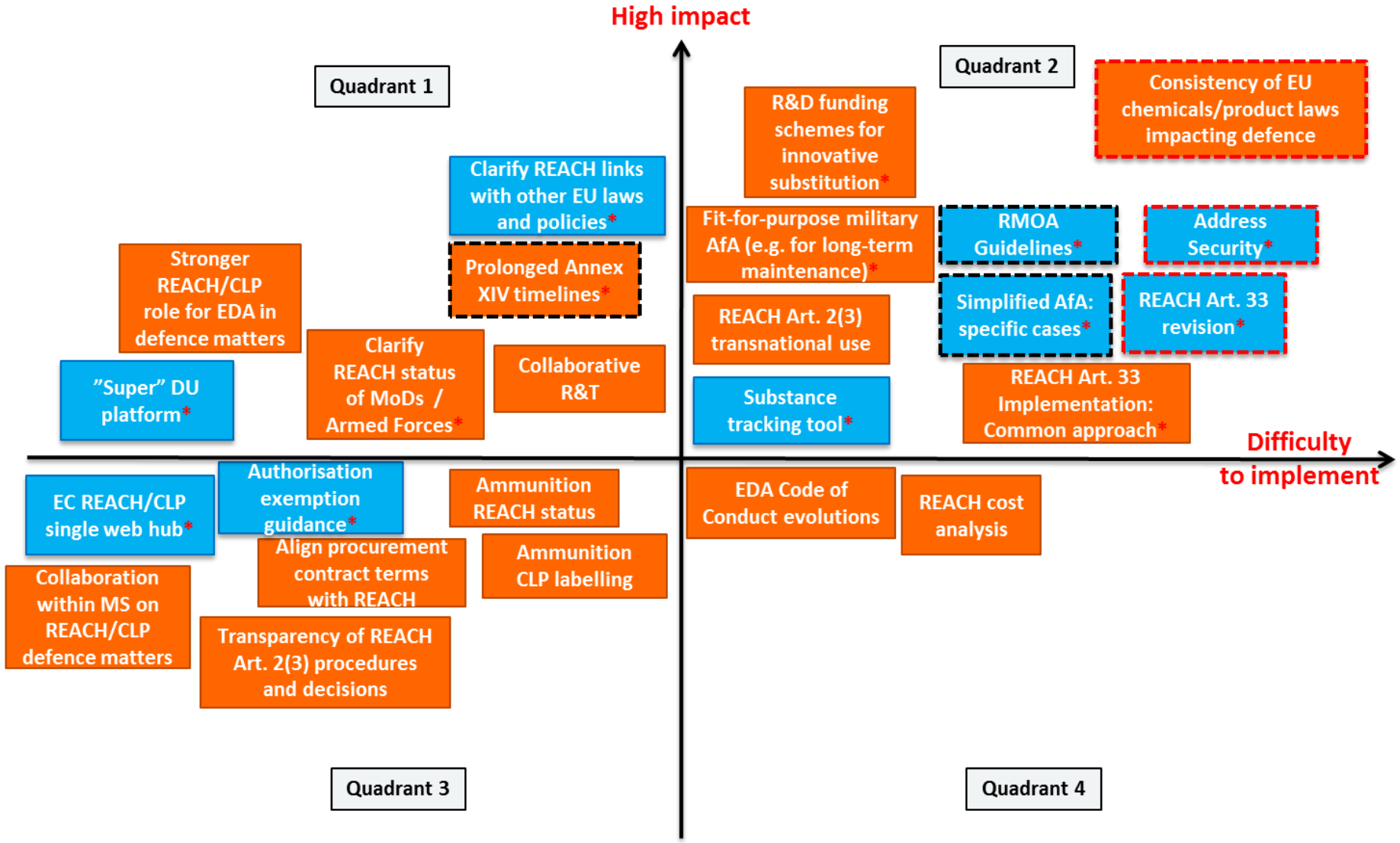
ADDRESS SECURITY: FOR AUTHORITIES IN CHARGE OF INTERNAL AFFAIRS

- **Consider national security issues vs. REACH (Member State authorities for internal affairs and EC DG Home)*** – Discuss the way forward in the Member States (including with MoDs).

The **priority** of the aforementioned improvement proposals is determined as a function of their implementation feasibility (difficulty) vs. the expected benefit (impact) for the European defence sector, as illustrated in a merely indicative way in the summary figure on the following page.[18] It shows that most proposals could be implemented without a change of the REACH legal text, a REACH Annex or implementing measure.

For the full details of the findings and improvement proposals outlined above, reference is made to the Study Report and the related Annexes. The detailed elaboration of improvement proposals contains the description of their rationale, which is (are) the addressee(s) and a possible implementation roadmap.

[18] The proposal related to an "exclusion for defence" is not displayed as it will require further examination to evaluate the necessity.



Legend: Defence specific proposal | General proposal (including defence) | Possibly requiring change of REACH legal text | Possibly requiring change of REACH Annex or implementing measure | *Proposal for the EC REACH Review 2017

STUDY REPORT

1 STUDY BACKGROUND AND OBJECTIVES

The EU[19] defence industry, strongly intertwined with high tech EU industries in other fields (e.g. aerospace, electronics) is a leader in innovation and value added, providing high tech jobs to the knowledge economy targeted by the EU. However, the EU defence industry is now facing the reality of trying to find short term substitutes allowing industry to cope with REACH constraints (registration, authorisation, restrictions) at the most reasonable cost. This calls for measures to improve competitiveness and innovation, and questions are raised about how this approach adds to the protection of human health and the environment considering how Substances of Very High Concern (**SVHC**) are in fact used by this industry today. The impact of REACH on the EU defence industry also has a direct impact on EU Member States (MS) (especially the national Ministries of Defence), and could in the long run affect defence capabilities on both a national and EU level. Hence, there is a need to identify the frequency and reality of actual risks of SVHCs used by the EU defence industry and to propose a sustainable way forward to ensure both a high level of protection of health and the environment as well as an enhancement in competitiveness and innovation.

Against this background, the European Defence Agency (EDA) commissioned REACHLaw Ltd. to conduct a *"Study on the Impact of REACH and CLP European Chemical Regulations on the Defence Sector"*. The **objectives** of this study were:

1. Impact analysis of REACH and CLP on EU defence sector, both industry and governments;
2. Practical proposals on improvements for REACH and CLP and their current implementation regime, to serve as a basis for the EDA, and its participating Member States' (pMS), input to the EC for the next REACH review and as suggestions for REACH evolutions beyond 2018;
3. Synthesis of information on the impacts of other chemical regulations on EU Member States MoDs and the defence sector (especially BPR, ODS, POP), their interaction with REACH and CLP, and a strategy (draft as a minimum) with proposals for improvements.

Figure 1 below illustrates the link between these three core study deliverables.[20]

It is important to see these study objectives in the light of the overarching goal to ensure the proper development of the EDTIB for the benefit of EU MoDs as EDA shareholders, as well as the preservation of capabilities, including sustainability of defence equipment maintenance processes performed by EU MoDs and related to equipment of EU or non-EU origin. Therefore, the analysis of impacts and proposals for their mitigation in relation to the defence industry is not to be seen in isolation, as they are intrinsically linked to the role of the defence industry to support Member States in retaining existing and/or developing new, critical defence capabilities in the future.

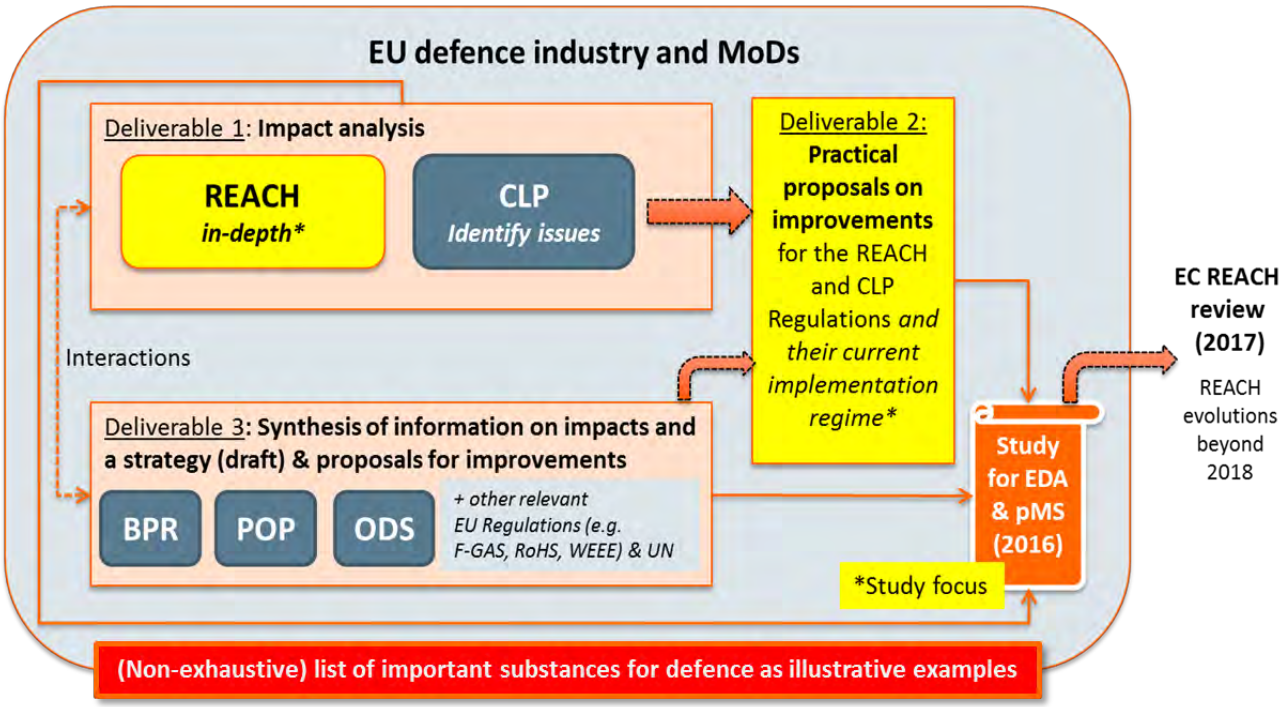
This is in line with the current highest political discussions related to the EU Global Strategy and its implementation plan for defence and security as recently agreed by Member States at the level of

[19] When making reference in this document to EU defence industry and EU Member States (MoDs), this shall also include **Norway**, which participates as non-EU (EEA) Member State in EDA activities based on an Administrative Arrangement of 2006 and applies the REACH Regulation (text with EEA relevance).

[20] More detailed information on the study methodology can be found in Annex A.

the Council of the European Union[21] which among others called for measures to strengthen the EDTIB *"…..In line with the European Council Conclusions of December 2013 on security and defence, the Council reiterates the need to enhance the effectiveness of CSDP and the development and maintenance of Member States' capabilities,* ***supported by a more integrated, sustainable, innovative and competitive European Defence Technological and Industrial Base (EDTIB), which also contributes to jobs, growth and innovation across the EU and can enhance Europe's strategic autonomy, strengthening its ability to act with partners****. The Council recalls that these efforts should be inclusive, with equal opportunities for defence industry in the EU, balanced and in full compliance with EU law."*

Figure 1 Synthesis of the core study deliverables



2 SHORT SUMMARY OF ACTIONS UNDERTAKEN

The study input to address its scope[22] was obtained through the combined use of (1) the Contractor's expertise and literature review, (2) close coordination and communication with the EDA and its REACH Task Force comprising experts from participating MoDs and – last but not least – (3) consultation of relevant stakeholders. Considering the tight study time frame (6 months study initiated in May 2016) efficient delivery was of critical importance.

The fruitful **stakeholder consultation** was of paramount importance for the proper impact assessment and preparation of improvement proposals. The EDA called on relevant stakeholders in a

[21] Council conclusions on implementing the EU global strategy in the area of security and defence, Foreign Affairs Council, 14 November 2016.
[22] See Annex A.1.

dedicated letter of 11 May 2016 to support the study.[23] With the support of the EDA and REACH Task Force experts[24] the Contractor prepared dedicated detailed **study questionnaires** for the different stakeholder groups (EU MoDs, defence industry, EC, ECHA and REACH Member State Competent Authorities (MSCAs). The stakeholder consultation, through **questionnaires and interviews,** was launched in the beginning of June 2016 and was supported by web alerts in order to reach the widest possible audience.[25] The consultation of key stakeholders (e.g. the ASD RIWG) was prioritised.

In total, responses have been received from over 100 stakeholder organisations in 20 EU Member States and the United States (US),[26] representing a solid evidence base for the impact assessment which, in turn, gave rise to the improvement proposals. For the defence sector alone survey responses were provided by 13 EU MoDs, 31 defence industry stakeholders from 10 EU countries as well as five individual major non-EU defence companies with operations in the EU.[27]

The MoDs that responded represent 90.5 % of the European defence expenditure[28] and, in terms of defence industry annual turnover, they represent 91.3 % of the European defence industry.[29]

In addition to the qualitative analysis of all survey responses, a statistical analysis of the responses from the defence industry and MoDs, to measure their views on impacts, was performed, giving the same weight to all responses. No weighting was applied to industry stakeholders. Therefore, SMEs answers have the same value as those of large system integrators, and those of defence industry associations the same as those of individual companies.

Important Note: **All percentages and comparative terms (e.g. majority of) mentioned in this Final Report are in reference to the overall number of stakeholders that responded to the study consultation, and not the overall number of stakeholders that were targeted for consultation.**

In addition to the collection of input from stakeholders; EDA and its REACH Task Force, the Contractor engaged in the identification and analysis of relevant reports, previous REACH impact assessments (e.g. developed as part of the EC REACH review 2012) and other publications on REACH and other related topics for this study.[30] The list of main study references used can be found in Annex O.

The detailed description of activities performed and remaining can be found in Annex A.

[23] See Annex A.2.
[24] Comments on the draft questionnaires were also provided by the ASD RIWG chair (for the industry questionnaire), the representative from the EC DG GROW attending the EDA REACH Task Force, and ECHA (for the ECHA questionnaire).
[25] On the websites of the Contractor and the EDA (EDA news alert).
[26] The full list of stakeholders that responded to the consultation through written questionnaire and/or interview - or are known to have contributed to defence association-level responses - is given in Annex B.
[27] A detailed overview of the consultation feedback received can be found in Annex A.4, Table 16.
[28] According to 2014 EDA defence data (https://www.eda.europa.eu/info-hub/defence-data-portal) and SIPRI database (https://www.sipri.org/sites/default/files/Milex-local-currency.pdf).
[29] EDA 2015 Study on Defence Industry Data Figures, Final Report. Greece is excluded from the defence industry turnover percentage, due to a lack of available data.
[30] Key sources included the websites of ECHA, the European Commission, the EDA and the Court of Justice of the European Union (CJEU).

3 THE EUROPEAN DEFENCE SECTOR WITHIN REACH

3.1 The sector at a glance

The overall European defence sector is organised hierarchically: relatively few companies can assemble **complex defence systems**, integrating different types of defence systems such as sensors and weapons, while at the same time acting as a reliable partner to their government customer – the end user. This top tier is supported by companies lower on the supply chain, who produce subsystems and equipment. They, in turn, are supported by their own suppliers – and so forth.

Component manufacturers, while being a key part of the supply chain, are not generally fully integrated in the defence sector since, in most cases, defence activities are only a small part of their overall business. As technology advances faster in the civil sector, and its costs increase, **the defence sector becomes more and more dependent on components developed for the civil market. Therefore, the sector will be impacted directly or indirectly by evolutions, restrictions, changes, etc. that impact those markets.** A recent example was the abandoning of lead in electronics due to RoHS (European Directive banning hazardous substances in Electronics) and similar regulations taken by other countries. While the defence sector was exempt, it was forced to abandon lead in order to continue using both the commercial off the shelf and custom components. This was because component manufacturers found the maintenance of a specific lead-based capability only for the defence sector uneconomical.

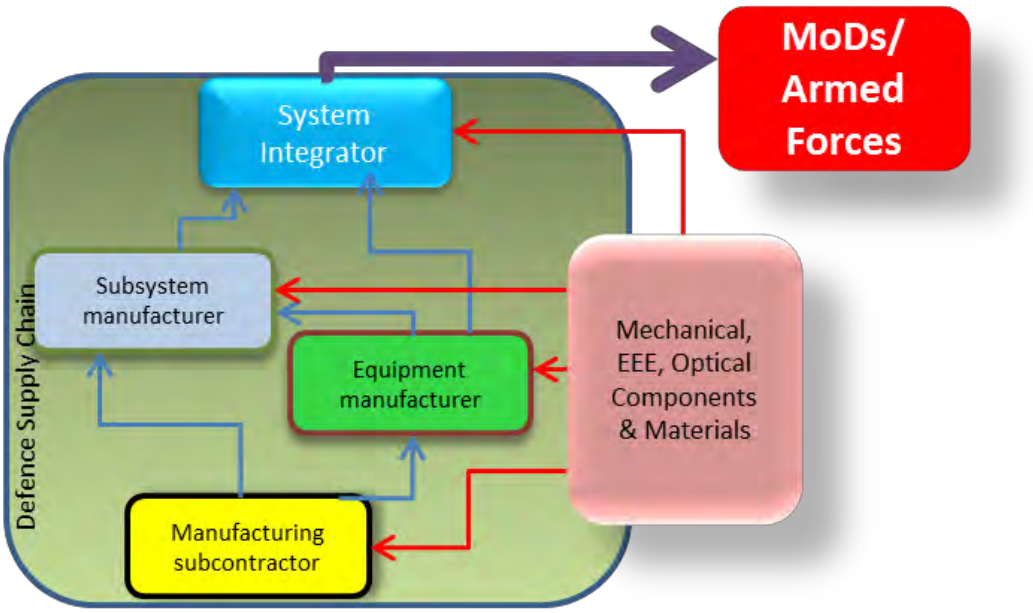
The **hierarchical structure of the defence industry** in the value chain has traditionally been comprised of Prime Contractors at the top of the pyramid and Tier 1 to Tier 3 contractors below.[31] The defence sector could be viewed as a conglomerate of companies that, taken together, constitute the **defence supply chain** with MoDs/Armed Forces as end users. Hence it incorporates all industrial sectors and technologies that generate defence products and services. This includes **dual-use products and services** (those that can be used for military or civil purposes). Thus, electronics, information technology, but also logistics are part of the sector as well as those companies that mainly operate in the civil market.

As a rule, the further upstream a company is in the defence supply chain, the higher is its dependence on civil markets. For most *components manufacturers*, the defence business is so insignificant that defence requirements are often disregarded and it is up to the defence company using the components to adapt to the civil requirements.

Figure 2 below illustrates the main actors in the European defence sector, their interconnections and the critical role played today by the Mechanical, EEE, Optical Components & Materials suppliers. In practice the *system integrator* could also be, at the same time, a subsystem manufacturer and/or manufacturer of equipment that they use for their systems and/or also supply to other system integrators.

[31] François CAUZIC et al., "A comprehensive analysis of emerging competences and skill needs for optimal and skill needs for optimal preparation and management of change in the EU defence industry", Final Report, Eurostrategies (May 2009).

Figure 2 Main actors in the European defence sector and their interconnection



The latest estimate by ASD[32] puts **military turnover** for all sectors (aeronautics, land and naval defence, space) at 102.3 billion euro in 2015. Additional economic data, including breakdown by sector, can be found in the quoted ASD publication.

Another recent study commissioned by the European Parliament [33] looks in depth at the main issues involved when developing a **European Defence Technological and Industrial Base (EDTIB)**. The study finds that the EDTIB remains far more national and less integrated than the size of the market would suggest, while at the same time their **supply chains are becoming more globalised.** The control exercised by the state over national defence assets[34] remains particularly strong in France and Italy, although state ownership is prevalent across the continent. The UK, Germany and a handful of smaller countries are the exceptions.

3.2 REACH-relevant features of defence products

Companies in the defence sector are primarily **producers (assemblers) of very complex articles** and **downstream users of chemicals** in military/defence applications. A number of features of defence products, which are REACH-relevant, have been unanimously put forward by all defence stakeholders consulted. They relate to: (a) The timelines of defence products; (b) Other substitution relevant features; (c) Safety relevant features of chemicals and defence equipment use; (d) Additional defence-specific complexities.

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[32] ASD, Aerospace and Defence Industries Key Facts & Figures 2015 (November 2016). In 2015 ASD member associations (and thus related figures) were spread across 19 countries, 16 of them in the EU plus Norway, Switzerland and Turkey.

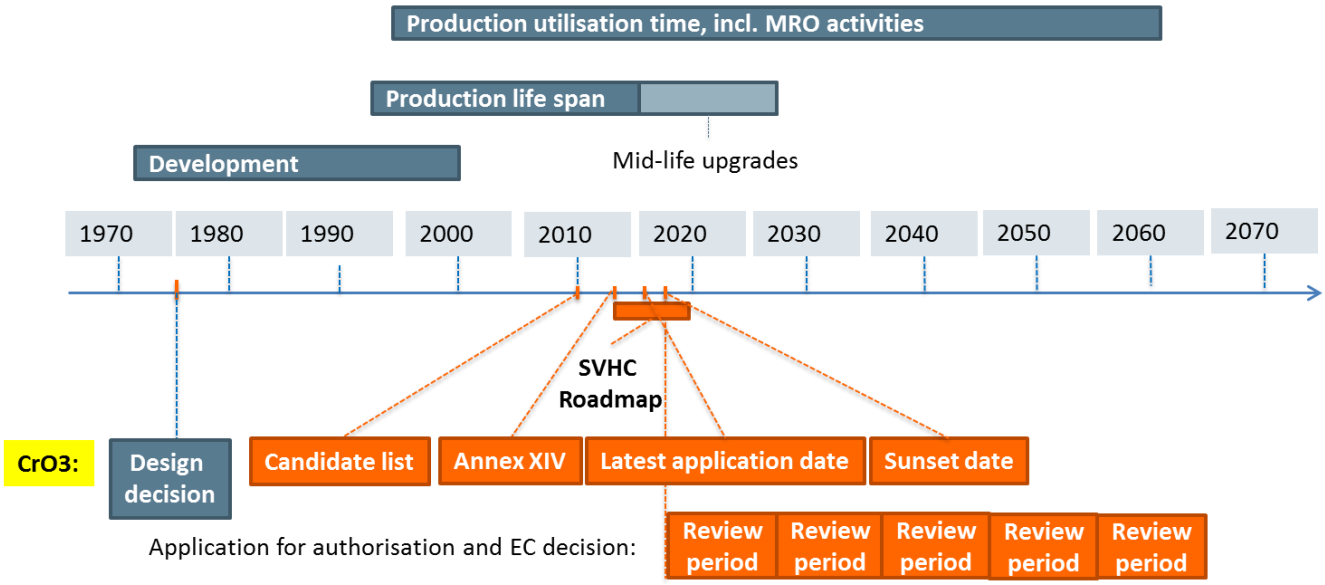
[33] Valerio BRIANI et al., "The development of a European Defence Technological and Industrial Base (EDTIB)", study for the European Parliament's Subcommittee on Security and Defence (June 2013).

[34] Assets mean all defence capabilities within the Member State: industrial, services, etc., and, of course, the armed forces themselves.

(a) Timelines of defence products

The defence products have long lifecycles in both the design and production phases, and can be in service for decades, generating the need for Maintenance, Repair and Overhaul (MRO) activities in order to keep the products in operational condition for the military customers. Furthermore, apart from initial production, the life span of military systems is also heavily reliant on usual *"mid-life upgrades"*. These timelines could be plotted against REACH authorisation timelines (sunset dates of typically 3 years after Annex XIV inclusion and review periods for granted authorisations ranging from 4,7 to 12 years) to illustrate the **profound misalignment between the two** (Figure 3):[35]

Figure 3 A typical defence product lifecycle vs. REACH timelines / example of chromium trioxide



The study survey has reiterated that the development and usage timeframes for defence products are very long when compared to other sectors particularly affected by REACH, like consumer, automotive, etc. Even for similar products like civil and military trucks, the military version is often sourced with a longer service contract. Timelines are different for different products but they can be quite long.

Typical timeframes for defence products can be

- **up to 20+ years** of **product development time**;
- **up to 30+ years** of **expected production lifespan**;
- **up to 50+ years** of **product utilisation time**.

[35] See very instructive illustrations of main timelines for specific military airplanes, helicopters and OCCAR (Organisation Conjointe de Coopération en matière d'ARmement) programmes in: Me Frédéric MAURO, Professor Klaus THOMA, The future of EU defence research (March 2016), page 39 and 89.

(b) Other substitution relevant features of defence products include:

- **Supply chains which are both international and highly complex** (typically ~ 30.000 supplier, many of them SME`s for a military aircraft);
- **Low production series** for single platforms;
- **Multi-national certification process** required for many defence products;
- Management of spare parts and application of regulated chemicals in **MRO of legacy programmes decades after the cessation of manufacturing;**[36]
- **High R&D effort** for substitution of regulated/banned substances under CLP/REACH;
- **Heritage**: Replacement solutions will not exhibit the same **heritage and maturity** as existing solutions using SVHCs, resulting in the risk of unexpected future performance or longevity impacts. It therefore takes time and experience before customers are confident enough to accept the products using substitutes, even where qualification and validation campaigns have been successful.
- **Specific substances, amongst them SVHC's, are absolutely critical** to ensure platform safety (esp. chromates for anti-corrosion protection in aircraft) and/or could be critical for the non-dependence of the European defence from non-EU sources.

(c) Safety relevant features of chemicals and defence equipment use include:

- The character of defence products as **Business to Business (B2B) products** having no wide dispersive use (e.g. are not distributed to private consumers);
- **Very low volume use of chemicals** (typically << 1 t p.a. and per legal entity, often a few kg only);[37]
- **Handling by well-trained and protected professional end-users**, and often through automatic processes in closed environments;
- Defence products have a **controlled lifecycle**, i.e. they are closely tracked during their service life;
- **Repair and overhaul** may only be undertaken **by approved organisations** in accordance with controlled and approved design data.

(d) Additional defence-specific complexities

- Some **imported products** (components, equipment, systems) manufactured in non-EU countries are subject to **restrictive legislation**, such as **ITAR (The International Traffic in Arms**

[36] For aircraft, the supplier specifies the maintenance and operating chemicals to be used to maintain airworthiness. They are normally decided during the design phase of an aircraft's lifecycle. Thus, given the time-consuming and costly process to approve alternatives, substitution in maintenance chemicals does not take place, according to some MoDs consulted.

[37] Both compared to the total defence equipment weight and the total quantity of defence components or equipment produced, which is usually extremely small compared to the civilian domain.

Regulations)[38] in the case of the US, which may preclude access to information on SVHC substances present in the product and EU MoDs / industry influence on design.[39]

- **Single-source supplies**: Defence portfolios have the specificity - compared to other industries – to have a high amount of single-source suppliers in very specialised and niche applications. Therefore, alternatives are often not available, leading to higher obsolescence risks or do at least need significantly longer duration and increased efforts to implement alternative technologies or qualify alternative suppliers.
- Development, manufacturing and MRO of highly complex articles (e.g. combat aircraft) managed in **transnational workshares** with industrial partners that also operate in other projects as competitors;[40]
- **Diversity of defence systems and components**, with partly the same, partly different challenges with regard to REACH and CLP processes and SVHCs to be tracked. The defence sector comprises a wide range of product sectors, rather than a product sector in its own right (Figure 4).

Figure 4 Different types of defence systems and components

Aeronautical systems	**Space systems**	**Nuclear systems**
Maritime systems	**Land systems**	**Munitions**
Electronics/IT	**Industrial chemicals**	**Commodities (e.g. textiles)**

Another key differentiator, when considering the above-listed features, is that the defence market is mostly **institutional** (government customer). In comparison, the satellite market, which is very close to the defence market and shares with it many of the product features listed, is, for Europe, roughly 50% institutional and 50% commercial. The increasing level of **joint procurement projects and programmes** for various defence products among EU MoDs coordinated by European organisations like OCCAR[41] and EDA is another notable development (see also Annex F.3).

To sum up, while it is true that most of the given features, taken individually, are not unique to the defence sector, it is their combination that makes the sector uniquely complex (Figure 5).

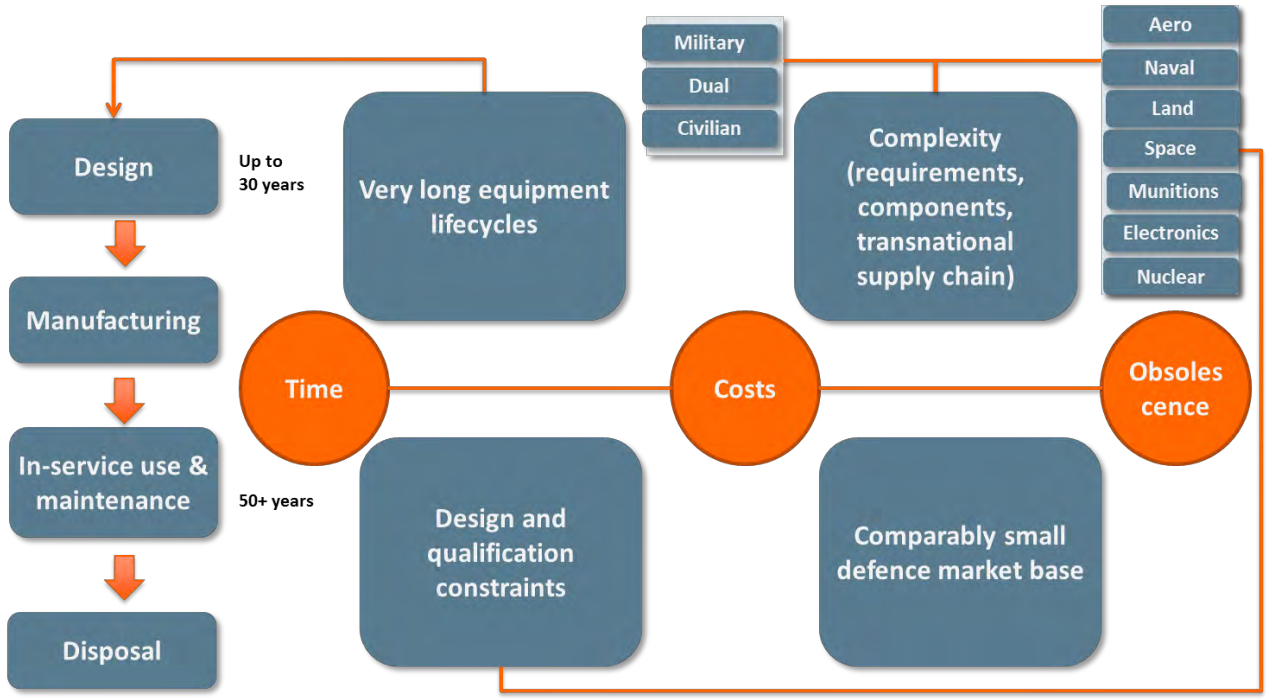
[38] See https://www.pmddtc.state.gov/regulations_laws/itar.html.

[39] A US manufactured radar system used for civil tracking will not be subjected to ITAR restrictions but a similar system using radar components to withstand a nuclear attack will probably be affected by ITAR.

[40] For example civil aircraft are also subjected to a very long and strict certification process as with military aircraft, but civil aircraft are most of the time a product of one company (e.g. Airbus, Boeing) while military aircraft are often the result of transnational consortia with industrial partners that also operate in other projects as competitors (e.g. Eurofighter Typhoon).

[41] http://www.occar.int/news. Some examples include (with variable participation of EU Member States): Airbus A400M transport aircraft, Boxer multi-role armoured vehicle, Eurofighter, NH-90 transport helicopter, Tiger combat helicopter.

Figure 5 Complexities of the defence sector



3.3 The REACH defence exemption: Experience and shortfalls

Recognising the need for EU Member States to protect their interests of defence, a special exemption possibility, **REACH Article 2(3)**, was introduced into the REACH Regulation. It states:

"Member States may allow for exemptions from this Regulation in specific cases for certain substances, on their own, in a mixture or in an article, where necessary in the interests of defence."

REACH Article 2(3) provides an important tool for EU Member States to mitigate negative impacts from the standard application of the REACH requirements in specific cases (only), in order to maintain a military capability. The study consultation of MoDs and defence industry has shown that there are generally **three key challenges** for its application with regard to its national (granting by Member States) and sectoral (defence only) character, which are reflected in this Section:[42]

- **National differences** with regard to defence exemptions (Section 3.3.1);
- **Limitation to "the interests of defence"** (Section 3.3.2);
- **Transnational use** in today's typical cross-border supply chains (Section 3.3.3).

[42] For more information on the defence stakeholders' experience with the REACH defence exemption see Annex F.

3.3.1 National differences with regard to defence exemptions

The granting of REACH defence exemptions is a **matter for the individual Member States**, who have **discretion** as to whether or not to grant the exemption, where necessary in the interests of defence. Most Member States consulted have already established national processes (example in Figure 6)[43] to assess and decide on exemption requests, and sometimes developed comprehensive guidance.[44]

Figure 6 The UK REACH defence exemption process

National differences of procedures, assessment criteria (e.g. regarding the use of a chemical safety assessment) as well as business scenarios (e.g. the extent of import from non-EU countries) have resulted in differences of the use of the defence exemption. Equally, the validity period and scope of defence exemptions granted for certain substances could differ (e.g. from a specific requirement of REACH or the Regulation as a whole[45]; product-based instead of substance-/use-based[46]). Also, national policies frequently foresee a conservative use of exemptions from health and environmental regulations.

Consequently the number of exemptions granted to date varies from MS to MS, from 0 to more than 60. A significant number of Member States have not granted any defence exemption to date, while the status in some Member States is not known (they have not contributed to the study and they have not, as yet, provided related information to EDA). Only 6[47] of the 27 EDA participating Member States are known to have granted defence exemptions to date. Table 1 provides an overview of the

[43] Annex F.1 (Table 21) provides a comparative overview of key aspects of REACH defence exemption systems and the current state of exemptions granted in the various Member States that responded to the study consultation for MoDs.

[44] See e.g. the guidance available for applicants in the UK: https://www.gov.uk/government/publications/reach.

[45] In Greece: Biministerial Decision 30458/30 issued in 2010, see https://reach.eda.europa.eu/greece.

[46] See also Annex F.2.

[47] Plus Norway, which participates as non-EU (EEA) Member State in EDA activities based on an Administrative Arrangement of 2006.

number of exemptions granted in different EU countries, based on responses received from MoDs and the information on the EDA REACH Portal.[48]

Table 1 Number of REACH defence exemptions in EDA participating Member States

EDA participating Member State	Number of REACH defence exemptions
CY	1
DE	15
EL	63
FI	3 (REACH and CLP)
NO	3 (each relates both to REACH and CLP)
PL	6[49]
UK	10
AT, BE, ES, FR, IT, NL, PT, RO, SE	0
BG, CZ, EE, HU, HR, IE, LV, LT, LU, MT, SI, SK	Not yet known – Mapping in progress by EDA

In order to reduce the differences and to **harmonise the use and assessment criteria for the granting of national defence exemptions,** in the interest of contributing to a level playing field for the EU defence industry, the participating Member States have developed and subscribed to the voluntary[50] **EDA Code of Conduct on REACH Defence Exemptions in March 2015 (EDA CoC 2015).**[51] It foresees:

- A **last-resort approach**, according to which the granting of REACH defence exemptions should be considered only after the following alternative methods have been examined: Complying with the requirements of the REACH Regulation; substitution of hazardous substance(s) with more benign alternatives;
- A common ***"Framework for Applying for a Defence Exemption from a Requirement of REACH"***,[52] which is drawing heavily on the REACH requirements.

[48] https://reach.eda.europa.eu.

[49] This reflects the status in November 2015, based on PL direct input/response to a related EDA questionnaire.

[50] I.e. legally non-binding, as all EDA intergovernmental instruments.

[51] See https://www.eda.europa.eu/docs/default-source/documents/eda-code-of-conduct-on-reach-defence-exemptions.pdf. The EDA Code of Conduct 2015 states that the subscribing Member States fully support the objectives of REACH. A summary of the EDA CoC can be found in Annex F.1.

[52] https://www.eda.europa.eu/docs/default-source/documents/annex-to-coc---framework-for-applying-for-a-defence-exemption-from-a-requirement-of-reach.pdf.

All EDA participating Member States as well as Norway, but with the exception of Poland, have previously subscribed and are participating in the implementation of the EDA CoC 2015. Poland is still examining internally potential subscription to the EDA CoC 2015 in the near future.

OVERALL STATUS OF HARMONISATION OF REACH DEFENCE EXEMPTION PROCEDURES

Based on information gathered by the EDA from Member States to date (November 2016), the following information reflects the status of national defence exemption procedures on the basis of the EDA CoC 2015, for each EDA Member State and Norway:

- National procedure exists and is fully harmonised/in line with the EDA CoC (8 MS and NO): **AT, DE, ES, FR, IT, NL, SE, UK, and NO**.
- National procedure exists and can be considered aligned with the principles set out in the EDA CoC (small differences exist). No actions for further alignment are envisaged (2 MS): **BE, FI**.
- National procedure exists - not harmonised with the EDA CoC. Actions are in process to harmonise/align national procedure with the EDA CoC (2 MS): **EL, RO**.
- National procedure does not exist yet. Actions are in progress to develop a national procedure in line with the EDA CoC (2 MS): **LT, PT**.
- Status is not known – no information has been received to date – EDA pursuing further input (12 MS): **BG, HR, CY, CZ, EE, HU, IE, LV, LU, MT, SI, SK**.
- Not subscribed yet to the EDA CoC (1 MS): **PL**.

Figure 7 illustrates the current status of the harmonisation of the REACH defence exemption.

Figure 7 Harmonisation of Exemption Procedures – Status (EDA, November 2016)

The current status confirms that there is a gradual improvement in the overall harmonisation at European level with regard to defence exemptions. However, national practices on specific issues, **which are not covered by the EDA CoC 2015,** differ between Member States such as:

- the administrative application (e.g. who can apply);
- decision-making processes;
- scope and validity period of an exemption;
- additional information to accommodate specific national requirements (e.g. in Spain);[53]
- the language of the procedure (normally the official language of the Member State);
- measures and procedures for acknowledgment of other Member States' defence exemptions.[54]

Some of these differences might be partly addressed in a future revision of the EDA CoC. However, a complete alignment of national exemption systems/procedures is unlikely to be achieved due to the different Member States national requirements, decision-making processes and differences of national administrative systems.

The **industry experience** with defence exemption requests is generally limited and as Member State-specific as the procedures themselves. Some level of exemption-related activity is mainly reported from France, Germany and the UK.[55]

3.3.2 Limitation to "the interests of defence"

A major limitation of the REACH defence exemption is that it cannot be used to support the continued use of a dual use substance outside the defence domain, i.e. for civil applications. Furthermore, questions have been raised by some MoDs about its possible use for national security purposes.

CIVIL APPLICATIONS

Civil markets often include sectors with lower performance requirements and hence better substitution prospects.

If a dual use substance is withdrawn from the civil market due to REACH constraints (registration, authorisation, etc.), and it continues to be legally available for the defence sector (due to exemption, authorisation, etc.), it may nevertheless become commercially unavailable or very expensive for military customers (see Figure 8).[56] The defence sector will have no choice but to mitigate such **commercial obsolescence risks** as it will be further explained in Section 4.1.2.2.

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[53] The EDA CoC 2015 foresees that *"subscribing Member States (sMS) can include any additional requirements as required to meet national procedures"*, but it is up to each Member State to specify such additional requirements.

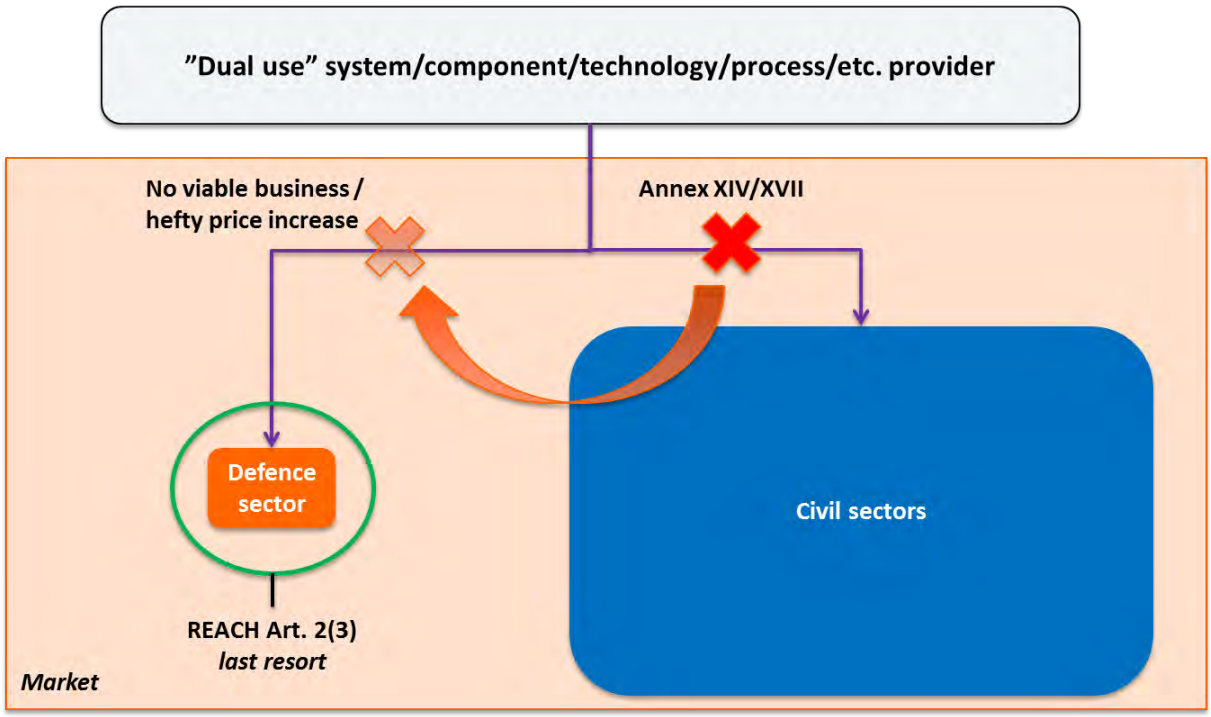
[54] The EDA CoC 2015 foresees that *"on a voluntary basis and in accordance with national law, establish suitable measures and procedures to recognise other subscribing Member States' exemption decisions"*. The actual measures and procedures are up to each Member State to define/establish.

[55] See Annex F.2 for more detailed information.

[56] This is relevant especially for substances and related technologies that originated in the civil sector and were later on used in defence, i.e. the bulk of the business is on the civil side.

Also, military applications should not be treated worse than their civil counterparts. The risk appears **when military uses are 'forgotten'** (for example in registration or restriction derogations), when external stakeholders assume that the defence sector is covered by the REACH defence exemption. **Common REACH compliant solutions on REACH issues impacting both civil and defence sectors should be aimed for whenever possible.**[57]

Figure 8 Dual use and associated commercial obsolescence risk



NATIONAL SECURITY

Some MoDs consulted consider that the REACH defence exemption could be falling short where the same use is also of interest to **national security** (example of sniffer dogs hereafter).[58] It is not clear whether REACH Article 2(3) may apply in the interest of Security.

[57] See info box "Omission of military aircraft in the restriction exemption proposal for decaBDE" in Annex F.3.
[58] For further information please see Annex F.3.

INFO BOX: Use of explosives for the training of sniffer dogs

To train sniffer dogs for explosives search, an independent research organisation acquires different explosives products to compose training kits for sniffer dogs for training to identify explosives. These training kits are supplied to the different dog training centres from Army, Air force, Marine and - both military and national - Police. Hence, training kits are dual use, Defence and national Police. Kits are replaced annually to avoid contamination. A defence exemption is in process for one explosives type, 2,4-DNT (EC 204-450-0), which is on REACH Annex XIV. The sunset date passed on 21 August 2015 and no authorisation application has been received by ECHA to date.[59] It is not clear whether and to what extent REACH Article 2(3) applies also in the interest of national security.

Indeed, there is an increasingly blurred borderline between "defence" and "security", given the current global situation, especially with respect to newly emerging potential security (asymmetric) threats in the interior of the EU/Member States, to which MoDs may be called to play a supporting role at national level. Intensifying collaboration between military and civil authorities has been reported, for example in the context of activities to prevent terrorist attacks (NL example: MoD agreement with anti-terrorist unit).[60]

3.3.3 Transnational use

According to the interpretation of REACH Article 2(3) by the EDA pMS, reflected also in the EDA CoC 2015, national defence exemptions are considered to be only valid in the territory of the Member State that has granted the exemption.

- During the drafting of the EDA CoC, the Member States experts then commonly expressed their position/interpretation that the ***"interests of defence"*** in REACH Article 2(3) were meant strictly at national level and that therefore the REACH defence exemption was valid within national boundaries, and was not to be interpreted on a pan-European level.[61] In Spain the national validity of its REACH defence exemptions is enshrined in its national legislation.
- As from now, one MoD explained in its study survey response that allowing an exemption from the REACH Regulation is per se valid for the entire (pan-European) area of application of REACH, regardless of the national or European interpretation of the "interests of defence": *"With regard to the necessary joint endeavour to maintain the bureaucratic effort established*

[59] See http://echa.europa.eu/fi/addressing-chemicals-of-concern/authorisation/applications-for-authorisation/received-applications (situation as of 17 November 2016).

[60] In 2005 the Dutch parliament decided that the Ministry of Defence would not be only a back-function to civil authorities in case of national security issues, but that Defence gets a broader task with earmarked capacities (to cooperate with authorities) to maintain homeland security. In the parliament letter of May 2006 the Minister of Defence lists the Defence capacities which are available for homeland security, see https://zoek.officielebekendmakingen.nl/kst-30300-X-106.html . As an example, military authorities in the Netherlands are responsible for all training of CBRN (Chemical, Biological, Radiological and Nuclear defense) knowledge to the civilian authorities (fire brigade-first aid responders and police). In Germany the discussion about military support to the police has also gained momentum again after the shooting rampage in Munich on 22 July 2016, see http://www.spiegel.de/politik/deutschland/amoklauf-in-muenchen-bundeswehr-setzte-truppen-in-bereitschaft-a-1104635.html

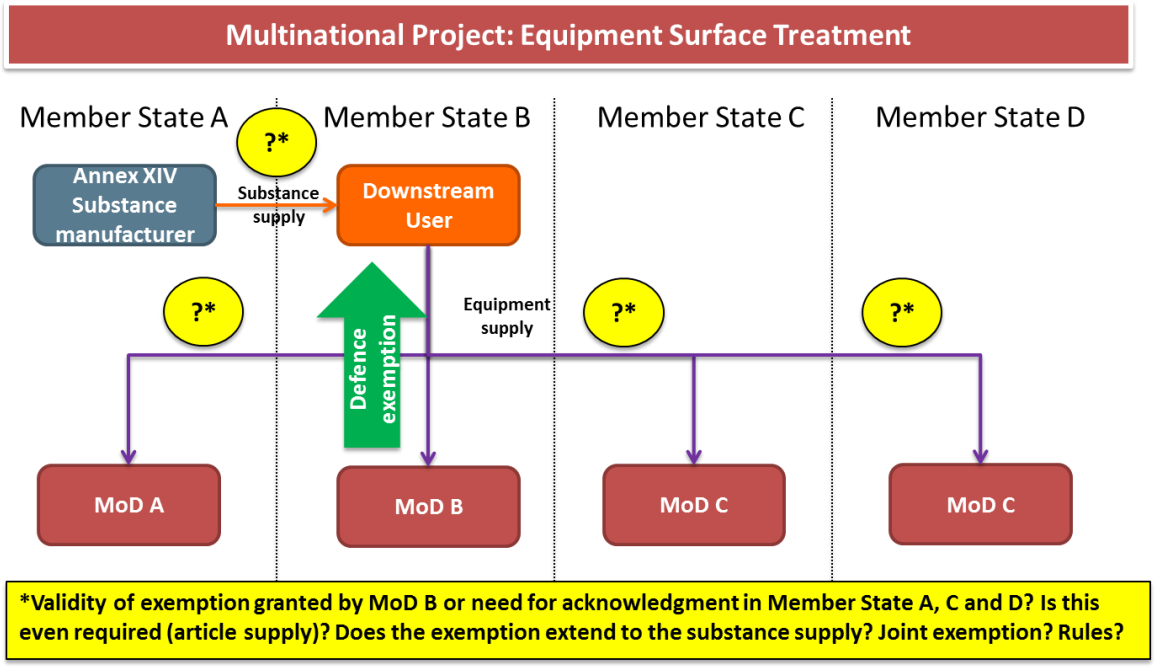
[61] The EDA CoC 2015 thus merely reflected this common Member States' position/interpretation. According to the EDA, if Member States agree in the future on a different position/interpretation of REACH Article 2(3), the EDA CoC could be amended accordingly to reflect this new pMS position/interpretation.

*by EU-legislation low, it might be useful to examine if such a restrictive interpretation / exegesis of Art. 2 (3) REACH is really required. A restriction on the own territorial jurisdiction is in fact explicitly not stipulated and therefore not necessarily to assume. This is supported, for example, as an argumentum a contrario by the formulation of an allowed deviation in Annex XVII, substance No. 59 Dichloromethane, par. 2 to in column 2 (page 252): „Member States may allow **on their territories** and for certain activities the use...".”* Hence, exemptions granted by individual Member States based on REACH Article 2(3) may be valid in all EU Member States.

Today the defence sector is a highly cross-border sector, where defence supply chains are transnational and complex, often scattered over several countries, and EU Member States collaborate for joint maintenance / other programmes (e.g. Eurofighter),[62] but there is **no documented process to address an exemption jointly. Some related discussions have started among Member States under the EDA framework on the possible joint application of the EDA CoC 2015 procedures, by more than one Member States if/when required in the future.**

MoDs and defence industry stakeholders consulted therefore agree that the REACH defence exemption process, especially under current widely accepted restrictive (national only) interpretation of Article 2(3), is **often no option**[63] or very difficult to manage in cases in which defence industries in more than one Member State are involved in a transnational supply chain. A number of questions were raised, such as acknowledgment of a foreign defence exemption and/or the need for further defence exemptions in other EU MSs, to which the defence materiel is supplied or where a substance use also takes place (see Figure 9). **Today, these issues are still largely unresolved and/or subject to different MS views, and would benefit from further clarification.**

Figure 9 National defence exemptions and multinational projects



[62] See further examples of international defence cooperation in Annex F.3.

[63] One MoD noted that a Member State cannot currently give an exemption to a supplier in another Member State.

The defence stakeholder consultation has shown that a clear majority of MoDs (73%) and defence industry (90%) responding would be in favour of an exclusion of defence from the REACH scope (fully or partly).[64] The overall message received from the defence industry is that an exclusion for defence, whatever its form, is very desirable since it would give more time to perform substitution adequately and enable the use in transnational supply chains.

3.3.4 Conclusions

The so-called "defence exemption" in REACH Article 2(3) provides an important tool for EU Member States to mitigate negative impacts from the standard application of the REACH requirements in specific cases (only), in order to maintain a military capability. Most Member States consulted have set up a system for granting defence exemptions, but only 6 of the 27 EDA participating Member States, and Norway, are known to have granted defence exemptions to date. Based on national implementation of the EDA CoC 2015 by Member States, there is a gradual improvement in the overall harmonisation at European level with regard to defence exemptions. A major limitation of the REACH defence exemption is that it cannot cover the common civil applications of dual use substances. Also, national policies frequently foresee a conservative use of exemptions from health and environmental regulations.

Furthermore the REACH defence exemption process is often no option, or very difficult to manage, in cases in which defence industries in more than one Member State are involved in a transnational supply chain. This is especially true under the current, widely accepted restrictive (national only) interpretation of REACH Article 2(3). Given the challenges to apply REACH Article 2(3) across national borders, a clear majority of MoDs (73%) and defence industry (90%) responding would be in favour of an exclusion of defence from the REACH scope (fully or partly), whatever its form.

In addition, it is not clear whether REACH Article 2(3) may apply in the interest of Security. Several MoDs have raised this question. There is an increasingly blurred borderline between "defence" and "security" given the current global situation, especially with respect to newly emerging potential security (asymmetric) threats in the interior of the EU/Member States, to which MoDs may be called to play a supporting role at national level.

[64] See the review of opinions in Annex F.4.

4 IMPACTS OF REACH AND CLP ON THE EU DEFENCE INDUSTRY

The EU defence industry is impacted by REACH both directly and via their supply chain.

Key challenges posed by REACH arise from the defence industry's **dependence** on actors in the upstream supply chain, especially as defence companies are typically producers of highly complex articles. Thus, the defence industry largely depends on the REACH compliance, delivery of information and continued supply by its **complex multi-tier and global supply chains** (Section 3.1 and Section 3.2 above). Therefore, defence companies are particularly vulnerable to upstream **obsolescence** of materials and processes. For complex multi-system producers the corresponding challenges are further complicated due to the **diversity** of defence systems and components (Section 3.2) with partly the same, partly different substances (and other regulations) affected, substitution requirements and supply chains.

The **general impacts** of REACH on the EU defence industry are elaborated below in Section 4.1.

The defence industry stakeholders consulted are mainly acting as *article producers, importers and suppliers*, as well as *downstream users* (hereafter also "DU(s)") in terms of REACH Article 3. Therefore, they are mainly affected directly by **REACH** communication (Article 33) and authorisation obligations. **Process-specific impacts** are elaborated below in Section 4.2.

The **comparative regulatory burden** of REACH vis-à-vis non-EU countries is addressed in Annex L.

4.1 General impacts

This section analyses the general impacts of REACH on the EU defence industry with regard to the aims of REACH, as set out in its Article 1(1):

- ***"to ensure a high level of protection of human health and the environment"*** (Section 4.1.1).
- ***"while enhancing competitiveness and innovation."*** (Section 4.1.2)

Certainty and predictability as another REACH-related concern widely shared by defence sector stakeholders and impacting business decisions is also addressed (Section 4.1.3).

The impacts are elaborated in more detail in the following sections.

4.1.1 Protection of human health and the environment

The impact of REACH for human health and the environment has been analysed with regard to Risk Management Measures (RMM) and Environmental Release Measures (ERM), safety information and data quality, and R&D and substitution.

RISK MANAGEMENT MEASURES AND ENVIRONMENTAL RELEASE MEASURES

The majority (59%) of industry stakeholders consulted had not implemented additional Risk Management Measures (RMM) and 74% had not implemented additional Environmental Release Monitoring Measures as a result of a REACH process.[65]

[65] See question 1.13. and 1.14. in Annex C.

The main reason for this was cited as being because the defence industry, like other industries, is subject to environmental health and safety requirements and regulations that govern various aspects, including the use, storage, discharge and disposal of chemicals, gases and other hazardous substances used in their operations. The need to comply with these environmental and worker protecting regulations pre-dates REACH.[66] Non-compliance with these regimes could result in the imposition of fines, suspension of production or a cessation of operations at national level. Failure to control the use of, or adequately restrict the discharge of, hazardous substances could result in future liabilities for the companies. The Member States are responsible for the enforcement of REACH.

Consequently, the EU defence industry considers that they have strict measures already in place to limit exposure and release. Where any potential improvements are identified, such measures have been implemented as a matter of course, according to the consultees.

Of the 41% of respondents that indicated that they **had made improvements** to their RMMs due to REACH, the main areas of improvement were cited as being due to:[67]

- Implementation of new methods to **identify SVHCs** in new and legacy products;
- Chemical risk reduction by **replacement of SVHC**;
- **Authorisation** driven improvements (e.g. following RAC recommendations);
- Improvements in the information contained in **SDSs**.

In conclusion, though the majority of companies responding believe that REACH has not had an effect on their health, safety and environment performance, a significant minority indicated that it had.

SAFETY INFORMATION AND DATA QUALITY

Of those that have implemented improvements, only a small majority believed that these measures delivered an actual benefit to the improvement to worker health and the environment, while the remainder pointed to existing (national) regulations that already covered safe use and suggested that there had been no significant change in benefit due to REACH. Nevertheless, it was pointed out that REACH has **supplemented** these national laws on some topics, in particular substance and mixture hazards with the information contained in SDSs, which in turn has **added to the knowledge base** for health, safety and environment planning.

Trades Unions consulted during the study noted that REACH has led to a more standardised European approach with the precautionary principle and improved RMMs in the EU. The benefits - with the increased level of knowledge - are considered positive for worker protection.

R&D & SUBSTITUTION

As mentioned above, chemical risk reduction by replacement of SVHC may contribute to the protection of human health and the environment.[68] But, as it will be discussed in this and subsequent

[66] REACH replaced a number of pieces of legislation, e.g. Directive 76/769/EEC, Commission Directive 91/155/EEC, Commission Directive 93/67/EEC, Commission Directive 93/105/EC, Commission Directive 2000/21/EC, Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94.

[67] See also the more detailed list of REACH benefits in Annex H.1.

sections, **substitutes are not necessarily less harmful and may offer less performance for a higher cost**, causing a loss in functionality, safety and/or market share, both for the organisations making articles or maintaining/using articles.

Some SVHCs could be replaced in the short term with relatively little effort, for example some SVHCs used in cleaning processes; while others are the result of years, if not decades, of painstaking research and improvements and cannot be easily replaced without major R&D effort and sufficient time. This is the case for lead in electronics; in the early stages of the electronics era in the 1950's, researchers found that adding lead to tin solder solved a major problem at the time which was the growth of tin whiskers; today, after more than ten years of R&D efforts, nothing performs as good as lead for solving this problem. Similarly, replacing hexavalent chromium in aluminium surface treatment preparations is extremely difficult. REACH and other chemical regulations, with its one-size-fits-all approach, being geared to short term, easy replacements targeting the protection of consumers, creates havoc in the defence and other high reliability sectors due to the mismatch of timelines.

The European defence sector has indeed been working towards a **voluntary replacement** of some of the most hazardous substances used in their products for several years or decades, **commencing before the entry into force of REACH in many cases**. In particular, a huge effort is currently underway on chromate substitution. However, despite collective mobilisation of the sector, alternative options are not yet mature enough to be used in critical applications.

There are several **essential uses** of some substances for which, to date:[69]

- either, **R&D has found no technically or economically viable substitutes** which are suitable and adequate to maintain reliability and performance,
- or, some alternatives have been found but the **industrial supply chain conversion** has not yet been fully achieved,
- or, some remaining applications of this substance are mandatory to maintain the existing equipment and designs in an operational condition and ensure their appropriate **maintenance** throughout their life cycle.

The consultation of defence industry shows a high level of REACH related R&D/substitution work by the defence industry: 78.6% of respondents to the survey acknowledge that their R&D activities have increased due to REACH.[70] However, the following limiting observations are important to add:

- **R&D does not always lead to timely substitution**. It is time-consuming, arduous and has a high chance of failure (this has been mentioned esp. for the replacement of *inorganic* substances, see also Chapter 6).

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[68] There are various drivers for substitution, such as reasons of business sustainability, compliance with legislation or minimization of potential liabilities towards employees and/or staff from customers.

[69] See in particular Chapter 6 and Annex D of this Report.

[70] See question 1.10 in Annex C. This finding is in line with a recent study done for ECHA, in which industry representatives surveyed (mainly chemicals manufacturers) identified REACH as the dominant driver to substitute hazardous chemicals in the EU: Joel TICKNER and Molly JACOBS, University of Massachusetts Lowell, Lowell Center for Sustainable Production, Improving the Identification, Evaluation, Adoption and Development of Safer Alternatives: Needs and Opportunities to Enhance Substitution Efforts within the Context of REACH (August 2016), page 42.

- **This increase in REACH related R&D/substitution correlates neither with the (much lower) increases of the companies' R&D budget to cover REACH nor with the aspect of innovation:**[71] Only 5.4% believe that this additional R&D has resulted in better products. 51% state that their R&D budgets have not increased which means that, for them, the REACH related R&D has been done in lieu of traditional R&D.[72]
- **The improvement for human health and the environment achieved by substituting an SVHC was in most cases not detectable**, mainly due to the fact that the defence sector considers that they can control the risks related to the use of SVHC substances for defence applications. This risk is considered to be very low for the reasons given in Section 3.2 (safety relevant features of chemicals and defence equipment use).
- **The effort required to substitute a substance/mixture can vary significantly depending on each specific case.** In some cases, like for hydrazine or chromates, the associated R&D could be of a very low Technology Readiness Level (TRL)[73] and last many years. In other cases, like for some solvents used in the manufacturing processes, the substitution could be straightforward with R&D of only high TRL.

4.1.2 Competitiveness

Based on the review of survey results, this section contains an analysis of the REACH impact on the competitiveness of the defence industry with regard to the following key aspects: **Innovation** (Section 4.1.2.1), **obsolescence** (Section 4.1.2.2), **economic impacts**, i.e. effect on prices, costs and procurement strategy (Section 4.1.2.3), **relocation risk** (Section 4.1.2.4).

REVIEW OF SURVEY RESULTS ON COMPETITIVENESS

The survey statistics show that only 13% of respondents (EU and non-EU Industry) consider that REACH has already impacted their business in terms of a gain of global competitiveness.[74] Many more respondents (49%)[75] consider a loss and even 70% envisage a specific threat in this regard.

There is a clear correlation between the **position of the respondent in the supply chain** and their response on gain/loss of competitiveness. None of the system integrators, at the top of the chain, have reported any gain or loss of competitiveness so far. At the other end, many smaller components/ammunition manufacturers, more exposed to competition, report loss of competitiveness due to REACH. However, when asked about **future threats**, more respondents, **at all levels of the supply chain**, see a real threat for their competitiveness.[76]

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[71] See below in Section 4.1.2.1.

[72] See questions 1.10, 1.11, 1.12, 1.33 and 1.34 in Annex C for full details.

[73] See definitions of each of the nine TRL levels at https://ec.europa.eu/research/participants/data/ref/h2020/wp/2014_2015/annexes/h2020-wp1415-annex-g-trl_en.pdf.

[74] See questions 1.21.-1.23. in Annex C.

[75] Comparable result: EC, Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs (December 2015), page 27, Table 3.2.1: 44.5% of end users responding said that their competitive position vis-à-vis firms from outside the EU had weakened/weakened substantially.

[76] Annex H.2 contains a list of significant explanations from defence industry stakeholders in relation to loss (and gain) of competitiveness.

4.1.2.1 Innovation

The difficulty of balancing the aims of protecting human health and the environment with industrial competitiveness and innovation is addressed in REACH Article 1(1). For further analysis of the impact of REACH on innovation it is necessary to clarify its definition.

INFO BOX: A definition for innovation

The term *"innovation"* is used differently by different people and its coverage may vary significantly, which can lead to some misunderstanding between those discussing the issue. The **OECD and the EC** have made an attempt to provide a formal definition:[77] *"an innovation is the implementation of a **new or significantly improved** product (good or service), or process, a new marketing method, or a new organisational method in business practices, workplace organisation or external relations."* In practice, there may be different views as to whether a given change in response to regulatory demands is actually innovation. Generally, for industry, **innovation is related to and underlies improved competitiveness** - new products or services that result in **increased profitability and market share** - rather than regulatory compliance or substitution (although the two might correspond, but not necessarily). Specifically, for the defence industry, enhanced competitiveness is conferred by technologies giving a *decisive operational advantage* to EU MoDs and their armed forces.[78] The study survey shows that the defence industry shares these definitions for innovation.

Hence, **substitution needs to be distinguished from innovation**, as shown in Table 2 below.[79]

Table 2 Differences between substitution and innovation

Substitution	Innovation
Substance based	Substance, process, equipment and systems based
Supply driven	Market driven
Legislation to promote substitution is in place (CMD, REACH)	Regulatory basis to promote not as defined
Dependent on availability of alternative substances	Linked to economic and performance drivers; aligned with competitiveness and with R&D

Innovation may result in substitution, and substitution may not require innovation. The **Green Propulsion initiative**[80] to eliminate SVHCs currently used in launchers/missiles/satellites is an example of innovative R&D leading to substitution. But the **timeframe** for Green Propulsion, 15 to 20+ years, is completely **misaligned** with REACH authorisation timeframes for replacement. This

[77] OECD/ European Commission, Oslo Manual – Guidelines for collecting and interpreting innovation data (2005), page 46. This approach also underlies the Community Innovation Surveys.

[78] Me Frédéric MAURO, Professor Klaus THOMA, The future of EU defence research (March 2016), page 31; see also Section 4.1.1.

[79] Based on Health and Safety Authority, Sharon McGUINNESS, Improving Substitution and Innovation, REACH Forward Policy Conference (1 June 2016).

[80] Green Propulsion Initiative. NASA in the US has been engaged in the Green Propellant Infusion Mission (GPIM) for many decades in an effort to replace hydrazine in satellite propulsion. In the EU, the European Commission, European Space Agency and national space agencies have or are funding several projects for hydrazine replacement e.g. RHEFORM, GRAIL, EPIC, GRASP and PULCHER.

misalignment is one of the core issues that the defence sector is facing when dealing with the impact of REACH (see Section 3.2 above).

The sector, as the Green Propulsion initiative shows, has developed and promoted green technologies (e.g. non-hazardous materials) for manufacturing processes, product & services in Research & Technology Development roadmaps to foster eco-efficiency and competitiveness. Doing so, the defence sector usually aims to achieve a **similar or better level of safety and performance**.

With REACH conforming substitutes, the best case is normally to maintain the status quo of performance of the product. Up to now REACH "R&D" substitution work, under the pressure of sudden obsolescence and short authorisation periods, has resulted in mostly lower technical performance of the product leading to higher costs (e.g. because of shorter maintenance intervals).

Due to the lack of time and resources, the result of substances being prioritised onto Annex XIV makes the industry work towards **"short term" substitution to avoid authorisation**. Taking a conservative approach to maintain the required performance and safety level, the solution the most similar to the one made obsolete by the regulation is often sought. Such solution has the increased potential of becoming itself subject to Annex XIV or Annex XVII inclusion in the future, and thus leading to **"regrettable substitution"**. The likelihood that such regrettable substitution occurs during the long in-service life of defence equipment is even higher.

For example, as zinc/nickel is considered as an acceptable substitute for some Cr(VI) and cadmium applications (where less performance is considered acceptable), the issue of *"regrettable substitution"* arises, if nickel salts were included in candidate list and Annex XIV in the future.

Furthermore, the overall view from the industry survey responses (both EU and non-EU companies), is that **REACH has caused enterprises to reduce their R&D and innovation programmes**,[81] although some of them, especially the larger firms, do not exclude that there might be benefits "in the future".[82]

INFO BOX: Consequences of re-prioritising R&D

Authorisation, and its associated pressure to find quick substitutions, is re-prioritising R&D to areas which do not necessarily add value. Though R&D had increased in areas to develop alternatives to Annex XIV substances focusing on improving production processes to manage the impact of REACH, **this is detracting from other R&D priorities like capability enhancements for existing products and platforms, e.g. in aviation NOx, noise and fuel burn reductions, reduction in greenhouse gases etc.** Some respondents stated that authorisation is harmful to R&D in a different way because the same materials and processes experts were involved in the authorisation application creation, which took years, to the detriment of their tasks on R&D for substance substitution.

Thus, **there is an overall consensus from all surveyed stakeholders that REACH has not been a driver for innovation** since the product performance, durability or safety has not improved. Consequently, the budgets used for REACH related substitution R&D do not (as normal R&D) improve

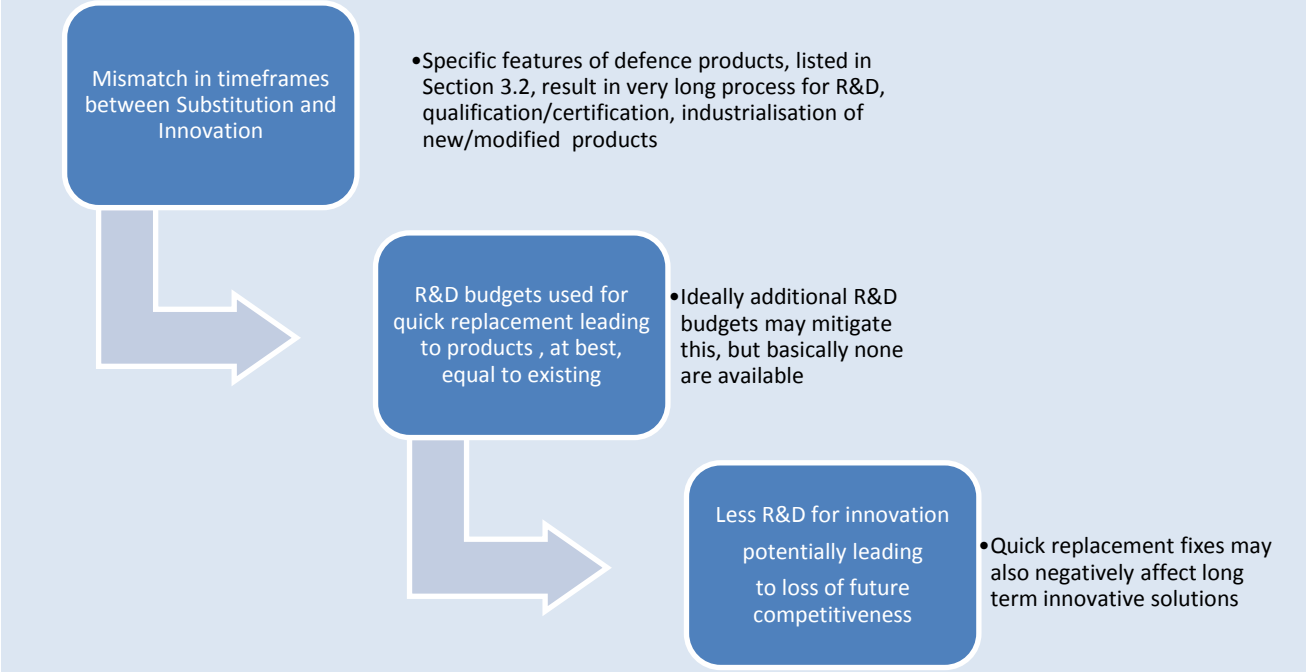
[81] See questions 1.10, 1.11, 1.12, 1.33 and 1.34 in Annex C for full details.

[82] They believe that the REACH Regulation does provide a stimulus for companies to consider options that do not include SVHCs, and this could have a long term effect on the direction of research and innovation in industry towards safer and more environmentally friendly technologies which could, ultimately, confer a competitive advantage.

the market position of the affected companies. As the global R&D budget available has mostly not been increased to cope with REACH related replacements,[83] the R&D activities linked to REACH have been undertaken **to the detriment of other R&D activities** which have been slowed down or postponed. **Diminished innovative R&D could, therefore, potentially lead to loss of future competitiveness**.

Figure 10 illustrates the cause-effect relationship explained above, based on the fundamental mismatch of timeframes and the diversion of existing R&D budgets to fund substitution.

Figure 10 REACH related competitiveness loss



Recent studies confirm the difficulties for industry to conduct innovative substitution under REACH:

- In a study for the **EC**[84] 1076 companies belonging to the chemicals and downstream industries were surveyed to analyse the impact of REACH on innovation. Only 10% of the companies sampled indicated that their R&D budgets had increased and for nearly half, R&D resources were transferred to compliance activities thereby reducing the effort devoted to R&D.
- A study for **ECHA**[85] identified the lack of company-level resources/funding as a major obstacle to SVHC substitution, highlighting a *"broad agreement among those that participated in this project that substitution is challenging, innovation takes time, and the regulatory signal of authorisation is often too late for impacted companies to undertake innovative research."*

[83] See Section 4.1.1.

[84] EC, Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs (December 2015), page iii.

[85] Joel TICKNER and Molly JACOBS, University of Massachusetts Lowell, Lowell Center for Sustainable Production, Improving the Identification, Evaluation, Adoption and Development of Safer Alternatives: Needs and Opportunities to Enhance Substitution Efforts within the Context of REACH (August 2016).

Thus, the REACH related substitution pressure clearly adds an additional challenge for the European defence industry, which is already facing a loss of global competitiveness due to a structural lack of defence R&D, according to another recent study[86] for the European Parliament.

This loss of competitiveness is not compensated for by an improvement in human health / environment achieved by substituting an SVHC, because the defence sector considers that they can control the risks related to the use of SVHC substances for military applications (Section 4.1.1).

4.1.2.2 Obsolescence

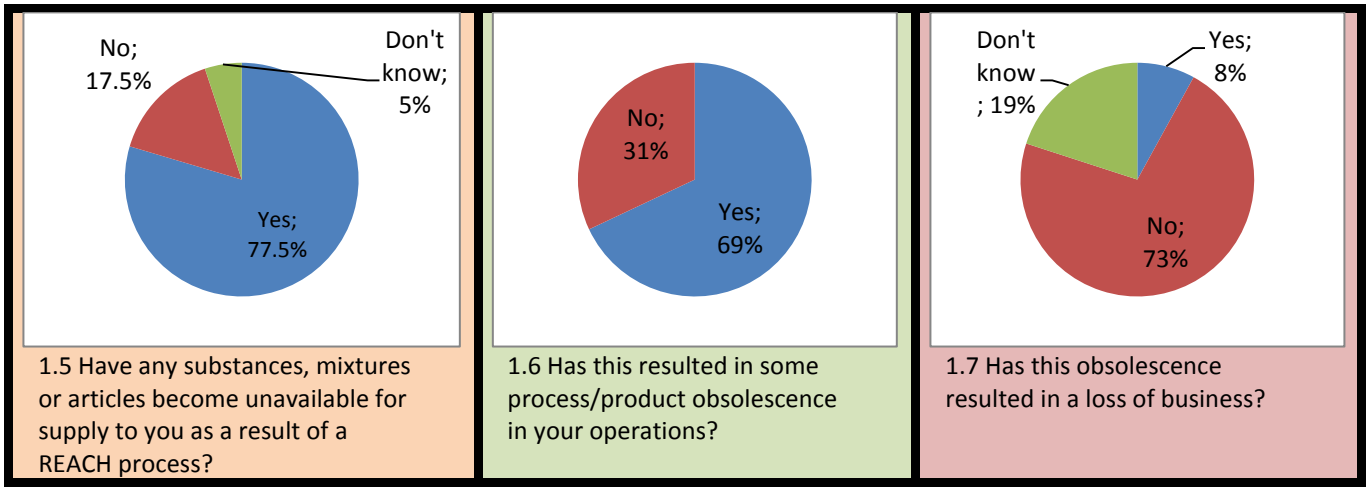
Obsolescence is a major issue for the defence industry, in particular for complex article producers. It can be defined as any impairment of quality and reliability or even loss of critical technologies for qualified materials and processes, which is induced by a substance's unavailability or substitution threat. In this regard, a range of critical substances have sunset dates in Annex XIV.

- For these substances, alternatives have to be found and implemented as far as possible prior to their sunset date, in order to **avoid the authorisation-related burden and uncertainties.**
- For many applications there are **no alternatives** that can satisfy the requirements for safety, airworthiness and other performance criteria critical for defence, within the given timeframe.
- Where potential alternatives do exist, their **validation in processes and products** typically take years to ensure that they satisfy performance requirements and thus obtain certification.

This mismatch between the timelines for REACH processes and the timelines for substitution in the defence industry (see Figure 3 above) **has been identified by all actors as a main threat to the Security of Supply (SoS) for the defence sector**. Please refer to Section 5.2 for more discussion on SoS. In this section, for the industrial impact, the focus will be on obsolescence.

In the survey for defence industry, three questions were intended to evaluate the impact of REACH induced obsolescence. The results are shown in Figure 11.[87]

Figure 11 Defence industry survey results on obsolescence



[86] Me Frédéric MAURO, Professor Klaus THOMA, The future of EU defence research (March 2016), page 8, 45 and 71.
[87] See questions 1.5. – 1.7. in Annex C for full data values.

Three conclusions on obsolescence impact can be drawn from these results:

Defence industry is already being impacted significantly by REACH related obsolescence from upstream suppliers[88]	**This obsolescence from suppliers has resulted in own product/process obsolescence**	**No significant business losses due to REACH related obsolescence because of successful mitigation[89]**

Therefore the defence industry, while being impacted by REACH related obsolescence, has been able to manage without loss of business up to now, through various mitigation activities (see below). Before this, however, the main obsolescence causes reported by the defence industry is given.

OBSOLESCENCE CAUSES

In general, REACH poses two major forms of obsolescence risks for defence activities:

- the **regulatory** obsolescence risk, mainly due to the legal ban for non-registered, non-authorised or restricted substances and their uses, respectively;
- the **commercial** obsolescence risk, e.g. when suppliers change or discontinue products critical for the small defence sector (which has grounds for authorisation or is exempted), because other – larger – markets can no longer be supplied due to regulatory obsolescence.

More specifically, REACH induced obsolescence may occur for several reasons, such as:

- The European supplier takes the unilateral decision to **stop manufacturing an SVHC substance** targeted in REACH when the deadline has arrived. Several companies confirmed the case of one supplier ceasing production **after the sunset date** (no authorisation applied for by supplier). Likewise, another supplier decided to no longer supply a substance after a registration deadline was reached.
- The non-European supplier decides to **stop exporting** the substance or mixture to the EU. Much of the 2018 registration risk is focused on imported mixtures. In such cases only the formulator has the information necessary to register (substance), and may need to register every substance themselves. For low volume niche products this is a challenging task.
- The supplier decides to **reformulate a mixture.**[90] This case is of grave concern to industry since the supplier, sometimes believing that the new formulation has the same specifications and properties to the old one, does not always inform the DUs. In the long, complex supply chains of the defence sector this cannot always be properly tracked and it could cause serious harm at the system integrator level in case of failure due to the reformulation.

[88] By comparison: EC, Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs (December 2015), page 200: Some 30% of survey respondents had experience of substance withdrawals.

[89] It is important that this conclusion is not misinterpreted. The management of obsolescence always comes at a cost, i.e. the amount of efforts and resources spent to achieve the solution. Furthermore, as concluded in Section 4.1.2.1 above, REACH (especially authorisation) motivates quick replacements and forces defence companies to divert R&D resources. A loss of business up to now is therefore not indicative for the future. Companies may also be reluctant to admit business losses.

[90] Some survey respondents have mentioned cases where suppliers of non-setting mastic and rain erosion paint reformulated their compositions due to REACH.

- The supplier **does not register** a substance for **defence-relevant uses**, and therefore does not supply it to the defence industry anymore.[91]
- Authorisation is not granted (has not happened yet).
- Authorisation is granted but the **review period** is largely **incompatible** with the defence needs, i.e. the time needed to identify (through R&D) and implement a suitable alternative. While authorisation renewal may be justified as such, the chemical supplier's interest to support continued authorisation is likely to diminish.

Mixtures, requiring registrations of each component, means that for niche mixtures for small sectors like defence and space, where the customer base is limited, it does not always make business sense for those with the registration obligations to register. With the approaching **2018 REACH registration deadline** for substances of 1-100 tonnes, such small, niche sectors like defence will be further impacted by **registration obsolescence**. This risk is further exacerbated as the defence sector uses a very large number of speciality substances and mixtures from **single-source supplies** given the specialised nature of the defence market (see Section 3.2). In contrast to other industry sectors, alternative sources are often not available meaning that the obsolescence risk is higher.

Furthermore, several defence companies and representative organisations have indicated that while some suppliers have issued **assurances with regard to future registration**, in most cases suppliers do not give specific answers.

OBSOLESCENCE MITIGATION

Some companies have introduced some kind of risk management process intended to mitigate the business disruption risk caused by REACH related obsolescence. The mitigation actions are REACH specific (e.g. authorisation, supplier inquiries); the generic process mostly follows the standard obsolescence management process of the companies.

Specific obsolescence mitigation actions reported by defence industry stakeholders may include:

- **Substitution and requalification** for individual cases;
- **Last time buys to create a stock** for concerned substances, mixtures[92] and articles; if there is foreknowledge of *substances* that might be affected by non-registration,[93] there is the option to pre-stock, which is a strategy which has been employed by both industry and some MoDs. This limits the initial impact of the obsolescence risk and gives time to adjust the supply chain to alternative suppliers. But it is very costly[94] and stocks may have a limited shelf life: After

[91] An example of an organo-mercury substance was given in the survey. It is used as a catalyst in polyurethane production but was not identified in pre-REACH SDS because it was below the threshold for inclusion. It was not registered by the manufacturer as it was recognised that organo-mercury substances would face action under REACH. This caused issues with the manufacture of some products because the change to the mixture required the substitute polyurethane to undergo significant qualification prior to acceptance for use in the end product.

[92] Note: Obsolescence mitigation for mixtures is often limited due to lack of ingredient information claimed as Confidential Business Information (CBI).

[93] The option to pre-stock Annex XIV substances is limited in the sense that they may not be used after the sunset date without authorisation or defence exemption.

[94] Unless targeted based on known threat of withdrawal. It becomes prohibitively expensive when many products are stock-piled at many levels in the supply chains without such targeting.

that they don't have the necessary performance for the manufacturing process or the integration into the system anymore.

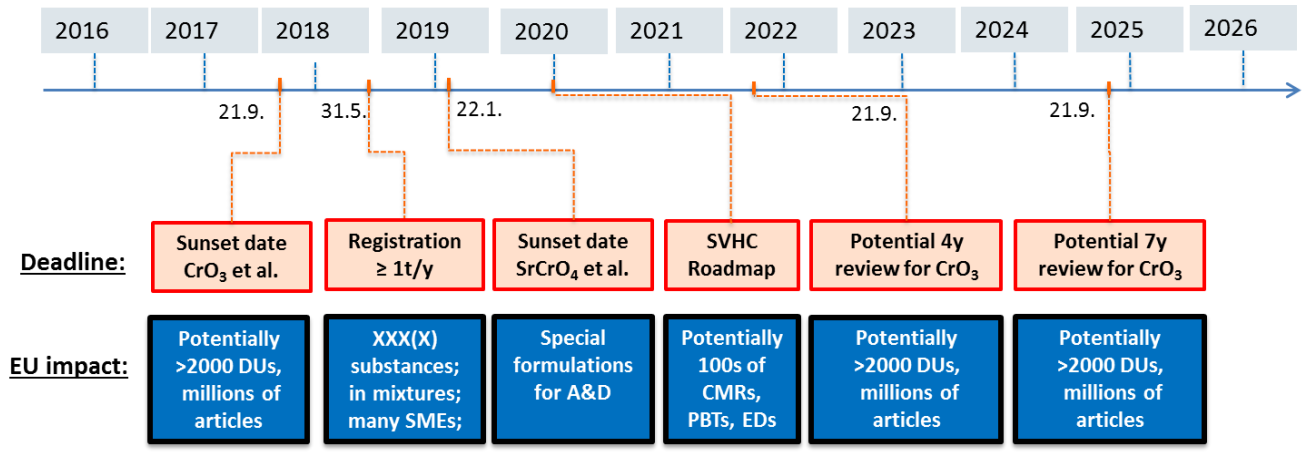
- **Affected production part has been replaced** by a non-affected equivalent /or production at supplier premises has been transferred outside the EU (see Section 4.1.2.4);
- In case the obsolescent substance or mixture is still available outside the EU, an application for **defence exemption** may allow mitigation via importation.
- **Redesigning** some of components of the system to a new technology;
- **Registration – by paying importer** to register concerned substances;
- **Adaptation of the procurement strategy** to avoid (own) registration or authorisation or switch to a reliable supplier able to cope with the REACH compliance burden.[95]

The management of *substance* obsolescence is much more difficult as it is not in the core business of the defence sector. The sector is facing a lack of upstream information.

OUTLOOK

A widely shared concern is that REACH related **obsolescence has not yet reached its peak impact** because the few substances that have disappeared from the market so far were not that critical to the defence sector. Defence industry stakeholders expect that this will change with the coming **sunset dates for chromates (start 9/2017), the further evolution of candidate list and Annex XIV under the EC SVHC Roadmap to 2020, and registration 2018. The past experience with relatively little impacts of REACH is not representative for the future scenario (see Figure 12).**

Figure 12 Major REACH challenges ahead for the defence sector (with a focus on chromates)



[95] For more information on adaptation of procurement strategies due to REACH see Annex H.4.

4.1.2.3 Economic impacts

The survey has shown that the economic impacts on industry fall under two categories, **direct and indirect**, as summarized in Table 3 below.

Table 3 Summary of economic impacts to defence industry

Direct costs	Implementation of REACH management structure, adaptation processes including response to REACH Article 33	REACH is very costly especially with regard the established transversal working groups on company level for the compliance aspects as well to the multifunctional working groups that tackle the day-to-day management of REACH in the programmes.
		REACH managers and regulatory experts are experienced and highly qualified persons, thus expensive as employees; the same applies to chemists and material engineers needed for substitution and authorisation application.
		Also significant costs are caused by the IT tools and data collection/processing necessary to implement REACH, keep track of substances in the company for anticipation and Art. 33 product declaration and this has to be done multiple times for all entities for the case of transnational companies.
	Costs of preparing authorisation dossiers	Industry is greatly concerned about obtaining an authorisation for maintenance activities. Costs and efforts are seen as disproportionate compared with the maintenance revenue. The requirement for the maintenance duration is clearly not in line with the authorisation duration.
	Fees payable to the ECHA	
	Costs of re-opening contracts with non-EU suppliers for inclusion of contractual terms	
	Cost of adapting workplaces to safety and environmental requirements	
Indirect costs	Loss of business competitiveness by increasing structural costs	The additional REACH related costs to industry - as listed above - are mostly within indirect functions and thus charged via price models towards customers, thus resulting in de facto price increases which dent competitiveness.
	Possible impact on product quality and customer dissatisfaction, and therefore cost of strengthening the control of the supply chain	
	Double approaches for the countries of the EU and non-EU area	
	Re-qualification, e.g. in case of change of provider or relocation outside the EU area	
	Obsolescence management	
	The need for development / redevelopment alternatives, adapting technologies	

As already mentioned (see Section 4.1.1), it has to be considered that **R&D does not always lead to timely substitution** (not to mention innovation). R&D is typically resource-intensive and has a high

chance of failure. While providing lessons learnt in the best case, such REACH-related R&D activities may also negatively impact competitiveness.

Price increases from upstream suppliers do not seem to have had a measurable impact. Few survey respondents (38%) believe they have already tracked some price increases from their suppliers attributable to REACH compliance. However, even for those few cases, suppliers tend to argue that price increases were not due to REACH. **On the other hand an overwhelming majority (85%) believe that they will be affected by future price increases.**[96]

Even though the main cost impact is expected in the future, most respondents report REACH related additional costs. However the reporting was not homogeneous and it was difficult to derive a global total cost. The REACH related additional costs (direct + indirect, **excluding R&D/Substitution**) for large companies are up to 7,000 K€/year and total overall REACH costs to date of up to 15,000 K€. For smaller companies additional annual costs are up to 200/300 K€/year and overall total costs are up to 600 K€ to date. More information can be found in Annex H.7.

A few conclusions on the economic impact can be drawn from the data collected:

- The nature and amount of the costs **depends on the position in the supply chain**.
- *System integrators* that make highly complex articles, consisting of thousands of individual items and materials, **spend a considerable amount of money on Article 33 compliance**. Obtaining the necessary information on SVHC use from the supply chain, integrating the Article 33 requirements into existing design/manufacturing/purchasing software (or introducing new ones) has become very costly for them. And this is even more so after the recent judgment of the Court of Justice of the European Union (CJEU) (Case C-106/14).[97]
- The economic impact on *makers of simpler articles (including ammunition)* and component manufacturers fall mainly on **substitution work**.
- Even though many respondents agree that there will be a future economic impact, few were able to quantify it.

4.1.2.4 Relocation risk

A possibility to avoid impacts of REACH (loss of competitiveness) is to relocate impacted production to non-EU countries. However, this possibility is limited in the defence sector.

For some **strategic products or components**, relocation cannot be considered. For contractual or regulatory reasons, certain products cannot be produced or exported outside a defined nation. Also, relocation would imply, in many cases, re-qualification and increased cost of products.

Yet, 45% of defence industry stakeholders consulted, and all non-EU headquartered defence companies consider or discussed the option of relocation of production due to a REACH impact, or at least foresee in the near future discussions about relocation of manufacturing facilities to non-EU countries due to REACH.[98] This could also apply to maintenance of REACH impacted products.

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[96] See questions 1.1 and 1.2 in Annex C.

[97] See the discussion of this judgment in Annex J and further information in Section 4.2.2.1.

[98] See question 1.24. in Annex C.

INFO BOX: REACH impact for non-EU headquartered defence companies

The reported impact for non-EU headquartered defence companies with operations in Europe is more or less similar to their EU competitors. However, the flexibility to move some hard-to-substitute processes or even the complete production out of the EU (e.g. to their home country) could be higher for non-EU companies. Some EU companies with existing operations outside EU may also have the option to relocate, but it is limited - for strategic and political reasons - to non-strategic components.

On awareness of specific examples of relocation to non-EU countries to continue using the substance 33% responded positively.[99]

- One EU-based **component manufacturer** surveyed has already transferred a technology that uses Annex XIV substances to one of its non-EU plants; by doing so they will be ready to relocate production of the affected articles when needed.
- There were remarks from consultees that **surface treatment processes** have been relocated outside the EU.
- One respondent mentioned that they were aware of cases where companies have moved operations outside of Europe, e.g. a manufacturer of metal bolts for the aviation industry using DEHP coating has moved to Morocco.

Respondents noted that from September 2017 onwards - with the first sunset date of chromates - more relocation activities are expected to be visible.[100]

One trade union consulted stated:

"We've seen some problems regarding ammunition and explosives where productions have been moved or partially moved to countries outside the EEA, not specifically because of REACH regulation, but due to lower standards regarding environment and health issues and it[s] *impact on costs, that may be related with REACH. We're also aware about the risk for the aeronautic sector due to the use of "chromates" that have not substitution to the day, and may lead to relocation problems."*

In summary, while evidence of actual occurrences of relocation in the European defence sector is still limited today, defence stakeholders consulted expect that this risk of taking related strategic long-term decisions could increase with the anticipated REACH impact in the future.

4.1.3 Certainty and predictability

Defence industry stakeholders have frequently expressed a high level of **uncertainty** and **associated business risks** induced by REACH in general and authorisation/the regulation of (potential) SVHCs in particular, as a key concern (see Figure 13 below). **Managing** these uncertainties around REACH means that defence companies need to put a significant amount of effort into handling its impacts

[99] See question 1.26. in Annex C.

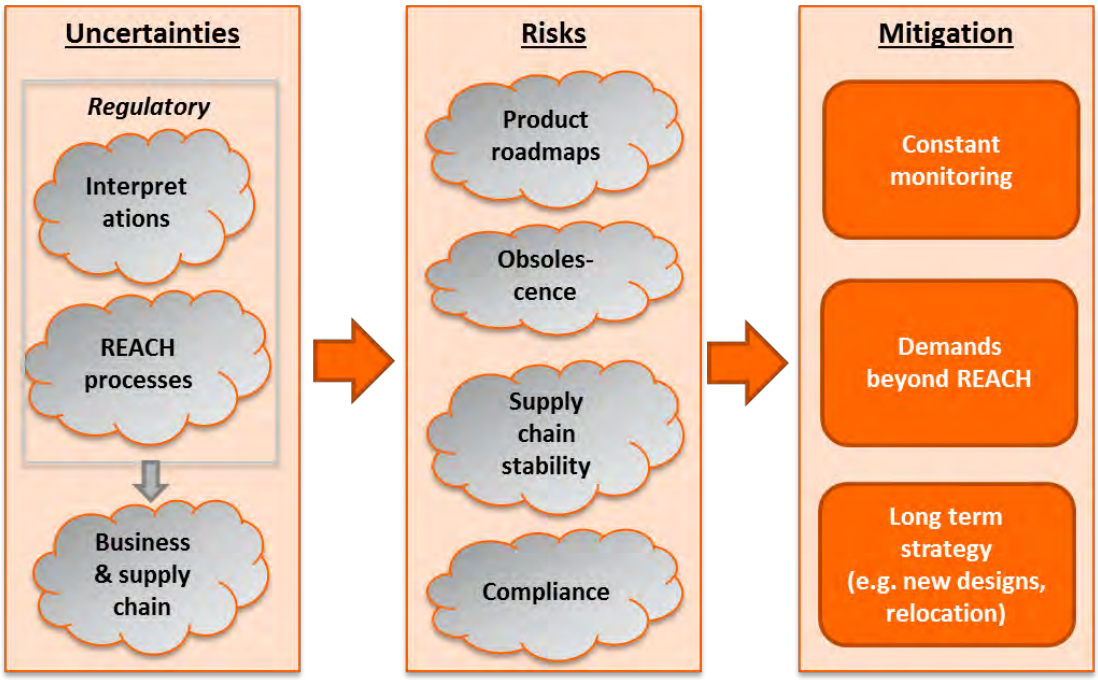
[100] The relocation risk was also confirmed in a recent report by Panteia, Economic Impact Authorisation Chrome VI (July 2016), page 14: *"It is expected that after the sunset date in case of no or short term authorisation, applicator enterprises will relocate production to non-EU countries (in which Chrome VI use is still permitted), or applicators' clients will import required products from enterprises from non-EU countries."*

for business continuity. The uncertainty relates to **regulatory aspects** (uncertainty of the **legal text** on the one hand and brought about by the **REACH processes** managed by the authorities on the other hand) and – mainly as a consequence - **within the businesses and highly complex supply chains**.[101] The relevant substance-level information is often lacking.

Defence sector stakeholders consulted have more or less unanimously expressed that the constant, yet unforeseeable evolution of the REACH substance lists (candidate list, Annex XIV, Annex XVII) as a moving target creates huge challenges and major risks for the companies.

There is a significant level of regulatory uncertainty due to the **unpredictability whether, when and in which process** a substance will be further regulated under REACH. The **visibility** of the substance list evolution is **not in line** with the defence companies' development and service cycles. This creates risks for **companies' product roadmaps and economic viability of their contracts** (e.g. potential regrettable substitution), in addition to the risk of obsolescence and supply disruptions (e.g. due to early replacement decisions of upstream suppliers), and overall risks on European industrial structures (e.g. due to relocation to non-EU countries, see Section 4.1.2.4). Proper risk mitigation requires a **constant effort to anticipate, assess and track** the evolution for substances of concern in the REACH substance lists.

Figure 13 REACH-related uncertainties, business risks and mitigation



Furthermore, the regulatory uncertainty typically results in **demands beyond REACH**, such as

- Customer demands to avoid any candidate list substances in the product;
- Disclosure of substances beyond REACH Article 33 requirements, e.g. also if below 0.1%;
- Safety data sheets (SDSs) for articles.

[101] See Table 23 in Annex H.3.

The impacts of this uncertainty on **strategic investment decisions** in the European defence sector, which is characterised by decades-long product development and service lifecycles, have just started.

Uncertainty also arises with substitution, as some alternatives currently qualified, developed and certified could become obsolete in some years if these substances are included in the REACH lists leading to Annex XIV (or Annex XVII); "regrettable substitution" (see Section 4.1.2.1)**.**

Indeed, environmental regulations are constantly subject to change in response to new information on identified actual risks. However, **REACH has seriously aggravated this change potential**: For substances with a harmonised classification and CMR Cat. 1A or 1B the ECHA/MSCA proposal to include the substance in the *"candidate list for eventual inclusion in Annex XIV"* (REACH Article 59(1)) may be limited to a mere reference to the classification entry in CLP Annex VI, *"if appropriate"*.[102]

Whereas regulatory uncertainties are not a specific issue for the defence industry alone, its position as a producer of very complex articles with long lifecycles and high performance requirements at the end of very complex supply chains and resulting dependencies on a high number of suppliers, materials and processes - and hence substances, including SVHCs - make it **particularly vulnerable** to it and **multiply the risk mitigation effort**. Defence has this issue in common with other - civil - downstream users sectors such as aviation and space. Given the close ties to their end users – the MoDs – the **capability for the defence industry to mitigate uncertainty through fast steering and quick decisions** appears even more limited than in other sectors.

The mentioned risks and resulting mitigation efforts are even higher where **substances with a very large application range** are included in Annex XIV, such as in the case of chromates.

INFO BOX: "Brexit" and its possible impacts on REACH regulatory compliance

The UK's vote of 23 June 2016 to leave the EU ("Brexit") is another major factor affecting certainty and predictability for the defence industry with regard to REACH, but also more broadly. The issue was not considered as a part of the survey which was launched before the referendum in the UK. However, some remarks are made here based mainly on the Contractor's expertise due to the importance of this issue to REACH regulatory compliance within the defence sector. The defence sector in the EU-28 does not operate in a bubble, with no exposure to external influences. Brexit is a serious issue, not just for multinational platform integrators and other large downstream users, but also for the wider manufacturing and distribution sector with complex supply chains spanning across the EU and beyond. The UK's post-EU arrangements will be determinant for the possible impacts. More information on Brexit and its possible impacts can be found in Annex H.9.

[102] See REACH Article 59(2)2 and (3)2. In a study by Milieu Ltd., Technical assistance related to the scope of REACH and other relevant EU legislation to assess overlaps, Final Report (revised) (12 March 2012) for the EC REACH review 2012 an automatism for the inclusion of CMR Cat. 1A/B in the candidate list was suggested: *"Similarly, substances already included in Annex VI of CLP and identified as falling in the scope of Article 57 of REACH should also be automatically included in the Candidate List."*

4.2 Process-specific impacts

This section analyses the impacts of REACH with regard to the following processes:

- Registration (Section 4.2.1);
- Substances (SVHC) in articles (Section 4.2.2);
- Authorisation (Section 4.2.3);
- Restrictions (Section 4.2.4).

In addition, the impacts of CLP are summarised (Section 4.2.5).

4.2.1 Registration

Registration is the obligation of manufacturers and importers of substances on their own or in mixtures. The role of *manufacturer* with registration obligations is only exceptionally assumed by EU defence companies, such as producers of ammunition (e.g. lead styphnate). More commonly they may assume the role of *importers* of substances on their own (e.g. hydrazine) or – mostly – in mixtures (e.g. maintenance chemicals for defence products purchased outside the EU). According to the survey the substance volumes sometimes exceed the registration threshold.[103]

While a majority of respondents have reported **experience of the registration process**, less than 30% noted that it was their own process (almost all of those were solely or partly producers of munitions). These figures are indicative of the **downstream nature of most defence companies** and the fact that they rely on their upstream supply chain to import substances and mixtures and also to manufacture some components that are included in their complex assemblies. Indeed, defence prime contractors are often 6-8 tiers away from the companies having the registration obligations. Many suppliers are **SMEs** and, due to the low quantities of platforms delivered spread over up to two decades of the production lifetime, the purchase volumes per supplier can be relatively low.

Hence, the impact for the defence industry depends on whether defence companies:

- **Rely on upstream registrations – Experience as downstream/end user (**= main case**); or**
- **Act themselves as a manufacturer / importer - Experience as a registrant.**

Given the **complexity of the defence supply chains**, several challenges were apparent from the last two registration deadlines and are projected to manifest again with the final deadline in 2018.

EXPERIENCE AS A DOWNSTREAM / END USER

Given the complexity of the defence supply chains defence companies typically do not know exactly what and how substances are used in what processes and component manufacture in their complex assemblies, and when registration is due. Their ability to mitigate **obsolescence** risks, therefore, is limited given that they do not know what and where these risks may arise until they impact them (see Section 4.1.3 above). In such a case the costs associated with non-registration - for materials

[103] However, for imported hazardous substances, including in (resulting) hazardous mixtures, importers have a C&L notification duty regardless of the volume, CLP Article 39(b), 40.

change, re-qualification of new materials or suppliers being required at short notice - may be very high.

Where registrations have been made by upstream suppliers, some defence industry stakeholders have reported difficulties with the **coverage of their specific (niche) uses** in the registration dossiers, mainly because the defence company is not able to communicate directly with the higher tier registrant. Consequently, many substance manufacturers and mixture formulators are **unaware of military uses of their products**. The following examples from the survey can be given:

- In 2010 a prime contractor had to intervene at a cost of about € 200k to ensure the **full registration and continued supply of sodium dichromate and potassium dichromate** as the registration was being limited to transported isolated intermediate use under strictly controlled conditions, which was not the use of the defence prime contractor.
- A munitions company needed to proactively notify its specific pyrotechnic use as the supplier didn't cover it in its registration and indeed stated it was a use advised against.

EXPERIENCE AS A REGISTRANT

In general, most of those defence companies that have direct experience of the registration process state that despite uncertainties surrounding future obsolescence, and some problems with SIEF transparency, **they found the process reasonably efficient**, with costs not considered excessive.[104] However, the respondents included mostly large defence companies, whereas the majority of companies in higher tiers of defence supply chains are considered **SME**.

Where registration obligations exist for these SME companies, those that responded noted that REACH processes such as registration or authorisation are highly complicated and impact users of substances not just those whose main business is in the chemicals industry. As the use of these substances sometimes requires their importation from non-EU countries e.g. for contractual maintenance obligations from a single source, these **SMEs** generally do not have the in-house expertise to undertake the registration process alone. ASD stated that while large defence companies can cope with these burdens, SMEs are struggling with resources, competences and capabilities in regards to REACH. Large defence companies can provide a level of support to their supply chain but it was felt that there needs to be more support from the European Commission.

REACH REGISTRATION IN 2018

The EU defence sector is likely to be strongly impacted by the final registration deadline in 2018 because of the following main factors, which were also reflected in the survey responses:

- the lower volume thresholds – manufacturers of low volumes may decide not to register;
- expected increase in SME registrations;
- more first-time registered substances with very small SIEFs (e.g. 1-5 members) and no possibility for read across, which may result in significant cost increases;[105]

[104] It was reported that some companies were unsure as to who held the registration obligations. This caused disagreements with suppliers and customers over who is "importer of record". Further, the importer definition, as well as that of intermediates, were highlighted as areas where there could be improved explanation in ECHA guidance.

[105] Additionally, some companies that have registration obligations in 2018 have pointed out that the prices for laboratory analysis of substances are increasing from contract laboratories, which is adding to the overall costs of the registration process for 2018.

It is expected by several defence industry stakeholders consulted that several substances critical to defence applications will not be registered by their current suppliers. In a worst case scenario, certain substances **will not be available** in the EU which will necessitate supply chain restructuring that could entail costly re-qualification of the product as well as suppliers. In order to secure supply, some defence companies are considering registering themselves by becoming an importer. However, typically any related obsolescence will not be visible to the end user until it occurs. This is also because there is only limited visibility on substances contained in mixtures (and articles), as REACH does not require full disclosure of composition in SDSs.

CONCLUSIONS

Overall, the survey has shown that registration has not been a major direct concern for the EU defence industry to date. Yet, some cases of non-coverage of defence specific uses, that had to be mitigated, were reported. However, according to the defence industry stakeholders consulted the impact is expected to increase sharply with the upcoming registration deadline in 2018 and the many SMEs potentially affected by it.

4.2.2 Substances in articles

The defence industry is strongly impacted by REACH Article 33, to a lesser extent by Article 7(2).

4.2.2.1 Communication according to REACH Article 33

Communication according to REACH Article 33 - together with authorisation - is the REACH process which affects defence companies as producers of highly complex articles most directly. REACH Article 33 provides:

"Any supplier of an article containing a [candidate list] *substance […] in a concentration above 0.1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance."*

The study consultation has confirmed that the implementation of REACH Article 33 has triggered significant challenges and resource implications across the European defence industry. As producers of very complex articles, they question the proportionality of compliance with the provision. The vast majority of defence industry stakeholders consulted fear that this situation will worsen following the "Complex Article" judgment of the CJEU of 10 September 2015 (case C-106/14) regarding the obligations under REACH for companies to report the presence of SVHCs in articles.[106]

The judgment clarifies that the **calculation** of the 0.1% threshold in complex articles for the application of REACH Article 33 should be done **based on each single constituent article (component article)** instead of the complex article as a whole - ***"Once an article - Always an article"*** **(O5A)**. As a result of the CJEU judgment, ECHA has launched a revision of its Guidance on requirements for articles (Guidance for Articles) in 2016.[107] ASD is involved in that revision as a member of the Partner Expert Group (PEG).

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[106] See the discussion of this judgment in Annex J.

[107] In December 2015 ECHA published a fast-track update to make "quick" corrections to the parts with references to the 0.1% limit that are no longer consistent with the conclusions of the CJEU judgement.

One key question of major importance for complex article producers, like defence companies, to be clarified in the revised guidance is whether the complex article supplier's **duty to communicate** is limited to a list of candidate list substances in the whole article (in addition to necessary safe use information[108]), or whether the duty also extends *by default* to indication of the component article where the substance is present (localisation information). The latter seems to be, for example, the current opinion of the German REACH MSCA.[109] The CJEU has not clearly decided on this question**. A review of the different opinions and proposed solutions is included in Annex N.5.**

CHALLENGES FOR COMPLIANCE WITH REACH ARTICLE 33

To understand the challenges of Article 33 compliance for the defence sector, it is important to recall that defence companies are typically producers of highly complex articles.[110]

INFO BOX: Challenges for producers of highly complex articles

Highly complex articles produced in the defence industry (e.g. tanks, submarines, jet fighters such as Eurofighter Typhoon 'EF-2000') consist of many millions of articles – a single electronic component is an assembly of articles. The supply chains leading to their production are complex, multi-tier and global. The sources of systems procured are diverse (e.g., integration of various weapons onto ships and aircraft). Major defence system integrators must deal with several tens of thousands REACH relevant suppliers. Collection of comprehensive chemical information throughout the supply chain is very challenging due to the various levels of data that are available, and because there is no aligned standard across all sectors and companies for delivery of substance information across the supply chain.

Aerospace and Defence (A&D) companies are working on addressing these challenges on a global level through the IAEG[111] and the IPC[112], by developing a common list of A&D declarable substances and a standard for reporting of chemical substances by A&D suppliers.

Defence industry stakeholders have more or less unanimously confirmed that the **administrative burden** to achieve compliance with Article 33 has been significant and a main cause of increased documentation and communication needs due to REACH.

Main tasks have included:

- Design and implementation of required (IT-based) substance-tracking, data collection and processing systems;

[108] This may also include localisation information, if there is an action required by the recipient or user for safe use reasons.

[109] See BAuA REACH-Info 6 (April 2016), page 47: *"Letztendlich muss der Lieferant seinem Abnehmer **für jedes in einem zusammengesetzten Erzeugnis enthaltene Erzeugnis** eine Mitteilung machen, sofern ein Kandidatenstoff darin zu ≥0,1% enthalten ist."* (Contractor's translation: *"Ultimately the supplier should make a notification to his recipient for each article contained in an assembled article, provided that a candidate list substance is contained therein at ≥0,1%."*). The BAuA has confirmed on 12.9.2016, that an English version of this document will be published in the near future.

[110] The challenges associated with complex supply chains are also further elaborated in Annex H.5.

[111] International Aerospace Environmental Group, through its Working Group "Chemical Reporting".

[112] E.g. there are initiatives under consideration eg IPC 175X series particularly 1754 and the 2.18k committee https://www.ipc.org/committeedetail.aspx?Committee=2-18K.

- Calculations, substance declaration and follow-up both up and down the supply chains.

These tasks induce significant **costs** (see already Section 4.1.2.3 above). Most defence industry stakeholders see a major risk that the already high administrative and cost burden on companies selling products in the EU caused by Article 33 compliance, which necessitates the capture of relevant information and delivery of this information to the customers, will dramatically increase in the near future due to the O5A judgment of the CJEU.

Access to information is another major issue. Defence industry stakeholders report that compliance with Article 33(1) – though linked with high administrative effort – is manageable for upstream EU suppliers. However, more difficulties have been reported to manage upstream non-EU suppliers of very complex articles (such as military aircraft), because they are not obliged by REACH. Due to **confidentiality aspects in the defence sector** (e.g. with regard to Intellectual Property Rights (IPR)), such information is very difficult to obtain, while the situation becomes even more difficult due to limitation of non-EU defence related legislation, especially ITAR in the case of US suppliers.[113] Therefore, it is much more difficult for defence companies to comply with Articles 7 and 33 of REACH in cases of import when compared to other industry sectors. Access to information for **legacy systems** is also very problematic.

Furthermore, the EU defence industry with its complex, multi-tier and global supply chains is highly reliant on **legal certainty and an EU-harmonised interpretation** in relation to REACH Article 33. With the O5A judgment the dispute that existed due to differences of interpretation by Member States about the 0.1% **calculation reference** is resolved, but the **content of the Article 33 declaration** remains unclear, at least until the ECHA Guidance for Articles has been revised (see also Annex N.5).

BENEFITS OF THE APPLICATION OF REACH ARTICLE 33

According to the consultation, defence industry stakeholders **do not see much added value to the safe use** of highly complex defence products. It is noted that useful information for the safe use has already been included in the exhaustive technical documentation (i.e. operational manuals / maintenance manuals) provided with the articles supplied.

However, the disclosure of SVHCs, actually or potentially present, in the article allows an improved anticipation of obsolescence risks for the customer. It could also be useful for careful and efficient dismantling at the end of life of the equipment[114] and also for originally unplanned maintenance / update scenarios. This usefulness is limited by the fact that Article 33 only applies to the candidate list at the time of supply, not considering future entries. However, defence industry stakeholders consulted report that the customers' requirements for reporting frequently **go beyond Article 33** and that military customers expect to have the same level of transparency as other industries.[115] The survey found that this improved communication along the supply chain is seen as the only positive impact of Article 33 compliance from an industry perspective. Major companies from the A&D sector

[113] See also the case study "Imported "black box" equipment and legacy systems" in Annex H.5.

[114] One MoD pointed out that the disposal of old aircraft results in removal of usable spare parts by qualified staff. These spare parts are then sold as second hand spare parts. Related information on SVHC in spare parts could be useful.

[115] This implies that corresponding requests need to be made to upstream suppliers. However, this is often difficult to achieve, especially with non-EU suppliers.

have been working together on a global level to standardise the process for collecting information on chemicals in A&D supply chains.

Table 4 below summarises the described challenges and benefits of Article 33 compliance.

Table 4 Challenges and benefits of Article 33 compliance in A&D supply chains

Challenges	Benefits
• complexity (number) of defence products • complexity of supply chains (multi-tier, number of suppliers, international) • resulting administrative and cost burden • restricted information, esp. for imported articles (IPR, non-EU restrictive legislation (e.g. US/ITAR)) • legacy systems • different Article 33 compliance approaches by suppliers and authorities leading to different levels of information	• improved communication along the supply chain • for end users (MoDs) and system integrators: improved anticipation of obsolescence risks; dismantling and unplanned maintenance / update scenarios

CONCLUSION

Overall, defence industry stakeholders consider that the effort to comply with Article 33 within extremely complex global supply chains, and with extremely complex products, has been **clearly disproportionate** with regard to the added value to safe use of the article targeted by this REACH provision.

4.2.2.2 Notification according to REACH Article 7(2)

Article 7(2) has not posed major concerns for the defence industry to date. Exceptionally, some EU defence companies reported the submission of notifications under Article 7(2) (e.g. for lead compounds).

Normally the threshold of 1 tonne per year for imported articles is not expected to be exceeded, and even if it is, then an exemption from the notification obligation can normally be applied when:

- The substance has already been registered for the use (REACH Article 7(6)); or
- Exposure during normal or reasonably foreseeable conditions of use including disposal can be excluded (REACH Article 7(3)1). It should be noted however that, in such cases, the producer or importer should still supply appropriate instructions to the recipient of the article.

However, concerns have been raised from the industry side with regard to possible higher demands in the ECHA Guidance for Articles[116] e.g. to demonstrate an exemption for already registered use.

[116] Currently under revision.

4.2.3 Authorisation

Together with REACH Article 33, the authorisation process creates the biggest impact on the EU defence industry.

4.2.3.1 Overview

The aim of authorisation, according to Article 55 of the REACH Regulation, is: *"[…] to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. "*

The defence sector has already been strongly affected by the Application for Authorisation (AfA) process, e.g. phthalates, lead sulfochromate yellow, lead chromate and severely for Cr(VI) compounds. While the allowance of defence exemptions under REACH Article 2(3) is reserved for specific cases, and does not cover civil applications of dual use substances, the AfA for military uses is often seen by defence industry stakeholders, but also some MoDs as customers and supporting the AfA, as disproportionate and not fully fit for purpose.

When asked about their overall experience of the authorisation process, many companies surveyed described it as being **expensive, complex, and unpredictable**. Some suggested it was overly time-consuming and poorly defined. Such opinions are possibly due to the belief that the defence sector, being a high tech sector, is already engaged in implementing RMMs to reduce risk as a matter of course, with authorisation introducing an additional burden. Evidence of the **clear socio-economic benefits of the defence sector** and the control of the risks in using SVHC substances can be seen from past applications in which military uses are identified (see Annex G.1) which show that the **simple average cost to benefit ratio**, for military specific or dual use, downstream user applications,[117] is approximately **1.77 million : 1**.[118] This raises questions of proportionality when having to go through such a burdensome process while the business case is generally clear.

Furthermore, the **scope for substitution** in defence equipment is **limited** (see Section 4.1.1). Defence products are often **developed in joint efforts** between multiple EU, and sometimes non-EU states, and are governed by international treaties on quality and interoperability. Consequently, non-EU companies find it difficult to understand why EU companies need to change a substance from an existing agreed and standardised joint process that already meets e.g. NATO standards and expectations,[119] leading to long validation/qualification cycles and costs not only in the EU but also outside.

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[117] This excludes applications for authorisation from consortia, where military uses may have been covered but for which other industrial activities e.g. civil aerospace or automotive were the main motivators behind the application (e.g. CCST, CTAC).

[118] Cost benefit analysis provides a framework for comparing the costs of not using the SVHC substance and benefits from risk management measures for the continued use of the SVHC substance. The present ratio was derived from military specific or dual use, downstream user applications. This means that for every €1 society benefits from not using the SVHC substances, in the defence and dual use authorisation applications analysed as part of this study, it loses €1.77 million.

[119] An example of this was given in that ammunition needs to comply with NATO standards in order to be interchangeable within the weapons of all NATO allies. Changing the composition of such ammunition in the EU is not possible unless the non-EU armed forces agree. Alternatives that are not accepted by the non-EU partners are not, therefore, feasible or viable alternatives, even if they could be considered technically feasible in a European context.

Moreover, the expenses incurred in applying for authorisation are **disproportionate** as implementation of authorisation in the defence industry does not help in achieving its stated aim, given that alternatives are not available that meet the needs of many uses of the industry.

While maintaining high standards of RMMs and protection to workers and the environment, some stakeholders also noted that **the current use of an Annex XIV substance ultimately ensures the reliability, quality, and longevity of important defence equipment**. Their use limits the potential for failure of equipment on an evolving battlefield and consequently, in the view of some MoDs and defence companies, the benefit of reliable equipment is higher than the strictly controlled risks in industrial processes.

Many applications including military uses are at various stages of the authorisation process, with very few having reached the end of the pipeline (see overview in Annex G.1). What is clear from consultations is that a **large potential impact** is foreseen with the forthcoming decisions on critical substances, e.g. Cr(VI), and the continued expansion of Annex XIV, if done without due consideration of socio-economic consequences, substitutability and overall priority goals.

*For **detailed further information** on authorisation applications and related impacts on defence companies reference is made to the Annexes D.4 "Cr(VI) compounds for surface treatment" (including a case study "authorisation impact on chromates"), G.1 "Overview of main REACH applications for authorisation relevant for defence", G.2 "Review of submitted authorisation applications covering military uses" and G.3 "Streamlining and simplification of the authorisation application process."*

4.2.3.2 Impact of the authorisation process for defence

SUBSTITUTION AND SUBSTANCE SOURCING

ECHA state, in the "Report on the Operation of REACH and CLP 2016",[120] that there are indications that substitution is taking place and that the process of authorisation is delivering the aim of promoting substitution. A reference was made to the plasticiser DEHP, which originally had 25 registrant companies and only three applications for authorisation. They further point to anecdotal evidence of shifts in registration dossier tonnages and the implementation of sector level black lists which focus on reducing or avoiding the presence of SVHC substances.

It is clear from defence prime contractors that there is a drive from their customers, the MoDs, to implement substitution where performance and use of the defence equipment is not adversely impacted, as 79% of respondents[121] stated that customers impose contractual constraints (e.g. ban or avoid use of certain substances, or notify further) beyond REACH requirements, i.e. some MoDs use the Candidate List, Annex XIV and Annex XVII, while some have national lists in line with their national environmental goals, of substances to be avoided.

Recognising the inability to substitute critical substances, while providing the necessary performance in agreement with international requirements, when asked 90% of companies responded that one or more of their **products requires the use of an SVHC substance to meet the expected requirements**,

[120] ECHA, Report on the Operation of REACH and CLP 2016 (May 2016).
[121] See question 1.30 in Annex C.

while 95% stated that they require the use of an **SVHC to achieve the expected performance and quality of the product**, with 79% noting that they are **contractually obliged** to use an SVHC.[122]

Despite moves towards substitution within the defence sector, listing of a substance on the candidate list or Annex XIV has had a negative impact for defence companies on their ability to source critical substances and mixtures. Such action does not hasten the ability of defence companies to substitute.

Shrinking numbers of suppliers, and in some cases **monopoly situations** (example of DBP, see Annex D.1), are arising due to registrants limiting their substance portfolios instead of applying for authorisation. This can be attributed to the belief by formulators and substance suppliers that it does not make business sense to incur the costs of the authorisation process for uses of substances that may not represent a large business segment for them, like for example military uses. Additionally, even when defence is covered by broad upstream use definitions, it is often overshadowed by the more important, non-defence business segments of the applicants. Further complications occur due to the lifespan of defence equipment which might require multiple, consecutive applications while alternatives are available for non-military uses as the review periods come to an end.

Furthermore, it was reported during study consultations that, within the A&D supply chain, it has been observed that **there has not been an increase in the number of companies offering or supplying suitable alternatives**, despite regulatory action on SVHCs.

INTERNATIONAL COLLABORATION

As mentioned previously, many defence projects are multi-national with partner countries from outside of the EU. With the aim of authorisation being removal of SVHC substances, some of which have critical uses in globally developed defence capabilities/systems, **authorisation can have a detrimental impact on multinational collaboration projects** and decisions to pursue the joint efforts further with EU nation states.

ANALYSIS OF THE STRATEGIES ADOPTED FOR APPLICATIONS FOR AUTHORISATION COVERING MILITARY USES

a) Upstream application:

Because of supply chain complexity, defence producers of complex defence equipment will generally not have sufficient knowledge of the materials or process substances used in order to be able to track and manage all potential needs for authorisation. Upstream applications alleviate this problem.

Though suitable for the complex supply chains of the sector, the niche nature of the defence sector can mean it is **overshadowed by other sectors** with which it is aggregated, despite the comparatively large socio-economic benefits of military uses. These other sectors also invariably have **larger use volumes and higher exposure potentials** compared to defence.

For **non-aerospace defence systems (e.g. land, naval)** this "overshadowing risk" may be even higher. An example of this is within the CTAC Submission Consortium's application for authorisation for chromium trioxide (consultation number 0032-05).[123] Defence is not mentioned in the use name,[124]

[122] See questions 1.29 – 1.31 in Annex C.

[123] See https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/10108/del/50/col/synonymDynamicField_302/type/asc/pre/2/view

but in the application documents in the context of other industries: *"The automotive, defence, marine, energy, oil & gas, electricity, building & construction, steel and non-ferrous metal, food packaging, material science, printing, paper, and many other sectors depend on chromium trioxide to meet their high requirements on products used under a broad variety of conditions."*[125]

This makes it difficult to explain the state of alternative development in the application, when there are significant differences between military requirements and those of other sectors.

It was also noted that the shortening of review periods for upstream authorisations has **market distortion consequences** since only larger downstream users have the capacity and the capability to apply for authorisation. This means that SMEs and complex product supply chains (like defence) are unduly impacted due to their dependence on upstream AfAs.

b) Downstream application:

The information contained within the downstream application dossier is specific to the company applying, though comparatively higher costs (consultancy, application fees, etc.) compared to consortia may be incurred. The use is also more exact and is either defence alone or dual use specific so the defence-focus is not overshadowed by other sectors. It is also easier to incorporate the opinions and support of various impacted MoDs compared to upstream applications.

Generally, at the level of downstream user AfAs, ECHA considered that the applicants have been able to make their case.

Authorisation applications by defence downstream users, however, have **limited impact** as they are at the bottom of complex, multi-tier supply chains. Any such authorisation would not cover their upstream supply chain, e.g. formulators, and so limits the coverage of the supply chain to the use of the applicant and the supply for use by the applicant (see REACH Article 56(1)(e)).

Additionally, given the more specific military use, it was reported that **more time was required to complete the application than non-defence downstream applications** to allow for the input and agreement of various ministries, including confidentiality checks to ensure that no military classified information is present.

c) Downstream sector driven, upstream application:

Similar to a "pure" upstream application, downstream sector driven, upstream applications alleviate the problem of end users needing to track and manage all potential needs for authorisation as the application covers the entire supply chain for a specific use, however, some of the drawbacks of the upstream application are also present.

The information contained within the dossier is specific to the company (or companies) applying meaning the use is less broad than for applications which cover multiple sectors. Additionally, there is a **grouping of similar companies**; all with the same, or similar, use and therefore the development of

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[124] "Surface treatment (except passivation of tin-plated steel (ETP)) for applications in various industry sectors namely architectural, automotive, metal manufacturing and finishing, and general engineering (unrelated to Functional chrome plating or Functional chrome plating with decorative character)"

[125] See CTACSub, Analysis of Alternatives (May 2015), page 15.

the non-use scenario, socio-economic impacts and alternatives feasibility is less complex than a broad upstream application. The defence sector is also not overshadowed by other sectors.

Potential problems exist with **engagement from the upstream formulator** to actually apply given that, though broader than downstream applications, this type might not cover all the uses of the potential applicant's supply chain. This is a problem within the defence sector as it generally makes up a small percentage of a formulator's, manufacturer's or importer's customer base.

INFO BOX: Sector-level approaches to authorisation

Sector-specific approaches are very suitable to make REACH processes fit for purpose. This applies in particular to the authorisation process with its strong reliance on the analysis of alternatives and socio-economic analysis covering aspects which are often sector specific and, hence, more or less shared by all stakeholders in the sectors and in this sense homogeneous. Consequently, sector-level approaches to authorisation are on the rise.[126]

For the defence sector, there is no dedicated sector-approach to authorisation today. Therefore, the typically strong defence-case for authorisation can be difficult to make without specific and robust assessments and/or for applications made by upstream actors who have little knowledge and information about their downstream users. At the same time the REACH defence exemption is intended to be used by EU MoDs only as a last resort, according to the EDA CoC 2015, and solutions still have to be found to cover the increasing number of transnational use cases (such as wide-dispersive surface treatment uses).

POSITIVE IMPACT

Nevertheless, of those companies that have gone through the process, the experience has had some positive impacts in that there is increased focus on health measures and the effectiveness of RMMs like local exhaust ventilation (LEV), etc. There is also a better understanding of some of the materials in the supply chain, the chemical risks in the workplace and on-going improvements as a result.

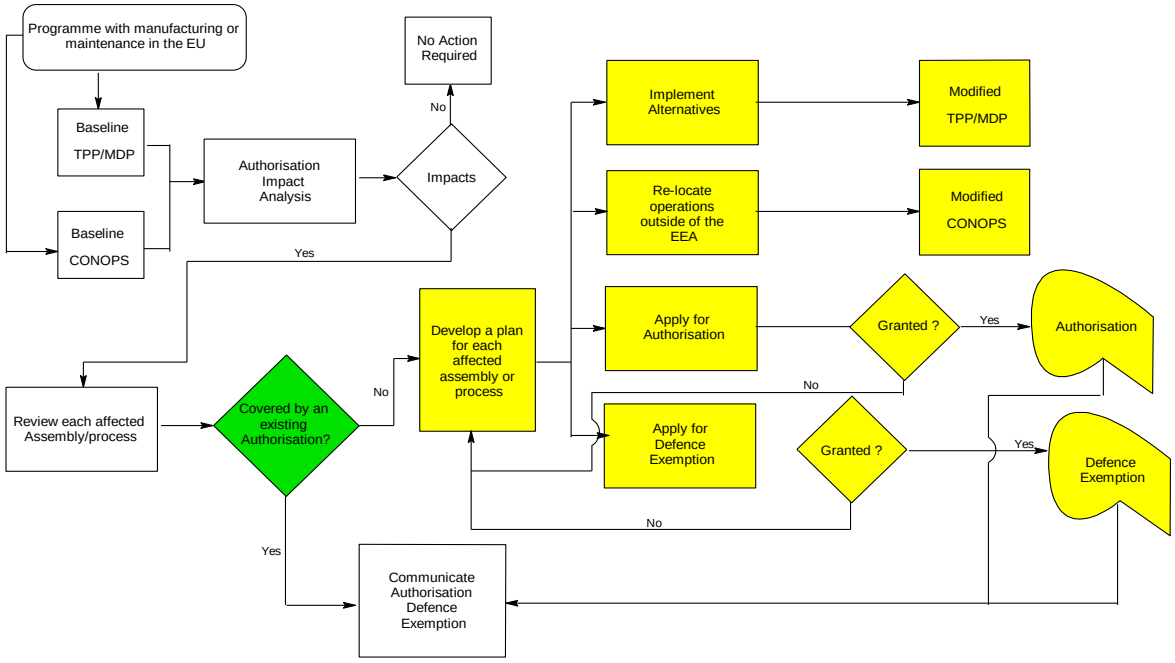
4.2.3.3 Uncertainty

Elastic processing times, including processing delays, from submission to a decision from the EC; uncertainty (see Section 4.1.3) regarding the outcomes (use conditions, review periods, use coverage) was highlighted as a key factor that increased pressure on businesses within the defence sector. The resulting supply chain uncertainty is a major problem that can have impacts beyond the EU.

As a result, defence companies need to examine the implications of an application in terms of its feasibility for success with the review period versus non-application and the potential lost business or relocation (see decision tree in Figure 14). For many European companies the option to relocate is limited, as already discussed in Section 4.1.2.4, however it remains a viable option for some companies, particularly non-EU companies that have subsidiaries based across Europe.

[126] Examples include: Space-sector task forces for chromates and hydrazine; applications for authorisation restricted to aerospace applications in the frame of CTACSub (consultation number: 0032-04) and CCST consortia (consultation number: 0046-02), see Annex G.1.

Figure 14 Example of an authorisation decision tree for defence companies



When a decision to apply for authorisation has been made, many companies in the A&D industry have been engaged for several years preparing the applications with the knowledge that should the decision be taken by the EC after the sunset date, the **compliance obligation is immediate** meaning that an immediate stop of production, or the need for immediate investment in additional RMMs/infrastructure, which could severely impact the delivery of defence equipment to European MoDs.

Furthermore, the length of the **standard 7 year review period** is not seen as sufficiently long for many military uses given, as described already, the long lifecycles of defence equipment and the need for continuous maintenance and spare parts throughout the equipment utilisation.[127]

With regard to the **EC initiative on streamlining and simplifying authorisation for use in low volumes and legacy spare parts** (see further details in Annex G.3), the lack of clarity on the scope and timeline for implementation of low volume applications is leading to supply chain uncertainty. Until it is agreed, formalised, and its implementation tested, it only adds to the uncertainties already present with the authorisation process, as decisions on plant investment and product substitution, or applications for authorisation may be deferred in anticipation of the streamlined process.

LACK OF A WORKED EXAMPLE HAS IMPACTED DEFENCE AUTHORISATION APPLICATIONS

It was stated during study consultations with REACH MSCAs: *"In some defence-related applications, it would have been possible for the applicant to improve the justification of the non-use scenario and the description of the benefits of continued use to demonstrate the socio-economic impacts of a refused authorisation more clearly (e.g. impacts of the non-availability of systems and components requiring the Annex XIV substance on the operational capability of the military)."*

[127] See Section 3.2 regarding the negative substitution potential for maintenance chemicals, especially for aircraft.

The **lack of a template "worked example" for defence** was cited as a major fault which contributed to excessive time spent on preparing authorisation dossiers and also meant that companies had different approaches to preparing their applications.

When this was discussed with those responsible for drafting several defence applications it was noted that, though **qualitative impact argumentation** related to operational capabilities of nation state armed forces and the use of defence equipment to protect national interests was acceptable, there have been difficulties for the ECHA's SEAC Committee to take these into account for its opinion making (cost benefit analysis). This is because the non-use of a substance in military equipment might not result in a large economic impact to the EU economy e.g. through job losses, loss of profits, etc. However, the geo-strategic and geo-political impacts of the inability to use the substance, resulting in either reduced or non-performance of military equipment and/or munitions, could have huge impacts on the **ability of Member States to safeguard their national and defence interests and also to comply with their international obligations as partner nations at European level (e.g. Common Security and Defence Policy (CSDP)) and wider field e.g. with NATO.** Applicants were informed that such topics were considered socio-politics and that the EC needed to decide on the validity of these matters. Thus, there is uncertainty about the sufficiency of such qualitative arguments in lieu of economic quantification.

In the military-specific application case of **Lead Chromate (Consultation Number: 0028-01)**,[128] despite acceptance that there are no alternatives available for the use applied for, RAC considered that the processes at the applicant's site were not suitably contained, meaning there was potential for exposure and contamination. As a result, RAC considered the RMMs and operational conditions as not being appropriate or effective in limiting risk. This led to a recommendation of a 7 year review period when the applicant had applied for a review period of 15 years. The application tonnage is 12 kg per year.

4.2.3.4 Conclusions

The defence sector has already been strongly affected by the AfA process, e.g. phthalates, lead sulfochromate yellow, lead chromate and severely for Cr(VI) compounds. While the allowance of defence exemptions under REACH Article 2(3) is reserved for specific cases, and does not cover civil applications of dual use substances, the AfA for military uses is often seen by defence industry stakeholders, but also some MoDs as customers and supporting the AfA, as disproportionate and not fully fit for purpose.

Given the current weaknesses of the authorisation system the typically strong defence-case for authorisation can be difficult to make without specific and robust assessments and/or for applications made by upstream actors who have little knowledge and information about their downstream users (Table 5).

[128] See also discussion in Annex D.2.

Table 5 Summary: Strong case – weak tool

Key defence-specific authorisation arguments	Weaknesses of current authorisation system
• small user, big socio-economic impact • importance of qualitative arguments, e.g. operational capability of the military • long product and qualification timeframes • No/limited substitutability for MRO chemicals for aircraft (airworthiness), esp. imported ones • work with non-EU partners (e.g. NATO): interoperability and interchangeability • close involvement of MoD customer in dossier development	• seen risk of being "overshadowed" by other - bigger – sectors (including those with a "weaker" case) in upstream AfAs • seen monopolisation of supplier markets for Annex XIV substances (example of DBP) • no templated "worked example" for defence, time-consuming and costly AfA preparation • Uncertainties around the authorisation process (review period/conditions)

Evidence of the clear socio-economic benefits of the defence sector and the control of the risks in using SVHC substances can be seen from past applications in which military uses are identified, which show that the simple average cost to benefit ratio, for military specific or dual use, downstream user applications, is approximately 1.77 million : 1. This raises questions of proportionality when having to go through such a burdensome process while the business case is generally clear, given the limited scope for substitution in defence equipment.

The process of authorisation (candidate listing, Annex XIV listing, authorisation granting) provides defence industry with a **strong signal that they need to initiate substitution** for targeted SVHCs. However the **timelines** of the authorisation process are **mismatched** with those for the defence sector. This is because identifying, qualifying and implementing alternatives takes significantly longer due to the required standards, long production and product lifecycles and the internationalised nature of the defence industry.

It was noted that authorisation is causing an **acceleration of R&D into the alternatives**. It is **not**, however, **pushing innovation** in a direction that is higher in value to the end customers, i.e. the MoDs, because REACH substitution is taking R&D money from other activities (see Section 4.1.2.1).

Authorisation costs, and through life maintenance activities using chemicals, are a particular concern, with the likely need for repeated renewals in high reliability sectors such as defence. Chemical supplier interest in supporting continued authorisation is also likely to diminish.

4.2.3.5 Exemptions from authorisation (other than Art. 2(3))

The application of exemption clauses from authorisation relates to the general concern of certainty and predictability (see above Section 4.1.3). Defence industry stakeholders reported various misunderstandings and uncertainties with the application of some exemptions other than REACH Article 2(3), i.e. not specific to defence. Two key exemption clauses functioning differently, which are very relevant for the defence sector, are discussed in this section: REACH Article 58(2) and REACH Article 56(4)(c)/(d). For information on intermediate uses and scientific R&D please see Annex G.4.

USES COVERED BY EXISTING SPECIFIC UNION LEGISLATION (REACH ARTICLE 58(2))

This clause **requires an explicit "activation"**: If the conditions of REACH Article 58(2) are fulfilled, a specific exemption may be included in Annex XIV (see Article 58(1)(e)). Normally industry should claim such an exemption in the ECHA public consultation on its draft Annex XIV recommendation.[129] So far, in spite of numerous attempts by industry, only one such exemption case has been accepted by the European Commission for DEHP, BBP and DBP.[130]

Defence industry stakeholders have reported that several MoDs still ask the defence industry to "use Article 58(2) REACH" or to justify why they did not do so (e.g. in the German defence exemption application). In this respect it should be highlighted that Article 58(2) may only apply if the risk control for the use to be exempted is addressed by *"existing specific Community legislation"*. However, **there is no such existing EU legislation addressing, specifically, the risk from military applications to human health or the environment**. Therefore, **REACH Article 58(2) cannot be used to justify defence-specific exemption entries in Annex XIV**.[131]

However, there could be a more frequent use of the REACH Article 58(2) exemption to the benefit of the EU defence industry in the future. In a recent judgment the CJEU has clarified the conditions for Article 58(2) in the case VECCO (T-360/13) with special regard to **EU-wide occupational exposure limits under Directive 98/24 (CAD) and Directive 2004/37 (CMD).[132]** Based on this judgment the inclusion of Occupational Exposure Limits (OELs) in CAD or CMD for candidate list substances recommended for Annex XIV is a potential area of application of REACH Article 58(2). In this context it should be noted that the Commission is currently pursuing[133] the setting of binding OELs for a number of candidate list substances, e.g. hydrazine and Cr(VI) substances (see Annex D for these and other substances concerned by the ongoing activities of DG EMPL).

USE AS FUELS (REACH ARTICLE 56(4)(c) AND (d))

Unlike the exemption under REACH Article 58(2), which requires positive inclusion in Annex XIV, the mentioned fuel uses **are automatically exempted by virtue of the REACH Regulation, *if* the legal conditions are fulfilled**. Industry is required to confirm and document that this is the case. The exemption is not "granted" (i.e. formal decision of an authority) as is the case in REACH Article 2(3). However, it may be necessary / advised to confirm with the EC and/or Member State REACH competent authorities, that the conditions of the exemption clause are fulfilled.

The case of **hydrazine** propellant use (see case study in Annex D.10) demonstrates that placing a substance on the REACH candidate list is a key milestone to trigger related industry activities on the

[129] See REACH Article 58(4)2: *"The Agency shall invite all interested parties to submit comments within three months of the date of publication, in particular on uses which should be exempt from the authorisation requirement."*

[130] Exempted (categories of) uses: *"Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC."* see Commission Regulation (EU) No 143/2011 of 17 February 2011 amending Annex XIV to REACH.

[131] The EC has confirmed in the frame of the study possible exemption entries in Annex XIV: *"From the wording of Article 56(1), and in particular paragraph (b) thereof, the Commission may only exempt uses or categories of uses from the authorisation requirement on the basis of Article 58(2) REACH (if the conditions set out therein are met). An exemption may only be granted on the basis of Article 56(3) for uses in product and process orientated research and development."*

[132] See summary of the judgment in Annex J. The judgment is currently still under appeal.

[133] Proposal COM(2016) 248 final for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

appropriate strategy to address the possible REACH authorisation requirement, but also consider the impact on design decisions during early phases of long-term programmes such as launchers and satellite platforms. However, it is also a striking example of uncertainties regarding the interpretation of "automatic" exemption clauses from authorisation.

CONCLUSIONS

There seems to be still a lot of confusion about the interpretation of REACH Article 58(2) (e.g. the relationship to EU workplace legislation); related questions have also frequently been raised in the frame of public consultations on ECHA's draft Annex XIV recommendations. The interpretation of REACH Article 56(4)(c) and (d) is also challenging, because terms given are not further legally defined. The latter also applies to the central notion of "scientific" in REACH Article 3(23). Clarifications on exemptions from authorisation are often only case-by-case, scattered in different places (ECHA website,[134] guidance documents,[135] EC replies) and thus hard to find / easy to overlook. This adds to the difficulties for industry to apply and decide whether an application for authorisation is required and overall, what course of action should be taken with regard to a given substance. It would be helpful to clarify the boundaries of authorisation exemption clauses in an easily accessible document.

4.2.4 Restrictions

Restrictions according to REACH Annex XVII are a flexible instrument for regulatory risk management under REACH. Traditionally they have mostly been used to ban certain consumer uses. The continued use of critical industrial applications may be allowed, subject to the conditions of the restriction.

Consequently, defence companies have **not** been significantly impacted **directly** by REACH restrictions to date. Sector specifics (for defence e.g. substitution challenges and the typically well-controlled use environment) have been taken into account in some conditions of restrictions ('derogations') in Annex XVII.[136] However, defence industry stakeholders have reported that restriction of other applications may have an **indirect impact** on defence applications in the form of commercial obsolescence cases or risks, if the banned applications constitute the main business for the supplier (e.g. cadmium for surface treatment of connectors[137] in *civil* applications).

A restriction having both direct and indirect impacts for defence is **Entry 23 for cadmium (Cd)**. The wording of entry 23 and the cumulative application of RoHS have made the application of Cd-related restrictions fairly challenging, as illustrated in Figure 22.[138] Given the complexities and the number of relevant EU and national legislations, one MoD of a Member State with a strong Defence Technology and Industrial Base (DTIB) advised that use of Cd must be evaluated on a case by case basis.

The cadmium case illustrates well that legal **derogations** to the benefit of the A&D sector, as a niche customer for the chemical industry, – **while necessary and useful – must be backed up by significant**

[134] https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/reach/authorisation

[135] E.g. Guidance on the preparation of an application for authorisation, Guidance on intermediates; Guidance on Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD).

[136] Most recently for decaBDE, see info box in Annex F.3.

[137] RoHS may directly apply to EEE connectors.

[138] As an example of direct impacts from Entry 23, land systems producers consulted have mentioned that the restriction generally applies to weapon systems affixed to an armoured vehicle (as opposed to the weapon system alone, e.g. a machine gun), unless the use "in safety devices" is documented. For further details see Cd case study in Annex D.12.

supply chain engagement to ensure continued availability. When the substance is strategic for high-tech and/or high performance uses, industry and MoDs are also more willing to invest to continue production.

Currently, several new restrictions of relevance for the defence sector are being discussed, e.g. for **diisocyanates** (Annex D.16) and 1-methyl-2-pyrrolidone (**NMP**) (CAS: 872-50-4). In the *semiconductor industry* a restriction impacting a substance present in equipment to manufacture semiconductor devices (as PFOA and related substances proposed for Annex XVII) could severely impact the ability to manufacture.[139] Sufficient time is required to adapt the supply chain and to allow for spare parts.

CONCLUSIONS

Restrictions according to Annex XVII of REACH have not **directly** impacted the defence sector much to date. Defence-specific derogations may be foreseen as, for example, in the cases of cadmium (entry 23) and decaBDE (temporarily). However, according to defence industry stakeholders consulted the interpretation of complex restriction entries may sometimes be challenging, and derogations might be more restrictive for non-aerospace defence systems (e.g. land systems in case of entry 23). Where there is no direct impact, the defence sector may still be **indirectly** affected due to substance or product withdrawals for restricted uses (commercial obsolescence risk).[140]

4.2.5 CLP

CLP Article 4(10) states as a general principle: *"Substances and mixtures shall not be placed on the market unless they comply with this Regulation. 'Placing on the market' means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market;"* (CLP Article 2(18)).

Based on the survey responses this section addresses the following issues:

- Labelling of ammunition;
- Lack of information on hazardous components in imported mixtures;
- CLP defence exemption.

LABELLING OF AMMUNITION

Most MoDs and the EU defence industry agree that the application of CLP labelling rules to ammunition qualifying as 'explosives' is causing concern and poses various significant challenges.

Acknowledging the existence of CLP interpretation uncertainties, the EDA requested input from ASD, in order for EDA and its pMS to better understand industry's practices and concerns. As a result a related paper was prepared by ASD and submitted to EDA.[141] According to ASD most military

[139] ECHA noted that there is likely to be a time-limited derogation for such machinery (the placing on the market of semiconductor manufacturing equipment for a period of 5 years after [date of entry into force].

[140] For substitution challenges in the defence sector see Sections 3.2, 4.1.1 and 4.1.2.1.

[141] ASD, Concerns, observations and suggestions for the EDA to consider on the application of CLP regulation to ammunition (as „explosive articles") (9 May 2016), page 4, hereafter also "ASD paper on CLP and ammunition of 9 May 2016".

ammunition types meet the definition of "explosive article" under CLP. Therefore it seems to be necessary to label ammunition according to CLP rules, regardless of their civil or military application.

A number of provisions in the CLP Regulation applying to "explosives" or "explosive articles" directly or in analogy[142] raise questions of their interpretation in relation to military ammunition. Annex K.1 contains a summary of key CLP provisions for the labelling of explosives.

According to ASD[143] there are a number of interpretation uncertainties, which already cause and have the potential for further CLP application differences in the EU Member States. They relate to:

- The general question whether or not military ammunition should be labelled according to CLP and whether distinction has to be made between different ammunition types;
- The application of the CLP defence exemption in Article 1(4);
- What elements are expected to be included in the CLP label for military ammunition;
- Where the CLP label should be placed (e.g. issues with space and packaging layers).

In line with this ASD observation, it was confirmed by one MoD that there are currently different approaches in the Member States with regard to the application of CLP labelling rules. A non-application (which may be achieved e.g. via CLP Article 1(4)) may be envisaged if there is no value added and the labelling is considered as too impractical. However, some other MoDs reportedly require all the information usually found in labelling in order to qualify a product for use in their MoD, especially in relation with ammunition, so if the information is not provided, the product is refused because not qualified by the procuring MoD for use by its Armed Forces.

EC, MSCA and MoD feedback received during the study consultation suggests that CLP labelling requirements **apply in principle** to military explosives/ammunition, but a reasonable interpretation is proposed for their implementation (see Annex K.2). In the Contractor's understanding all opinions expressed are consistent. However it was felt that a solution still needs to be found for complex cases, namely when there are several levels of intermediate packaging or none at all.

Nevertheless, MoDs and defence industry largely agree that CLP labelling for military ammunition adds little value (if any) to the trained user, or is even further regarded as a disruptive element negatively affecting the defence capability.

There are already a number of **existing requirements on ammunition safety**, which include labelling and supplied documents, and which are quite sophisticated, such as:

- UN Recommendations on the Transport of Dangerous Goods (UN RTDG), e.g. ADR,[144] RID, IMDG and ICAO;
- NATO resp. military standardisation,[145] e.g. STANAGs[146], AOPs[147] and AEPs[148] issued by CNAD[149]/AC326[150] and NSO.[151]

[142] When only "substances" and "mixtures" are explicitly mentioned, such in CLP Article 1(4) (Defence Exemption).

[143] See the ASD paper on CLP and ammunition of 9 May 2016.

[144] International Carriage of Dangerous Goods by Road. Current ADR labelling components already cover the risks in transportation and are derived from UN requirements.

[145] These requirements cover the safe design, test, use, transport and storage of ammunition (not referring to labelling).

[146] NATO Standardisation Agreements, e.g. STANAG 2953.

- Pyrotechnic Safety Data Sheet (PSDS) for safety provided by industry to MoD (in France).

Rules for handling ammunition already provide for stringent controls of storage, transport, handling, use of PPE where necessary. Thus, the field of ammunition labelling and information supply is well controlled.

In addition, a number of **general reasons** against the meaningfulness for CLP labelling are brought forward, in particular:[152]

- Military ammunition is used by trained professional users only.
- Military users are well trained in the use, handling and dangers associated with munitions.
- During the battle situation, the risk from handling ammunition with dangerous chemicals is generally less relevant than the risk from enemy action.
- **CLP labelling of ammunition therefore does not add value, but potentially increases the risk for the user due to the visibility of the label.**

LACK OF INFORMATION ON HAZARDOUS COMPONENTS IN IMPORTED MIXTURES

Defence sector stakeholders have voiced concerns about the fulfilment of labelling and C&L notification obligations for hazardous components in imported mixtures, where such components are not disclosed by the non-EU supplier (e.g. US manufacturers) with reference to trade secrets.[153] Therefore, compliance with labelling (see CLP Article 18(1) and (3)(a)) and C&L notification obligations (see CLP Article 39(b) and 40(1) (b) and (c)) may be impossible.[154]

EXPERIENCE WITH CLP DEFENCE EXEMPTIONS

According to CLP Article 1(4) *"Member States may allow for exemptions from this Regulation in specific cases for certain substances or mixtures, where necessary in the interests of defence."*

Overall, defence stakeholders consulted have very limited experience with the application of the CLP defence exemption (CLP Article 1(4)). It is also not covered by the EDA CoC 2015, since its scope was only focused on the REACH Regulation.

The following two cases have been reported:

(1) Import of hazardous mixtures with unknown composition

The NO MoD reported the use of an exemption from C&L notification and identification of hazardous components on the label in case of non-EU imports due to lack of information (trade secrets, see

147 Allied Ordnance Publications, e.g. AOP-2C, AOP-15.
148 Allied Engineering Publications.
149 Conference of NATO Armament Directors.
150 NATO Ammunition Safety Group.
151 NATO Standardisation Office (http://nso.nato.int/nso).
152 See the list on page 4-5 of the ASD paper on CLP and ammunition of 9 May 2016 (*"However, EU Defence Agencies have named various arguments to point out that CLP labelling of military ammunition might not be sensible: …"*).
153 See info box "Trade secrets in safety data sheets – Example of the US" in Annex H.5.
154 The same applies to SDS disclosure requirements according to REACH Article 31 and Annex II.

above).[155] Presently, similar issues are expected for maintenance chemicals required in the frame of a multinational project (F-35), that could affect several EU MoDs, calling for a common solution not covered by the current EDA CoC 2015, if possible (see also Section 9.3.6 "joint exemption process" and Section 9.5.7).

(2) Labelling of ammunition

In another case a MoD asked a foreign defence company not to label ammunition sold to this MOD. The defence company asked its national MoD successfully for *"mutual recognition of this defence exemption."* Generally, the EC and ASD have pointed to the possibility of using the CLP defence exemption from labelling requirements for military ammunition/explosives.

CONCLUSIONS

In terms of CLP the defence industry is mostly affected by the CLP labelling provisions for military explosives/ammunition. In this regard the ASD paper on CLP and ammunition of 9 May 2016, which points to a number of interpretation uncertainties, which already cause and have the potential for further CLP application differences in the EU Member States, is proposed to be addressed by the EU MoDs and the EDA (see Section 9.5.6).

EC, MSCA and MoD feedback received during the study consultation suggests that CLP labelling requirements apply in principle to military explosives/ammunition, but a reasonable interpretation is proposed for their implementation. In the Contractor's understanding all opinions expressed are consistent. However it was felt that a solution still needs to be found for complex cases, namely when there are several levels of intermediate packaging or none at all.

The lack of information on components in imported mixtures is another specific issue.

As the (limited) experience with the CLP defence exemption shows, CLP Article 1(4) may be one potential avenue to mitigate these impacts in the short term. The EU multinational nature of the two issues raised (labelling of ammunition and lack of information) calls for an evaluation to extend the EDA CoC 2015 (see Section 9.5.7).

4.3 Conclusions on industry impacts

Overall the consultation of defence companies operating on the EU market has shown that competitiveness and innovation have not been tangibly enhanced by REACH implementation to date. While a large majority of the defence industry has already been affected by REACH related obsolescence, major threats are seen in the near future (REACH Registration in 2018 and Annex XIV).

The actual **benefits to human health and the environment** have been relatively limited, where the use of substances is typically in low volumes and already well controlled. It is largely felt by the consultees that these benefits are not commensurate with the efforts and costs.

The high level of **uncertainty** and **associated business risks** is a key concern for the defence industry.

[155] A corresponding (REACH) defence exemption from SDS disclosure requirements on identification of all hazardous components has been granted by this MoD.

Registration has generally not been a major direct concern for the EU defence industry to date. However, the impact is expected to increase sharply for the 2018 deadline, with many SMEs and (imported) mixtures potentially affected. Key uncertainties persist about upstream registration intentions and the REACH status of ammunition (need to register certain substances).[156]

REACH Article 33 compliance efforts are seen by most defence companies producing very complex articles as clearly disproportionate with regard to the added value to safe use of the article targeted by the provision. It is feared that the situation will further deteriorate soon due to the "Complex Article" judgment of the CJEU. For articles imported from outside EU the compliance challenge is further increased.

REACH authorisation efforts to be spent, uncertainties and timelines associated with the process are often seen as disproportionate for substances used in (very) low volumes, in highly controlled work environments and with an established performance and safety requirement to ensure military capabilities. This is the default situation for SVHCs used in the EU defence sector. It appears that the process is **not fully fit for purpose today** to make the typically strong case for authorisation of military-related uses. A large potential impact is foreseen with the forthcoming decisions on critical substances, e.g. Cr(VI), and the continued expansion of Annex XIV, if done without due upfront consideration of socio-economic, substitutability and overall priority factors.

For **exemptions from authorisation** (other than the REACH defence exemption, e.g. under REACH Article 58(2)) there is a need for more legal certainty and ease to access available interpretations.

Restrictions according to Annex XVII of REACH have not much directly impacted the defence sector to date, also with regard to sector-specific derogations. Main issues reported relate to the coverage of non-aerospace systems, clarity of the legal text and the issue of commercial obsolescence.

CLP poses two major issues that are proposed to be further addressed, according to the consultation: Labelling of ammunition ("explosive articles") and lack of information for imported mixtures.

The reported impact for **non-EU headquartered defence companies** with operations in Europe is more or less similar to their EU competitors (see Annex C.1). However, the flexibility to move some hard-to-substitute processes out of the EU (e.g. to their home country) could be higher for non-EU companies. Some EU companies with operations outside EU may also have the option to relocate, but it is limited – for strategic and political reasons – to non-strategic components.

[156] See also Annex H.8.

5 IMPACTS OF REACH AND CLP ON EU MINISTRIES OF DEFENCE/ARMED FORCES

The impact of REACH (and CLP) on MoDs/Armed Forces (AF) is mainly determined by the following three elements:

- **Impact of REACH (and CLP) on the defence industry, mainly EU** (see Chapter 4);
- **Impact due to the administration of so-called "defence exemptions"** from REACH (see Section 3.3.1 as well as Annex F) and CLP (see Section 4.2.5);
- **(Other) own impacts** (this Chapter).

5.1 Are MoDs/Armed Forces addressees of REACH?

Consulted MoDs (or their subordinate agencies) in the EU Member States procure defence materiel, especially complex articles for use by their Armed Forces, as well as substances (often mixtures) for the continued maintenance of the aforementioned materiel, from both EU and non-EU defence companies and also from non-EU governments.

Hence, EU MoDs/Armed Forces may also "import" and "use" substances, mixtures and articles for their own (MoD's/Armed Forces') use, and may be a re-seller of (e.g. surplus) defence equipment mainly to other governments. It is also possible that substances (mixtures) procured by the MoD/Armed Forces are handed over to private companies, e.g. for the maintenance of defence equipment.[157]

This raises the important question, whether MoD's/Armed Forces could themselves be addressees of REACH and have the associated obligations, especially:

- to register as an "importer" (REACH Art. 6(1));
- to apply for authorisation as an "importer" or "downstream user" (REACH Art. 56(1), 62(2));
- to provide information as a "substance/mixture/article supplier" (REACH Art. 31-33).

In the case that the substance or mixture is handed over by the MoD/Armed Forces to private companies, the further question – in addition to possible REACH obligations of MoDs/Armed Forces themselves - is, whether such private companies then have certain REACH obligations, and hence, whether they are REACH compliant.

EU MoDs consulted have different views as to whether their own activities (and those of their Armed forces/subordinate offices/agencies) are to be subsumed under the legally defined REACH actors of e.g. "importer", "downstream user" or "supplier" in terms of REACH Article 3.

[157] Maintenance activities in higher echelons are often carried out by private subcontractors, whereas lower echelons are processed more often internally using own staff.

INFO BOX: REACH "addressees"

REACH Article 3 legally defines who – in the context of the regulation – is an importer, a downstream user, a supplier of a substance, mixtures or article (see also the list of definitions in Annex P). Depending on the role "fulfilled" certain REACH obligations connected to them apply (such as registration, authorisation, safety data sheet provision / implementation).

The terms of "end user" and "consumer" are not legally defined, as they do not have obligations under REACH. The ***consumer*** is – explicitly – not a downstream user according to Article 3(13).

Therefore – regardless of the laws of occupational health and safety – the consumer has a right to request information on SVHCs in articles from his supplier (Article 33(2)).

Self-evidently, it is therefore crucial to determine as a prerequisite whether or not a REACH role of "importer", "downstream user" or "supplier" in terms of REACH Article 3 is fulfilled.

LEGAL ANALYSIS BY THE GERMAN MoD

Regarding direct obligations of MoDs/Armed Forces as addressees of REACH, representatives of the German MoD have

- based on their experiences at the interface of the MoD/Armed Forces to the industry,
- in the undertaking of simplifying the implementation of an EU Regulation like REACH,
- based especially on the catalogue of legal definitions in Article 3 REACH, and
- deeming legal expertise of all Member States in general necessary to evaluate the implementation of REACH,

raised the question and legally examined as follows, if EU MoDs/Armed Forces as end-users themselves have obligations according to the REACH Regulation at all.

In Recital 16 to REACH it is already stated that this (cit.) *"Regulation is based on the principle that **industry** should manufacture, import or use substances or place them on the market with such responsibility and care as may be required to ensure that, under reasonably foreseeable conditions, human health and the environment are not adversely affected."*

Correspondingly, REACH Article 1 connects the free circulation of substances in the internal **market** (par. 1) to the precautionary principle in environmental legislation (par. 3) and commits the **economic actors** (manufacturers, importers and downstream users) who are the addressees of REACH (cf. Recital 16).

Government bodies, such as Armed Forces, however, are merely **consumers and end-users** of armament materiel.

They are neither "manufacturer" according to REACH Article 3 No. 9; nor do government bodies as end-users or consumers fulfil the conditions to be classified as "downstream user" according to REACH Article 3 No. 13: The "downstream user" uses a substance in a supply chain (REACH Article 3 No. 17) **as part of his industrial or commercial activities** – different from end-users or consumers.

Additionally, government bodies (e.g. MoDs, Armed Forces) do not fulfil the conditions to be classified as an "importer" according to REACH Article 3 No. 11. An "importer" is any natural or legal

person established within the Community – which means **registered in a Commercial Register** with a location / site inside the Community, different from governmental entities, which are legal persons and local authorities of public law (in German: "Gebietskörperschaften") and do not have to be "established" within the Community – who is responsible for the import. Government bodies, however, are part of the administrative authority, e.g. the Federal Republic of Germany, and are neither industrial, nor economic "actors in the supply chain" according to REACH Article 3 No. 17.

The consumer – e.g. a governmental body – hence is not a manufacturer, importer or downstream user, nor is he a supplier according to REACH Article 3 No. 32 and 33. Because the collective name of the "supplier" includes the manufacturer/producer, importer, downstream user, distributor or any other actor **in the supply chain**. The distributor is defined in REACH Article 3 No. 14 as a person established within the Community, including a retailer, who only stores and places on the market a substance/mixture. He does not have own interests in using it, but passes it as intermediate or distribution station to third parties.

Based on this legal analysis, the representatives of the **German MoD** have come to the conclusion that:

Consumers or end-users, e. g. government bodies/MoDs/Armed Forces, do not have obligations under REACH (see the List of definitions in* [Annex P]*).

Only in the case that government bodies become an economic actor (e. g. in the case of a governmental ownership in defence companies) it could be that REACH´s obligations may apply.

Furthermore and regarding the **law of occupational health and safety** the representatives of the **German Federal Ministry of Defence** noted that this legal situation has no impact on the obligation of government bodies as **employers** to provide for **information necessary to ensure safety and protection of their employees**. According to REACH Article 2(4)(a) this Regulation shall apply without prejudice to Community workplace and environmental legislation. Safety and health risk management at workplaces remains unaffected. So the appropriate Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work is still valid: Based on its Article 6(3)(a), the employer has the obligation to evaluate the risks to health and safety caused by hazardous materials at workplaces and if necessary to take measures to reduce safety and health risks of employees to an acceptable level. German law – for example – consequently demands that the employer has to comply with the relevant information provided to him in compliance with Title IV of REACH in the form of a standardised safety data sheet containing all information necessary for health and environment risk management.

VIEW OF THE 11[158] OTHER MODs CONSULTED

In the course of discussing this legal review, other MoDs consulted consider that they themselves may have direct obligations as they are addressees of REACH according to the definitions of REACH Article 3. A list of explanations given by these MoDs can be found in Annex I. Therefore compliance with the corresponding REACH obligations is seen – by **some EU MODs** – as required, unless there are

[158] The 11 MoDs consulted that provided input on this issue are BE, EL, ES, FI, FR, IT, NL, NO, PT, SE, UK. Further to 11 MoDs, CZ also responded but only to substance-specific questions for MoDs.

grounds to obtain a national defence exemption according to REACH Article 2(3) from the national granting authority.[159]

Accordingly, some MoDs have reported submission to ECHA of e.g. a **PPORD notification** (REACH Article 9(2)) and several **pre-registrations** (REACH Article 28(1)) with registration deadline in 2018 as **"importer"** of substances to the EU. In the latter case it is not currently determined whether registration by 31 May 2018 will be required or if another REACH-registered supplier can be found. One MoD has granted **defence exemptions** to the benefit of its own national Armed Forces. The aforementioned situations stem from the fact that the MoDs involved consider that they have direct obligations as addressees of REACH.

Based on responses received from MoDs, in some cases the views they expressed on this issue for the purposes of the study consultation have not been confirmed with the MoDs' legal services or their national REACH MSCAs.

OPINIONS OF THE EC AND REACH MSCAs

The EC and REACH MSCAs of the six LoI countries and Greece[160] were also consulted on the question of REACH status of national MoDs/Armed Forces. An EC official answer has not been received to date. The MSCA responses received show that there is no clear view on this issue.[161]

REASONS FOR DIFFERENCES IN MoD OPINIONS

Based on initial expert discussions and exchange of views at the level of the EDA REACH Task Force, some indications on possible reasons for the differences in opinion were provided e.g. due to

- the need of a thorough legal expertise on these questions,
- the very different degree of control exercised by their state over national defence assets (including the defence industry),
- the existence of specific activities in some MoDs that would be normally carried out by industry which (according to these MoDs' interpretation) would result in them having direct obligations as addressees of REACH.

IMPACT OF DIFFERENCES IN MoD OPINIONS

The practical impact of the difference in MoD opinions could increase in the future in view of the upcoming last registration deadline on 31 May 2018 for substances and the further evolution of the authorisation list.

The indirect impacts of a legal clarification could have consequences on the interface of the MoD/Armed Forces to the industry.

[159] Depending on the determination of national competences for REACH Article 2(3), both applicant and granting authority may be part of the same MoD organisation.

[160] Because reference was made to earlier consultation with the MSCA in Greece on this question in the study interview between the Contractor and the Hellenic Ministry of National Defence.

[161] A number of MSCAs did not express a position when responding. See list of MSCA answers received in Annex I.

CONCLUSIONS

As of today, there is legal uncertainty and a difference in views in the Member States consulted concerning this issue.

Due to the need for further legal consultations within MoDs so that a final legal position is taken by (each of) them, the underlying reasons for the existence of differences in opinion, or even further the possibility of reaching a potential common view among MoDs, could not be explored during the limited duration of the study and thus needs to follow, after the study is concluded.

5.2 Security of Supply (SoS) / obsolescence

The globalisation of defence production and markets has turned Security of Supply (SoS) into a multi-faceted problem. It now has a military and an industrial dimension which are pertinent to REACH considerations (Table 6):

Table 6 Security of Supply – Industrial and military dimension

Industrial SoS	Military SoS
concerns the supply of raw materials, technologies or critical parts of components to industrial producers	concerns the supply of spare parts, components, or entire systems by industrial producers **to the purchasing governments** (especially from some third (non-EU) countries)

In addition, there is a third dimension to SoS: The **dependency of domestic industry on exports to foreign markets**. This is related to the fact that, due to the high cost of modern defence systems, exports to foreign markets have to be considered in order to justify the launch of a new programme. As an example, the removal of Cr(VI) treatments will affect the longevity of defence products. This will potentially also negatively impact the defence export market. Such a negative impact in export volume can be a significant factor as to whether a defence product is commercially viable and any loss will have a direct impact on the availability of these military capabilities to European MoDs.

The risk to SoS has technological, economic, material, bureaucratic and political reasons. REACH, with its associated obsolescence potential, has created a new risk to both Industrial and Military SoS coming from European regulations. EDA has already performed a study on defence dependencies.[162] The present study shall focus on the new REACH related risks to the SoS. The survey shows that **only a small fraction of MoDs consulted (8%) believe that REACH is not a challenge to maintain SoS while 67% believe it is** (25% do not know).[163] Some MoDs even strongly believe that *"REACH may impact the actual operability of the armed forces, therefore imposing a risk of European armed forces not being able to carry out their duties of defending national interests"*.

Obsolescence is seen as the main REACH related challenge to SoS.[164] MoDs consulted see a major risk of supply disruption due to REACH, especially if SMEs and producers of defence-critical chemicals

[162] FOI/ONERA/RAND, Addressing Key European Defence Technology and Industrial Dependences, Executive Summary (11 May 2012).

[163] See questions 2.1, 2.2 and 2.3 in Annex C for full details.

[164] Please refer to Section 4.1.2.2 for a detailed analysis of obsolescence and Annex H.6 for a list of more significant comments by MoDs on SoS.

in small volumes (e.g. special military paints[165]) leave the market, because the business is no longer profitable under REACH, or because of (unannounced) reformulation of mixtures.[166] **MoDs have already reported occurrences of shrinking supplier base,[167] monopoly situations[168] or complete cessation of production by single source suppliers[169] due to costly REACH compliance requirements (esp. authorisation).** It has also been said that even if an authorisation or a defence exemption was granted, an increase in the cost of the formulations can affect procurement and MRO activities especially for long lifecycle systems, impacting defence capabilities; a clear example are chromates used in surface treatments for air, maritime, land and weapon systems.

MoDs manage obsolescence risk in a multifaceted approach, for example**:**

- They impose **clauses in their contracts with suppliers** to manage obsolescence of products. It imposes security of supply on the supplier.[170] The hope is that these requirements (such as avoidance of candidate list substances for new designs, or standard hazardous materials mapping requirements by equipment type) will help reduce the number of obsolescence cases due to REACH or at least help with anticipating future risks. Furthermore, it is also hoped that it will spread more uniform procurement practices within the supply chain in relation to REACH.[171]
- **The procurement strategy is adapted on a case-by-case basis**, either in favour of EU suppliers (to secure REACH compliant supplies) or in favour of non-EU suppliers (to mitigate obsolescence within EU).
- In MoD maintenance centres, they can check if their suppliers are covered by the relevant authorisation. Suppliers would need to be changed, if their use of chemicals is not sufficiently covered by the authorisation or because of the economical obsolescence risks due to ">1t/year registration" limit (2018 REACH registration deadline).
- They may change their approach to maintenance. Under **traditional maintenance contracts**, industry gets paid to manage the supply chain and to provide parts. But in a **performance-based logistics model**, industry gets paid to provide readiness. So the MoD tells the industrial

[165] Unique and specialist coatings required for extreme military spectrum of operating environments (arctic, marine, temperate tropical and desert) could potentially become unavailable to produce creating some very serious capability gaps in the future, according to some MoDs.

[166] One MoD consulted has provided a longer list of occurences of non-approved reformulation traced back to REACH, requiring immediate mitigation actions upon discovery (e.g. costly conformity testing, substitution). See also Chapter 7 regarding the risk of premature reformulation due to multiregulation pressure.

[167] For example, the supplier base for Cr(VI)-containing formulations has already shrunk, according to some MoDs.

[168] See example of DBP in Section 4.2.3.2 and Annex D.1.

[169] The example was given of a specific adhesive, with the MoD being the only customer requiring it. The single source supplier ceased production due to the cost of authorisation of MDA (sunset date: 21 July 2014). The MoD had to procure all available stock. Research and testing of alternatives is estimated to take 5 years at minimum.

[170] For instance the FR MoD has spent several years negotiating standard REACH requirements with the FR defence industry association (CIDEF) and these keep being updated to take into account return of experience.

[171] Example: "The defence sector's criteria document" in Sweden states requirements that are beyond national and EU regulations in order to be proactive and try to foresee problematic substances prior to them being listed on Annex XIV.

contractor what level of readiness they want and Industry provides that, assuming all the risks and all the costs associated with that.[172]

Relocation of EU companies involved in the production of defence equipment (e.g. producers of critical components) to non-EU countries, in order to avoid the burden and use limitations associated with REACH (see Section 4.1.2.4), is seen as another major risk to Security of Supply by most MoDs consulted.[173] Supply chains that reside outside the EU, resulting in the need for imports of products into the EU, are more difficult to control, manage and monitor (e.g. due to design restrictions as well as regulatory restrictions e.g. due to ITAR, if the production is moved to the US). In addition, there are concerns that some products may not meet the required specification or may even be counterfeit.[174]

5.3 Economic impacts

PROCUREMENT COST

The economic impacts due to REACH reported by MoDs mainly concern the direct costs. In this context one third of the MoDs consulted (33%) confirmed price increases from their suppliers attributable to REACH, although 50% state that they do not know. On the other hand, an overwhelming majority (82%) of MoDs declare they expect such increases **in the future**.[175]

Some MoDs fear that the granting of an authorisation for a manufacturer or importer puts them in a strong position as a sole supplier.[176] Such market concentration, over time, as well as increased pressure from the REACH regulation, may lead to an increase in prices throughout the European defence market supply chain. Furthermore, the costs of R&D invested in substitution efforts may have an impact on an increase in prices.

HUMAN RESOURCE COST

Most (64%) MoDs report increased manpower costs due to REACH as additional manpower is needed to prepare procedures and handle exemptions. Most of the consulted MoDs see this additional cost impact as being bearable and some (18%) actually state that there is no need for extra human resources, since they are using current resources to deal with REACH related tasks. However, a common view amongst the MoDs is that the need for manpower and the related administrative costs are likely to increase **in the future**. The highest reported manpower cost came from the MoD of a MS with a strong Defence Technology and Industrial Base (DTIB) which evaluated the additional effort at 15 people (MoD procurement agency + MoD maintenance centres) spending 2/3 of their time mainly on REACH but also other EU environmental regulations. They quoted a total cost of 1,000 K€/year.

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[172] Sandra I. ERWIN, Military Challenges to Maintain Decades-Old Aircraft, The National Defense Industrial Association (NDIA) Business and Technology Magazine (January 2015).

[173] See questions 2.7-2.9 in Annex C.

[174] Counterfeit products using cheap materials are becoming more attractive as the profit margin is increased.

[175] See questions 2.5, 2.10 and 2.11 in Annex C.

[176] One instance was reported during the consultation, where the price of an authorised substance got multiplied by 4.

R&D / REPLACEMENT COST

45.5% of MoDs report increased R&D costs. However, as many (45.5%) declare they do not know. According to the Contractor, this may be a reflection of varying national schemes for R&D funding, due to the fact that in those countries R&D funding for substitution is managed by other ministries e.g. industry, economy, etc.[177] Most of those that reported increased costs have a budget they can use to directly fund substitution activities in their respective countries.[178] The amount spent on R&D varies considerably between the MoDs, for example, a major EU MoD has spent ca. 50,000 K€ since 2014 (substitution studies for Cr(VI) and cadmium) while a MoD of a Member State with small DTIB, who mostly buys off-the-shelf equipment, has spent 300 K€ in the time period 2013-2016.

MAINTENANCE COST

Maintenance costs could increase due to substitution with less performing alternatives, resulting in shorter maintenance intervals (see Section 4.1.2.1), as expected e.g. in case of Cr(VI) replacements for tank barrels, airplanes and ships (see Annex D.4). Quantitative information is not available today.

5.4 R&D / substitution / innovation

About half of MoDs surveyed are performing, financing or promoting R&D activities for SVHC substitution (see detailed results in Table 19 in Annex C, questions 2.12, 2.19, 2.20 and 2.21).

They all report that their budgets have not increased and that the R&D for substitution is performed to the detriment of other R&D activities. One MoD of a Member State with strong DTIB pointed out: *"It is felt that REACH is driving a "bow-wave" of R&D work with limited resources and expertise available."* A significant majority (64%) agree that additional funding should be made available at a European level for substitution R&D. This is an interesting finding since it may mean a strong willingness from those MoDs to collaborate at a European level for that work. Some of the more significant comments on EU level support made by the MoDs surveyed are presented hereafter:

"Put in place something like an EU "DARPA" to finance long term solutions which will be a real technological breakthrough towards sustainable chemistry."

"A major effort by the EU is required to release more funds. Chrome free paint scheme, alternative propellants"

"Yes, by all means. Calls within Horizon 2020 that promote the substitution of hazardous chemicals need to be expanded. "

"Focused Research and Development is crucial for the proper and efficient implementation of a market and industry-oriented chemical legislation, as REACH. The necessity of "energetic" solutions such as public funding would be good to be highlighted within the present study."

"We believe that EDA has a significant role to play in this field, to promote EU MS collaborative efforts towards substitution of SVHC. Relevant actions are of course under way and may need to be stimulated."

[177] See question 2.12 in Annex C.

[178] One MoD pointed out that the R&D budget is not for substitution, a decision has to be made to reallocate resources.

Indeed, funding for substitution-related R&D is not common today, and more emphasis would be required to open up funding opportunities which benefit substitution of SVHCs.

EU FUNDING FOR DEFENCE-RELATED R&D

Defence policy is primarily a national competence of the EU Member States. However, most EU governments have been driving down defence costs, with defence R&D being the main victim,[179] while major non-EU nations have been significantly strengthening their defence R&D. To date there has not been EU-level funding for defence only R&D. Work on dual use technologies can be supported under existing EU funding schemes (such as the European Structural and Investment Funds 'ESIF' and Horizon 2020). Therefore areas of dual interest should be highlighted.

Recent developments[180] in the frame of INEA (Innovation and Networks Executive Agency) call for SESAR (Single European Sky ATM Research) show an encouraging trend for EU R&D funds to become available for the defence sector. The EU's **Preparatory Action on defence research** may foresee for the first time a limited amount of defence-related R&D funding opportunities from 2017-2020.[181] It has also been confirmed by President of the EC[182] in September 2016: *"For European defence to be strong, the European defence industry needs to innovate. That is why we will propose before the end of the year a **European Defence Fund**, to turbo boost research and innovation."* If successful, this Preparatory Action would prepare the ground for a more significant European Defence Research Programme (EDRP) under the next EU Multi-Annual Financial Framework (see Section 9.1.1).

EDA R&T activities

REACH is one of the factors taken into account in EDA's R&T-related activities in the frame of its Capability Technology Groups (CapTechs[183]). Since there is no dedicated REACH budget, the funding of these activities relies entirely on the contributing Member States. The total R&T funding amounts to ca. 40-70 million EUR per year, out of which ca. 1 million EUR per year can be roughly attributed to REACH (for CapTech *Materials and Structures*).

The CapTech *Materials & Structures* selected the *"REACH Compliant Materials"* as one of the relevant material categories for the R&T work of the group. Work in this frame has been undertaken in particular on corrosion protection coatings in aeronautical (**ECOCOAT** project) and naval (**CCNS** project) systems, in order to work towards substitution of substances such as hexavalent chromium and cadmium.[184] An earlier EDA project for the naval domain, *"Antifouling Coatings for War Ships (**ACWS**)"* (2008-2011), also had the compliance with present and future environmental legislations, health and safety regulations (REACH, Biocidal Products Directive 98/8/EC, etc.) as an objective.

In the frame of the CapTech *Technologies, Components and Modules (TCM)* applications at risk in electronic products (such as gallium arsenide and lead) and ammunition technologies are also

[179] Between 2006 and 2013, defence R&D (-29.2%) has decreased at twice the rate of defence expenditure (-14.7%) in EDA countries: Me Frédéric MAURO, Professor Klaus THOMA, The future of EU defence research (March 2016), page 7.

[180] https://www.eda.europa.eu/info-hub/press-centre/latest-news/2016/08/31/inea-call-2015-results-in-53.5-million-for-military-sesar-projects.

[181] EC, European Defence Action Plan – Roadmap (November 2015).

[182] Jean-Claude JUNCKER, President of the European Commission, State of the Union 2016.

[183] See definition of CapTechs in Annex P.

[184] For more information about these projects see Annex E.1.

addressed in the light of REACH and its regulation of (potential) SVHCs, but currently not as R&T projects. This also applies to the project "Critical Space Technologies for European Strategic Non-dependence"[185], where the EDA CapTech TCM is liaising with the European Space Agency (ESA) and the EC on a number of activities including applications at risk with regard to REACH constraints (see Table 7). The approach is to investigate critical military applications and closely follow the substitution-related activities supported by the EC and ESA in the civil sector for dual use cases. Only where gaps not addressed in the civil domain are identified, MS discussions could take place with regard to the possible initiation of R&T activities in the frame of the EDA CapTech TCM in the future.

This shows that better awareness of relevant SVHCs to be phased out may help steer further R&D activities towards substitution at the EDA level, subject to funding commitments by the EU Member States. Both defence industry stakeholders and MoDs consulted have expressed interest in such collaborative activities, as far as they are compatible with national priorities, thus **avoiding duplication of work** at a national or company level and contributing to overall cost savings.

Table 7 provides an overview of EDA CapTechs REACH-related work/activities to date.

Table 7 Overview of EDA CapTechs REACH-related work/activities

CapTech/WG	Application(s) at risk	Activity/ies
CapTech *Technologies, Components and Modules*	GaAs for electronic products	Defence electronic component industry initiative against SVHC identification & authorisation (low risk, indispensable)
	Lead for electronic products	Adjustment of military standards for lead-free transition
	Adhesives for component assembly and coating (e.g. several include Bisphenol A); material for passive thermal control layers, primers	**"Critical Space Technologies for European Strategic Non-Dependence"** (jointly between ESA, EC and EDA) • N28 – Non Dependence of materials and processes
CapTech *Materials & Structures* **selected the "REACH Compliant Materials" as one of the relevant material categories for the R&T work of the group**	Antifouling systems for navy applications	**ACWS** (Antifouling Coatings for War Ships): 2008-2011
	Corrosion protection coatings (e.g. cadmium and 6-valent chromium)	**SRA Technology Gap 2.1. Self-healing materials or coatings** • Proposal on "REACH compliant coatings" for (**ESIF**) 2015 call for proposals • **ECOCOAT** (Environmentally Compliant Coating in Aeronautic) – finalised in 2013 • **CCNS** (Corrosion Control on Navy Ships): launched in 2013 • **CONVINCE** (Vulnerability Reduction Technologies for Large Maritime Composite Structures): closed in 2014
	Textiles with insect repellents (e.g. Permitrin)	SRA Technology Gap 4.9. Textiles which protect against insects and infection (bactericidal): Adaptation of civil developments to military environment. help to substitute Permitrin
CapTech *Ammunition Technologies*	Energetic Materials (EM)	e.g. Cat B Project "Energetic Materials Towards Enhanced European Capability (**EMTEEC**)": is also taking in consideration REACH

185 See https://www.eda.europa.eu/info-hub/press-centre/latest-news/2015/03/19/critical-space-technologies-for-european-strategic-non-dependence and EC/ESA/EDA, Critical Space Technologies for European Strategic Non-Dependence, Actions for 2015/2017.

NATO-LEVEL PROJECTS

NATO has also started to study the potential opportunity of R&T that supports substitution of SVHCs in defence applications. Two ongoing examples are (see Annex E.2 for their brief descriptions):

- ***"Environmentally Compliant Materials & Processes for Military Vehicles"*** (AVT-247/ RTG-084, 2016-2018);
- ***"Effect of Environmental Regulation on Energetic Systems and the Management of Critical Munitions Materials and Capability"*** (AVT-293/RTG-103, 2017-2019).

The examples given above clearly illustrate that SVHC substitution for more common applications in the military domain is seen more and more as a challenge that is best addressed collaboratively and at a transnational level.

5.5 Environment Health and Safety (EHS) impacts (benefits)

The majority (75%) of MoDs responding had implemented additional Risk Management Measures (RMMs),[186] while 25% had not. In relation to additional Environmental Release Monitoring measures only 30% have implemented new measures, while 50% had not and 20% were unsure as to whether this had occurred within their defence forces.[187]

The need to comply with environmental and worker protecting regulations pre-dates REACH. Consequently, MoDs already have strict measures in place to limit exposure and release. Where any potential improvements are identified, such measures have been implemented as a matter of course. It was noted, that the requirements under REACH had complemented these policies, for example it was noted in discussions with the Swedish MoD that their "Criteria Document" list of hazardous substances has been updated based on inputs from REACH.

For those MoDs that didn't implement additional RMMs or Environmental Release measurements, many stated that national environmental health and safety requirements were the reason why there was no need.

Overall, of the MoDs responding, there was a generally **positive** impression of the effects that REACH has had on the **standardisation and harmonisation of information** used in EHS planning and implementation across the EU. This was tempered, however, by the fact that many only saw REACH as adding to the situation that existed on a national level for many years previous to REACH and also because not all information was available from the supply chain. Also, the lack of progress on improving the quality of EHS data of substances was criticised, as this may potentially result in a precautionary worst case approach (candidate list and Annex XIV), while RMMs would be sufficient.[188]

[186] See Annex H.1 for a list of main improvement areas mentioned.

[187] See question 2.22. and 2.23. in Annex C.

[188] REACH registration dossiers are the main source of information for ECHA's annual screening activities to determine substances for possible further regulatory action. Therefore, dossier quality may influence screening results.

5.6 Collaboration within the Member States

Within the Member States there are concurring REACH responsibilities of different authorities:[189]

- **MoDs** with regard to REACH Article 2(3);
- **Member State Competent Authorities (MSCAs)** with regard to REACH in general;
- **National Enforcement Authorities (NEAs)** with regard to REACH enforcement.

The study consultation targeted EU MoDs and MSCAs.

COLLABORATION MOD - MSCA

Overall, MoDs and MSCAs surveyed have reported a good level of collaboration with each other within the Member States. In some cases MSCAs have also responsibilities in the defence exemption procedure, and related EU-level discussions have taken place at CARACAL (Competent Authorities for REACH and CLP).

However, when asked in the study questionnaire for REACH MSCAs whether they are familiar with the specific challenges for producers of complex defence systems/components to cope with the progressive placement of substances on the candidate list and Annex XIV, most of the MSCAs responding said no, while some others referred to their national MoD. Only one MSCA explicitly acknowledged that long life times of equipment present specific challenges.

Some comments also suggest that there may be misconceptions (e.g. mentioning that the need for derogations for the defence industry is none or very limited) or that the commercial obsolescence risk posed by the REACH authorisation process for high-end niche sectors such as defence with potentially long future equipment maintenance needs is underestimated (e.g. by noting that authorisation does not mean that the substance becomes unavailable).[190]

Furthermore, the study has shown that a number of MoDs have significant expertise on substances, use needs and supply chain issues. This MoD expertise could be very beneficial for their MSCAs when considering regulatory action for specific substances.

COLLABORATION MOD – NEA

The collaboration of MoDs with their NEAs has not been studied in detail. However, its benefit to better coordinate enforcement at the national level - where defence exemptions are granted - has been stressed by the EC during the study. This could involve for example the sharing of knowledge as to why substances are exempted according to REACH Article 2(3).[191]

[189] See Annex P for Definitions of Member State Competent Authority and National Enforcement Authority, as well as CARACAL.

[190] See Section 4.1.2.2 and Section 5.2 with survey results and examples of REACH-induced obsolescence, including due to the authorisation process.

[191] Unless there are grounds for the MoD to not disclose this information.

5.7 Conclusions on MoD impacts

The important question whether MoDs/Armed Forces are addressees of REACH and hence **directly impacted** by its provisions, is still subject to difference in views in the Member States today.

The key impacts of REACH on MoDs as end users are in any case **indirect**, because MoDs rely strongly on their industrial suppliers for the delivery of high-performance defence equipment. The majority of MoDs believe that REACH is challenging **Security of Supply**, with **obsolescence** seen as the main REACH related challenge to it.

Economic impacts of REACH on MoDs (direct costs, e.g. for manpower, R&D) may be significant. Overall however, available information able to be gathered within the limited timeframe of the study is limited (see also Annex H.7). In relation to procurement costs, an overwhelming majority of MoDs consulted foresees REACH-related cost increases in the future.

About half of MoDs surveyed are performing, financing or promoting **R&D activities for SVHC substitution**, including through EDA CapTechs, while related budgets have not increased. As pointed out by one MoD of a Member State with strong DTIB: *"It is felt that REACH is driving a "bow-wave" of R&D work with limited resources and expertise available."* A significant majority therefore agree that additional **funding** should be made available **at the European level** for substitution R&D. Examples of EDA (ECOCOAT, CCNS) and NATO (AVT-247/RTG-084, AVT-293/RTG-103) - see Annex E for both - clearly illustrate that SVHC substitution for rather common applications in the military domain is seen more and more as a challenge that is best addressed **collaboratively** at a transnational level.

The clear majority of MoDs responding had implemented additional **Risk Management Measures** (RMMs) as a result of REACH (see Annex H.1). They typically complemented the strict measures already in place to limit exposure and release, in line with the numerous requirements predating REACH. Where any potential improvements were identified, such measures have been implemented as a matter of course.

As a consequence of the impacts already occurred and still expected, some MoDs strongly believe that REACH may impact the actual operability of the Armed Forces, therefore imposing a risk of European Armed Forces not being able to carry out their duties of defending national interests.

Based on the study consultation of MoDs and MSCAs there is generally a good level of collaboration with each other within the Member States. However, the limited awareness of most MSCAs consulted of defence sector specificities with regard to REACH/CLP as well as the expertise of some MoDs on substances, use needs and supply chain issues suggest that there is room for enhanced information exchange. The collaboration of MoDs with their National Enforcement Authorities has not been studied in detail. However, its benefit to better coordinate enforcement at the national level – where defence exemptions are granted – has been stressed.

6 SUBSTANCE- AND DOMAIN-SPECIFIC IMPACTS

This Chapter elaborates on substance- and domain-specific impacts on the European defence sector, based on the stakeholders' consultation and the Contractor's further analysis. Following an initial overview highlighting substance criticality factors for military uses (Section 6.1), specific issues for inorganic substances are discussed (Section 6.2). Substance specific examples are provided (Section 6.3). Domain specific impacts are illustrated using the examples of munitions and electrical connectors (Section 6.4). Finally, Table 9 and the related detailed Annex D highlight a **significant panel of important SVHCs** at different stages of REACH authorisation or restriction processes.

Important note: Substances are discussed in this report for illustrative purposes only. Their discussion does not imply that they will be targeted for further prioritisation actions at EU level. They were chosen because their military use(s) is (are) well known and because they are at various regulatory stages.

6.1 Overview: Substance criticality factors for military uses

Due to the plethora of complex systems and components produced and used for defence purposes the defence sector is actually and potentially affected by a very high number of SVHCs. They have been required, and thus been used, for performance reasons or as process chemicals for the production and maintenance of defence equipment for many years and decades.

Their **criticality** (importance) for the defence sector is mainly determined by **(1)** wide-dispersive use, **(2)** difficulty to substitute and **(3)** recognition as a Critical Raw Material (CRM) by the EC,[192] as detailed in Table 8. Critical substances such as inorganics highlight the need for a diligent choice of the REACH authorisation process and other Risk Management Option(s) (RMOs) by the competent authorities.[193]

Table 8 Three key factors for criticality of a substance for defence

Criticality factor	**Wide-dispersive use**	**Difficult substitution**	**Critical Raw Material**
Regulatory implication	Extensive substitution efforts to be spent by a significant number of industrial actors and for different systems. For widely used substances there is no drop-in alternative.	It is technically and/or economically challenging to replace the use of the substance. The technical challenge of replacement has been often highlighted for *inorganic* substances (see below in this Chapter with examples).	CRM are raw materials with a high supply-risk and a high economic importance for Europe. Under its *Critical Raw Materials Initiative* the EC maintains a list of such CRMs (latest version of 2014, next update 2017)

Apart from the specific criticality factors for defence it should also be considered, that a substance with SVHC properties may be important to achieve the EU's key policy objectives in areas such as

[192] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52014DC0297; see Annex N.3 for further information on CRMs, the related EC policy and possible conflicts with regards to REACH.

[193] Related improvement proposals can be found in Chapter 9, in particular: Sections 9.1.1-9.1.3, 9.2.1-9.2.3, 9.3.1, 9.3.2.

energy and climate change, green transport, clean air, resource efficiency and circular economy.[194] The **circular economy** in particular aims to minimise waste through long product life and recycling or reuse. Substances with SVHC properties targeted by REACH may be important to ensure the longevity of defence equipment (e.g. those applied for corrosion protection purposes). Hence, REACH authorisation, and also REACH Article 33, are potential hurdles for the circular economy idea, especially for products with long lifecycles such as complex defence equipment.[195]

The substance- and domain-specific impact analysis shows that the impact for the defence sector (authorisation and substitution) is very high particularly for substances which are already on Annex XIV and the candidate list.

Future Annex XIV inclusion of substances, especially inorganic substances, with widespread applications in the defence sector, would have a major impact on performance and production capabilities in the EU of defence products. A similar challenge could arise from the setting of too low **binding EU-wide Occupational Exposure Limits (bOELs)** under the EU workplace legislation, which could make substance use impossible in practise. New bOELs are currently under development e.g. for beryllium, chromium (VI) compounds, hydrazine and refractory ceramic fibres. These new EU workplace limits also highlight the issue of the relationship of EU OSH legislation and the REACH authorisation process, which requires further clarification.[196]

6.2 Inorganic vs. organic substances

Inorganic substances are characterised by ionic bonding and many gain their properties (shape, reactivity, melting point, boiling point, etc.) from the presence of specific metal atoms in particular oxidation/valence states, which tend to form cations (i.e. lose electron density) when forming compounds. Such reliance on the particular properties of the metal core adds to the difficulties in substitution activities. Inorganics differ from organic compounds which are generally covalently bonded, meaning electron density is shared between the bonding atoms.

Indeed the difficulty in replacing inorganic compounds in military uses is evident with **almost 89% of authorisation applications being for inorganic substances** (See Annex G.2). This demonstrates the importance of inorganics to specific uses within the defence sector and underscores the point that like-for-like substitution of one metal with another; even within the same group of the periodic table; or even of the same metal in a different valence state, is difficult in some cases, while it is impossible in most. Even when a substitute can be found, the potential that this would have the same, or similar SVHC properties, is also high given the nature and chemistries of the metals.

The importance of inorganic elements and compounds to the wider EU community is also evident given that all those listed on the EC's CRM list are inorganic in origin.

When, in the USA, investigations[197] were undertaken to identify potential alternatives to 62 metals in materials for identified major industrial uses, it was found that for many materials no suitable

[194] See e.g. Nickel Institute, Economic and Strategic Importance of Nickel Compounds.

[195] Please see Annex N.3 for further information about possible conflicts of REACH with the circular economy policy.

[196] See already Section 4.2.3.5 (Uses covered by existing specific Union legislation (REACH Article 58(2)) and more general information on the interface of EU OSH legislation and REACH authorisation in Annex N.3.

[197] GRAEDEL T.E., HARPER E.M, NASSAR N.T., RECK K.R., On the Materials basis of Modern Society, Proceeding of the National Academy of Science, 112 (20), 2015, pages 6295-6300.

alternatives could be identified.[198] Moreover, it was also stated that product performance would suffer markedly under substitution of these materials.

Though the specific focus by Graedel et al. **was not the defence sector**, many industrial processes used within defence supply chains were examined. When examining Table 9; the illustrative examples of critical substances (or groups) for defence and correlating this to the Greadel study, the overall (non-defence specific) difficulty in substitution of inorganic materials is evident (Figure 15). Please also review the clarifying explanations following this figure).

Figure 15 Substitute performances of selected inorganic elements (based on Graedel et al.)

A few clarifications on this are important to be made:

- It should be noted that the results of this study were non-defence specific and, as such, the ease or difficulty of substitution may not be representative of the actual situation in the defence industry.
- Though Gallium Compounds, Cadmium and Borates would appear to have potential for replacement in some processes, a deeper examination of the study shows that, for the processes most applicable to defence, either the alternatives proposed have SVHC properties (e.g. alternative to Ga in laser diodes, light-emitting diodes, and solar cells is given as indium phosphide; which has a harmonised C&L for carcinogenicity (Carc. 1B)) or that the use most associated with defence in fact has no alternative (e.g. Cd in Ni-Cd batteries for industrial uses and Cd used in coatings), but as defence represents such a small proportion of the overall substance market, these uses are overshadowed and given less importance in the scoring.
- It should also be noted, that the study was not performed in Europe, where REACH considerations would likely have been prioritised when examining potential for replacements. As a result, some potential alternatives that are suggested could not be viable within the EU.

[198] The results are scaled from 0 to 100, with 0 indicating that exemplary substitutes exist for all major uses and 100 indicating that no substitute with even adequate performance exists for any of the major uses.

- **Neither the study by Graedel *et al*. nor the present study can replace a case-by-case analysis of the alternatives pertaining to the specific uses at hand.**

Nevertheless, the study by Graedel *et al.* serves as an example of the difficulty in substitution of inorganics in industrial processes.

Additionally, unlike organic substances, which are generally included on Annex XIV, XVII and the Candidate list of SVHC substances as single substances, the trend thus far has been to include inorganic substances in the form of metals either entirely or in particular valence states; examples being chromium in its +6 oxidation state (Cr(VI)) and Nickel salts. This approach does not limit the inclusion to just one inorganic substance but instead affects classes of inorganic substances. Though understandable given that toxicity is, for the most part, caused by the metal core, this causes problems in industrial settings as the use of several substances based on the same metal are prohibited at the same time, affecting multiple industrial processes and equipment, each potentially requiring development of a unique solution, and/or multiple applications for authorisation for each use. In a nutshell, this leads to a main challenge for replacement, increasing its cost as well as the post-substitution cost, e.g. for maintenance: **Several substitutes may be necessary to cover the full spectrum of applications of the banned substance.** This was seen for asbestos, and it is being seen for chromates.[199]

Such impacts are also felt in the defence sector which produces a plethora of complex systems and components that are used in defence equipment. As a result, it is potentially impacted by a very high number of SVHCs, for example use of many substances for their corrosion resistance properties, use of substances in alloys for their strength and weight, and in munitions for their reactivity. In addition to the direct impact from their own substance uses, defence stakeholders are also affected by the impacts on their upstream component manufacturers.

6.3 Substance specific examples

To further highlight the importance of inorganic substances to the defence sector, some illustrative examples are introduced. For further **detailed information** on these and other critical substances to defence, **please see Annex D**.

- **Cr(VI) containing substances** have been used for many decades for metal surface treatment (corrosion protection, surface preparation, electrical continuity, equipotential bonding, thermal resistance) in a very wide range of sectors such as aerospace, naval vessels, land vehicles, munitions and EEE equipment. As can be seen from Figure 15, Chromium substances are poorly substitutable for the uses examined in the study by Graedel *et al*. Continued use for critical applications in the foreseeable future, well past the authorisation review periods currently envisaged by the ECHA Committees, is expected to be required by many defence stakeholders consulted.

  Chromium is listed by the EC as **Critical Raw Material** (CRM).

  The main applications of Cr(VI) containing substances in the EU defence sector are given in Annex D.4.

[199] As one of several examples given by a major MoD, Cr(VI) surface treatment as Chromic Acid Anodising (CAA) used both for anticorrosion and/or bonding applications has up to 7 alternative solutions qualified for different applications.

- **Borates** have critical uses in many fields. Of particular interest to defence is the use of boric acid in electrolytic deposition of metals such as Ni, SnPb, Co, Cd; Chromate Conversion Coating but also in the control and emergency stop of nuclear reactions within nuclear submarine propulsion systems.

  The main uses of borates in the EU defence sector are given in Annex D.8.

- **Refractory Ceramic Fibres (RCFs)** are used as heat protection insulator in a flight safety-critical recording system, used on all military and civil aircraft. Continued use is considered as critical, as there is no known validated alternative. Furthermore, RCFs could be an example of regrettable substitution as they were once the replacement to asbestos in a few niche applications, even though not specifically developed for that purpose (see Section 4.1.2.4 and 4.1.3 for more information about "regrettable substitution" especially during long product lifecycles).

  The main applications of RCFs in the EU defence sector are given in Annex D.7.

- **Lead and its compounds** are widely used in the defence sector in several domains including: munitions (primer caps and detonators); land, sea and air (lead batteries, soldering for EEE, dry lubricant coatings, in lead containing alloys etc.). As can be seen from Figure 15, lead substances are very poorly substitutable for the uses examined in the study by Graedel *et al*.

  For the four lead compounds recommended for Annex XIV by ECHA on 10.11.2016,[200] uses in the manufacture of lead-based batteries are already addressed by several pieces of existing "lead specific" EU legislation protecting human health and the environment.[201]

  The main applications of lead metal and its compounds in the EU defence sector are given in Annex D.9.

- **Cadmium** is used in galvanic cadmium plating for corrosion protection, soldering and brazing alloys, surface lubrication and improvement of electric conductivity, battery technology, as well as many other uses in defence equipment.

  Though targeted by several provisions in the RoHS Directive, REACH Annex XVII entry 23 and lately the REACH candidate list, recognizing the importance of cadmium to the defence sector both RoHS and REACH Annex XVII entry 23 contain defence exemptions/derogations. Nevertheless, supply problems have been highlighted by defence stakeholders due to the niche nature of the defence sector.

  Further details on the uses of cadmium in the EU defence sector are given in Annex D.12.

- **Nickel salts** are critical substances for the defence sector with widespread uses are in surface treatment (including for maintenance activities): corrosion protection such as Zn-Ni, adhesion promotion for metal plating and Ni-Cd batteries.

  Nickel salts are used in ZnNi plating that are under study to replace cadmium for connector plating, however its use is in doubt given the current regulatory uncertainty surrounding this class of substances. In addition, it was noted that nickel substances were also considered as

[200] Lead monoxide, lead tetroxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate.
[201] http://ila-reach.org/wp-content/uploads/2016/07/Consolidated-paper-Pb-compounds-alliance.pdf.

potential alternatives to chromium in surface corrosion protection. This is another example of regrettable substitution. As can be seen from Figure 15, Nickel substances are poorly substitutable for the uses examined in the study by Graedel *et al*.

Further details on the uses of nickel salts in the EU defence sector are given in Annex D.18.

- **Beryllium** is used in a number of structural components, semiconductors, optics, aircraft inlet probes or nonmagnetic material. Copper beryllium alloys are made into the terminals of electronic and electrical connectors in military vehicles, aircraft, satellites, missiles, ships. Beryllium substances are poorly substitutable for the uses examined in the study by Graedel *et al*.

  Beryllium is listed by the EC as **Critical Raw Material** (CRM).

  Further details on the uses of beryllium in the EU defence sector are given in Annex D.14.

- **Gallium Arsenide (GaAs)** is used in limited quantities. The substance is a critical building block for semiconductors, e.g. in thermal cameras and is widely used in microelectronics. Due to its double harmonised classification there is a risk that GaAs could be included in the candidate list soon, which would result in complications for the European semi-conductor industry, and by extension the defence sector.

  Gallium is listed by the EC as **Critical Raw Material** (CRM).

  Further details on the uses of GaAs in the EU defence sector are given in Annex D.17.

In addition to the above, a **new harmonised classification as CMR Cat. 1A or 1B in CLP Annex VI** poses a general concern for the wider defence sector stakeholders in general, due to the fulfilment of criteria for inclusion in the REACH candidate list (REACH Article 57) and the direct consequences under other EU "downstream" legislation. Current topical substance examples include lead metal (see Annex D.9), titanium dioxide (CAS 13463-67-7),[202] nitric acid (CAS 7697-37-2), nickel, E-glass and nonylphenols.

6.4 Domain specific impacts

All defence domains; **aerospace, munitions, land, naval, nuclear and electronics** are heavily impacted by REACH.

An illustrative example of the impacts on one of these domains is **munitions**:

- The role of manufacturer with **registration obligations** within the defence sector is only unusually assumed by EU defence companies, such as producers of ammunition (e.g. lead styphnate). Almost all of the defence companies with registration obligations are solely or partly producers of ammunition. See Section 4.2.1 for more details.

[202] The German Chemical Industry Association (Verband der Chemischen Industrie, VCI) considers that the French proposal for harmonized classification as Carc. 1B is not justified and would have serious and disproportionately negative impacts due to automatic reference to classification and labelling in existing legislation, see VCI statement of 4 July 2016: https://www.vci.de/vci-online/themen/chemikaliensicherheit/einstufung-kennzeichnung/2016-07-04-vci-stelllungnahme-zum-vorschlag-einer-harmonisierten-einstufung-von-titandioxid-vci.jsp.

- The anticipation of possible obsolescence risks for munitions is vital. Of the 19 illustrative substance examples listed in Table 9 below, 12 are considered critical for munitions.[203]
- **Substitution work** in this domain can be significantly more **dangerous** due to the development of new and unpredictable energetic materials.
- Many ammunition manufacturers, more exposed to competition, report **loss of competitiveness due to REACH**. Furthermore the economic impact of REACH on makers of ammunition is from substitution work. See Section 4.1.2 for more details.
- It was reported that ammunition and explosives production are being partly or entirely **moved to countries outside of the EEA** for cost saving reasons as well as lower environment and health standards. See Section 4.1.2.4 for more details.
- The application of **CLP labelling rules to ammunition qualifying as 'explosive articles'** is causing concern and poses various significant challenges. More or less all stakeholders agree that CLP labelling adds little value and there are already a number of requirements on ammunition safety independent of the CLP. See Section 4.2.5 for more details.
- **Legal uncertainties** exist with regard to **REACH article status** (see Annex H.8) and application for **exemptions from authorisation** for critical substance uses (e.g. hydrazine propellant) which may lead to needless spending of resources.

Another illustrative example is **electrical connectors**:

- Substitution of hazardous component substances poses particular challenges due to contradicting performances (need for electrical conductivity and at the same time avoid conductivity provoking corrosion).
- Connectors are mainly supplied by SMEs and often sourced from outside EU already today. An increased risk of REACH-induced relocation for their production is seen from the MoD side.

6.5 Conclusions

REACH impacts the military uses of many inorganic substances, including those linked to Critical Raw Materials which, according to the EC's related policy, are very hard to substitute (e.g. beryllium, borates, cobalt salts). New OELs under the EU workplace legislation (e.g. beryllium, hydrazine, refractory ceramic fibres) and Circular Economy are emerging as additional requirements, on top of existing ones (e.g. for lead and its compounds). The link between these EU laws and policies and REACH risk management options such as authorisation is not very clear today, leading to possible EU policy inconsistency. The case of chromates raises questions about the appropriateness of authorisation as a blanket risk management instrument for certain substances, which cannot be easily replaced; are broadly used in various sectors including high tech domains such as defence; and are also addressed by other EU policies.

All defence domains; aerospace, munitions, land, naval, nuclear and electronics are heavily impacted by REACH, but domain-specific impacts may vary in subject. Munitions have a number of REACH & CLP issues, ranging from registration and authorisation to CLP labelling ("explosive articles").

[203] One MoD of a Member State with strong DTIB maintains a database for munitions composition down to the substance level to anticipate possible obsolescence risks.

The following table provides an overview[204] of some critical substances of concern for the EU defence sector based on the survey and highlights the impact of their Annex XIV inclusion (actual or potential) on defence systems and components. **It is important to note that this list is non-exhaustive and will have to be updated according to evolution of the substances impacted by REACH**. For more details about each substance example please view Annex D.

Table 9 Illustrative panel of critical substances (or groups thereof) for defence

Substance / substance group	REACH/CLP status	Air-Naval-Land	Space	Electronics	Nuclear	Munitions	CRM	R&T ongoing*
Phthalates	Annex XIV: first sunset date passed 21.02.2015	+				+		YES
Lead chromate (CAS 7758-97-6)	Annex XIV: sunset date passed 21.05.2015	+				+		YES
Trichloroethylene (CAS 79-01-6)	Annex XIV: sunset date passed 21.04.2016	+				+		YES
Cr(VI) compounds	Annex XIV: first sunset date on 21.09.2017	+	+	+		+	Chromium	YES (high)
Cobalt salts	Annex XIV recommendation (2011) - on hold	+	+				Cobalt	Not known
ADCA (CAS 123-77-3)	Annex XIV recommendation (2014)					+		Not known
Refractory ceramic fibres	Annex XIV recommendation (2014)	+					Silicon metal	Not known
Boric Acid (CAS 10043-35-3)	Annex XIV recommendation (2015)	+	+		+		Borates	YES (some)
Lead and its compounds	Annex XIV recommendation (2016) - partly	+	+	+		+		YES
Hydrazine (CAS 302-01-2)	Candidate list (20.06.2011)	+	+		+	+		NO (F-16)
Lead titanium zirconium oxide (CAS 12626-81-2)	Candidate list (19.12.2012)	+		+	+			YES
Cadmium (CAS 7440-43-9)	Candidate list (20.06.2013)	+	+	+	+	+		YES (some)
Ammonium perchlorate (CAS 7790-98-9)	RMOA (after substance evaluation)		+			+		YES
Beryllium (CAS 7440-41-7)	RMOA	+	+	+	+	+	Beryllium	Not known
Bisphenol A (CAS 80-05-7)	SVHC proposal and intention; restriction	+						Not known
Diisocyanates	RMOA concluded: Annex XVII proposal	+	+	+	+	+		Not known
Gallium Arsenide (CAS 1303-00-0)	CLP Annex VI			+			Gallium	YES
Nickel salts	RMOA	+	+	+		+		YES (some)
Petroleum substances, e.g. in NATO fuel	SVHC Roadmap to 2020 / PetCo Group	+						YES (some)

Legend: Annex XIV | ECHA recommendation | Candidate List | (Potential) SVHC | *Information on R&T based on MoD and defence industry survey

[204] The table sorts the substances in the order of their advancement in the authorisation process: (1) Annex XIV – by their earliest sunset date; (2) ECHA recommendation – by their earliest prioritisation for Annex XIV; (3) Candidate list – by their earliest candidate list inclusion. The final category "(Potential) SVHC" is sorted alphabetically.

7 OTHER EU CHEMICALS REGULATIONS AND THE DEFENCE SECTOR

The EU defence sector is impacted by chemical regulations also other than REACH and CLP. The other regulations regulate a **more limited number of substances** than REACH but within their specific scope they can potentially have a profound effect on the viability of the operation or maintenance of a particular system. Even where the defence sector is not directly affected, chemical regulations can inadvertently cause supply chain disruption several steps upstream from defence sector which still has a significant indirect impact also on defence. For this study the focus has been placed on

- Biocidal Products Regulation (Regulation (EC) No 528/2012) ("**BPR**");
- Ozone Depleting Substances (Regulation (EC) No 1005/2009) ("**ODS**");
- Persistent Organic Pollutants (Regulation (EC) No 850/2004) ("**POP**").

SYNTHESIS OF SURVEY RESPONSES ON IMPACTS OF OTHER EU CHEMICAL REGULATIONS

Table 10 provides an overview of the systems particularly affected by other EU chemical regulations, based on the study consultation (Table 10).

Table 10 Main impacted systems, substances and uses

Product group / substance	Use	System	Regulation
Preservatives	Anti-microbial	**Aerospace**	BPR
Organotin antifouling coatings	Anti-fouling	**Naval**	BPR
Permethrin	Textiles treatment (tents, soldiers' clothes)	**Commodities**	BPR
Halon 1301 (monobromotrifluoromethane)	Aircraft fuel tank inerting	**Aerospace**	ODS
Halons	Fire extinguishing agent	**Aerospace, land, naval**	ODS
DecaBDE	Fire extinguishing agent	**Aerospace systems**	POP[205]
PFOA	High performance tubes, hoses and cable insulation	**Aerospace systems**	POP[206]

[205] DecaBDE has been recommended by POPs Review Committee (POPRC) in September 2016 for global elimination in Annex A of Stockholm Convention for the Conference of Parties to make a final decision in April-May 2017. The expected time of implementation of the elimination in the EU under the POP regulation is expected in the autumn of 2018 at the latest. There is a potential conflict with the REACH restriction for decaBDE as adopted by the REACH Committee in September 2016 (due to take effect 24 months after the regulation takes effect) which includes an exemption for military aircraft whereas the POPRC recommendation makes no similar exemption. If the Conference of Parties does not amend the text and the substance is placed on the POP list, the REACH Annex XVII entry for decaBDE will be deleted and a full ban according to the POP text will be implemented in the EU.

[206] Similar future challenges to decaBDE in being due for global elimination under POP by the year 2020 while also subject to a proposed REACH Annex XVII restriction.

GENERAL CONCERNS RELATED TO THE COMBINED REGULATORY EFFECT OF REACH AND BPR

Several MoDs have expressed concerns about the forced **reformulation** of mixtures used for defence purposes (e.g. fuel additives, paints and surface treatment products) due to the combined pressure of **REACH and BPR** (e.g. biocides used in military aviation to avoid microbiological infestation). The **costs** to obtain substance approval or biocidal product authorisation under BPR are considered as disproportionately high, especially when compared with the generally low volumes of chemicals needed in defence products. Reformulation usually takes a long time and involves a lot of R&D. If substitution of certain substances in chemical products is stressed, it will most likely result in **reduced performance and reliability of the products**. As an example, the removal or substitution of specific additives in fuels may result in an increase in growth of microorganisms in the fuel which will be devastating for the function of the fuel when used in defence equipment. Reformulations and substitutions should be authorised by the MoD, but **may be missed** due to the complexity of the supply chain.

A further, authorisation process related concern, expressed by the aerospace coatings manufacturing industry was that the authorisation processes of REACH and BPR are not consistent in the sense of taking into consideration equivalent factors. The REACH authorisation process includes detailed **consideration of socio-economic impacts** of authorisation whereas the BPR authorisation process does not include a consideration of these impacts.

As a response to the concerns over long term sustainability of current maintenance practices joint R&T activities of the Member States coordinated by the EDA have started targeting military uses. An example is the CCNS project *"Corrosion Control on Navy Ships (CCNS)"* (for more information about this project please see Annex E.1).

IMPACT OF SUBSTITUTION PROCESSES ON THE LONG TERM OPERABILITY OF DEFENCE SYSTEMS

Substitution pressure for defence-critical substances is exercised not only by REACH (and CLP), but also by other pieces of EU chemical legislation, as shown in the brief analysis of BPR, F-GAS, ODS, POP and RoHS from a defence-sector point of view (Table 11).

From the table it can be seen that **defence related provisions** are addressed differently in different pieces of EU chemical legislation, raising questions about regulatory consistency:

- Generally no exemption, focus on elimination of substances from the market: POP;
- Case-by-case defence exemption possibility: REACH, CLP, BPR;
- Exceptionally permitted critical uses include identified military applications: ODS;
- Disapplication/exclusion: RoHS.

Several MoDs consulted have highlighted the need for a consistent approach or "unification" of the legislative treatment of defence issues within the various EU chemicals regulations and directives, as it would help the defence sector to better and more easily comply.

The analysis also shows that the cumulative application of several pieces of EU chemical legislation may fall short of the overall effectiveness in terms of the targeted high level of protection of human health and the environment, especially if looked at in isolation.

Table 11 Analysis of relevant non-REACH Regulations from a defence-sector point of view

Regulation	Regulates	Defence related provisions	Potential impact on defence	Simultaneous application areas & links to other regulations
BPR	Biocidal products and treated articles	Article 2(8): Member States may allow for exemptions from this Regulation in specific cases for certain biocidal products, on their own or in a treated article, where necessary in the interests of defence	Unavailability of active substances and biocidal products due to withdrawal or non-approval/non-authorisation. Also, compliance requirements for treated articles need to be considered.	Substances in complex mixtures such as paints are subject to elimination pressure from multiple regulations. Regrettable substitution: Regulatory pressure on reduction of VOCs has led to increased use of water based paints which in turn requires increased use of biocides (see more information in Annex M)
F-GAS	Fluorinated greenhouse gases	Several exemptions for 'military equipment' as defined in Art. 2(35): Article 11(1) and Annex III, Article 13(3), Article 15(2)(d); specific labelling and reporting obligations	Impact of restrictions in spite of defence exemptions	Regrettable substitution: Phase out of hydrofluorocarbons (HCFs) under F-GAS, after introduction as a substitute under ODS. Phase out in production and maintenance can have a major impact on long service life naval systems as indicated by the input from one MS.[207]
POP	Persistent organic pollutants	None, so inclusion of a substance means ban without exemption (or authorisation) possibility unless a highly specific exemption can be agreed to otherwise global elimination.	Unavailability of substances prohibited or restricted. Also, compliance with conditions of restrictions is required.	Regrettable substitution: Replacement of regulated (POP&REACH) long chain Perfluorinated Compounds (PFCs) leading to increase in use of unregulated short chain PFCs of not much improved hazard profiles and inferior technical performance
ODS	Ozone-depleting substances	Annex VI: exceptionally permitted critical uses of halon include identified military applications	Unavailability of substances and of products and equipment containing or relying on controlled substances due to prohibition	Phase out of halons with long transitional periods is seen as an example of a phase out mechanism preferable to REACH authorisation but the approach is likely be unworkable for any broader group of chemicals.
RoHS	Electrical and electronic equipment [208]	Article 2(4)(a): disapplication for "equipment which is necessary for the protection of the essential interests of the security of Member States […] "	Potential commercial obsolescence risk (e.g. lead, see Annex M); potential inclusion of new substances	REACH Annex XVII (e.g. Cadmium, Entry 23)

[207] Input from one Member State does not necessarily mean that only one Member State is affected. This input may also be applicable to other Member States, however it was not possible to confirm this during the duration of the study due to lack of participation of industry or other government naval experts to the study.

[208] Restricted today are: Lead, mercury, cadmium, hexavalent chromium, Polybrominated biphenyls (PBB), Polybrominated diphenyl ethers, DEHP, BBP, DBP, DIBP.

To summarise the results of the comparison of defence related provisions in Table 11, it can be seen from the variety of defence related provisions that there is currently no one-size-fits-all provision that would generally be used to safeguard the interests of defence. The defence related provisions are purpose-built during the legislative process to meet the needs of defence in relation to the specific uses of the particular substance group being regulated.

The EC has responded in the study consultation that, for the time being, no action has been taken yet to address defence exemptions in general. The EC suggests that MoDs and EDA may contribute to a certain analysis and provide recommendations for improvement of the situation.

For substances used in critical applications such as for pilot safety or essential maintenance related uses often each substitute comes with a set of problems of its own and forcing several substitution steps in a quick succession that can lead to major complications (see Domain Specific Impacts below).

DISAPPLICATION IN ROHS ARTICLE 2(4)(a)

In relation RoHS, its Article 2(4)(a)[209] does not explicitly refer to the power of the MS to apply the exclusion, unlike REACH Article 2(3) ("Member States may allow…"). However, some MoDs are of the opinion that it is for the MS to decide whether RoHS Article 2(4)(a) applies or they follow an approach of voluntary compliance regardless of the exclusion possibility (e.g. NL MoD). The UK MoD pointed out that, according to its policy, RoHS Article 2(4)(a) requires a specific disapplication by the UK Secretary of State to confirm that the equipment is ***"necessary for the protection of the essential interests of the security of Member States"***.[210] According to the UK MoD this decision is therefore not up to the industrial supplier, which is often misunderstood. Similarly, the FR MoD reported that RoHS should be applied unless the contractor can explain why he needs the application. Other MoDs' views are not known today. RoHS contains several other exclusions which also cover defence products, like for *"means of transport for persons or goods"* (RoHS Article 2(4)(f)). Those exclusions do not require MoD approval. Given that additional substances are being included into RoHS, the question whether RoHS Article 2(4)(a) legally requires an MoD decision or whether MoD compliance demands with regard to RoHS are merely of voluntary nature may become even more relevant.

DOMAIN SPECIFIC IMPACTS

- **Cumulative regulatory impact on the use of halons particularly in aerospace systems**

As a group of substances subject to significant ongoing substitution efforts the use of halons is still of particular importance today for aerospace systems, while its progressive phase-out is taking place under a step-by-step regulatory regime for new equipment facilities and existing/legacy systems.

Halons as a group of substances are classified as "Ozone 1 (H420 - Hazardous to the Ozone Layer)". The **use** of halons remains authorised in the EU only for critical uses listed in Annex VI of ODS. Halons are still used in some legacy aerospace, land and naval systems. The main uses are protection as fire extinguishing agent, protection of occupied spaces and crew, aircraft fuel tank inerting and making inert spaces where there is a risk of dispersion of radioactive matter, flammable liquid or gas.

[209] A similar clause is included in Waste Electrical and Electronic Equipment (Directive 2012/19/EU).

[210] UK MoD, Joint Service Publication (JSP) 418, leaflet 5, Management of Hazardous Substances and Restricted Materials, June 2016, Section 16. b. (page 4) and Section 31. (page 12) with footnote 8:."MOD Regulators may give specific mandates on the use of permissive disapplications or exemptions with particular emphasis on *essential interest* of Defence, national security or for specifically military equipment."

The only known alternative for **Halon 1301** as a fuel tank inerting gas is nitrogen. However, to reach the same level of protection a lot more nitrogen is needed. Since it is not generally possible to incorporate more bottles in the aircraft structure, aircraft should be fitted with an On-Board Inert Gas Generating System but these tend to be very costly and inefficient. For legacy aircraft this solution is not cost-effective so this essential use of Halon 1301 needs to continue for the protection of pilots.

Progressive halon phase-out is taking place step-by-step. First, after the ***"Cut-off date"*** under Regulation 744/2010 halons must not be used in the specified type of **new** equipment and new facilities. The Cut-off dates range from 31 December 2010 to 31 December 2018 for the listed applications. Second, there is an ***"End date"*** after which **all** use (including in existing systems) should also stop. The End dates range from 31 December 2013 to 31 December 2040. The deadlines are set by the EC to reflect the level of technical and economic challenge that halon replacement or conversion represents. More time has been given for applications without identified alternatives.

Compared to REACH authorisation this progressive phase-out system provides more flexibility and gives more time for the defence sector to undertake halon replacement as a part of planned equipment upgrade or refit programmes. However, ASD noted that this system only works for very niche or specialised chemicals, where there is a close communication and relationship between manufacturer and the Original Equipment Manufacturer (OEM). For more general commodities such as industrial chemicals it is hard to see how to implement or enforce such a system.

- **Cumulative regulatory impact on maintenance and refitting in long lifecycle naval systems**

Beyond the questionnaire further information was received from MS experts. The following cases reported are included to illustrate the issue of multiple involuntary substitution steps leading to increasingly poor technical performance characteristics and safety concerns for naval systems.

The total service life of naval systems can extend over 30-40 years with dry-docking intervals of ca. 5 years. While during the long service life the interior of the ships can be retrofitted with new technical solutions, for example for refrigeration and firefighting, the new solutions will need to conform to multiple design restrictions. There is limited space and there are efficiency and EHS requirements to be met. More generally, in order not to impact operational capability, there are limitations for the design of new equipment being fitted in an existing ship: mass, volume, electrical needs, thermic release, ageing speed of equipment and frequency of its replacement. The unintended effect of multiple retrofitting cycles under disparate and cumulative regulatory requirements over the service life of the ship is to reduce the choice of acceptable design solutions to near zero. At the point when acceptable design solutions have been exhausted each new regulatory design limitation will then negatively impact performance (including ship availability). Cumulatively the effect of new regulatory restrictions can be to make it unworkable to maintain the necessary ship building and maintenance service functions within the EEA.

As an example of multiple substitution steps in a rapidly changing regulatory environment, under the ODS there is an obligation to replace chlorofluorocarbon (**CFC**), hydrochlorofluorocarbon (**HCFC**) and **halons** (see above) with less ozone depleting substances since the year 2000. The industry solution for refrigeration was to substitute the regulated substances with hydrofluorocarbons (**HFC**) for refrigeration and as fire extinguishing agents. However, already in 2006 a new regulation F-GAS was adopted to regulate greenhouse gases. Among the regulated substances under this regulation are HFCs. The original F-GAS is being replaced by a new regulation adopted in 2014 which applies from start of the year 2015. This new F-GAS introduces a number of far-reaching changes with the aim to phase out HFCs in production and, from 2020, also in maintenance functions. As a result of this multi-

regulatory substitution pressure HCFs are now being replaced by hydrofluoroolefins (**HFO**). However, HFO does not have the technical performance characteristics to fit within the design margins, such as electric consumption or refrigeration power in terms of volume and mass or safety characteristics of the substances it is used as a substitute for. According to the expert comments from one MoD[211] this progressive substitution process due to increased regulatory substitution pressure has a major impact on naval systems. Each new alternative offers less efficiency, more bulkiness, and in some cases there seems to be a serious risk of fire in case of accident. This risk is not viewed as acceptable for certain kinds of ships. So today, even if the chemical and refrigeration industries have been looking for alternatives to HFC, none of them are sufficiently mature to cope with ship retrofitting design constraints contrary to what was said during the Kigali agreement (October, 2016) updating the Montreal protocol.

- **Substitution of antifouling and anticorrosion substances for war ships**

Another major issue impacting naval maintenance and the development of ships, especially of ship hulls and sea water circuits of naval ships, are regulations that limit the availability of antifouling and anticorrosion choices. Tributyltin (**TBT**) was banned in 2008 under the International Convention on the Control of Harmful Anti-fouling Systems on Ships. It has been mainly substituted by mixtures including copper (**Cu**) and cuprous oxide (**CuO**). Around 95% of antifouling coatings now contain Cu or CuO derivatives. Cu-based antifouling coatings generally also **require booster biocides** in order to be effective; biocides which themselves may present additional problems (for example organic algaecides such as Irgarol and Diuron with a wide spectrum of environmental effects[212]). The use of Cu is problematic particularly in closed seas and marinas such as the Baltic Sea or the San Diego Bay. Therefore, it is likely that Cu will also be impacted by regulations, for instance banned on the BPR list of antifouling paints category (Product-type 21) but at the same time the EU has approved Cu use in antifouling until 2026.

A second-generation substitute for TBT paints would be Full Release Coatings (**FRC**) solutions with a different approach to antifouling by letting the fouling take place to a point and then relying on the motion of the ship through water to wash-off biofouling when the ship reaches full speed or a threshold speed. However, this may not be good enough for war ships which spend around half of their service time docked in a harbour. These coatings also contain octamethylcyclotetrasiloxane (D4) soon to be regulated by POP and the Stockholm convention, which might impact D4 use in the manufacturing process unless it is proven that it is only used as a monomer in the production of silicone polymers and therefore exempted. There is no obvious solution in sight. The issue is being managed by reducing the Cu content and adding substances to compensate that are not regulated under the current regulatory regimes. That is why other antifouling strategies are under research and development efforts.

Another related problem is the biocidal treatment of **sea water circuits**. BPR also regulates the use of Cu in the water treatment solutions category (Product-type 11) but it is not known if Cu content will be further regulated and to what extent. All current solutions containing Cu present the same issue as with antifouling and anticorrosion use. Another approach would be electrochloration as a biocidal solution but it corrodes metals so needs to be used at low dosage reducing its effectiveness and releases have to be controlled and treated. There is research on alternative solutions without biocidal

[211] Input from one Member State does not necessarily mean that only one Member State is affected. This input may also be applicable to other Member States, however it was not possible to confirm this during the duration of the study due to lack of participation of industry or other government naval experts to the study.
[212] http://www.eea.europa.eu/publications/late-lessons-2/late-lessons-chapters/late-lessons-ii-chapter-12

products but there are also difficulties for example in treating the water with physical methods such as light or sound. These methods are not killing all bacteria and the resistant forms may then be released into the sea environment. It is then necessary to closely monitor biofilm growth but this may not be a sufficient solution to the problem.

A variety of approaches has also been contemplated for use in anti-corrosion and anti-dirt coatings. Here the issue is how to replace hard chromium which is regulated under REACH but there are substantial constraints to finding efficient solutions. Any substitutes will first need to be developed, qualified, registered and certified over an extended period of time for the particular uses while they may still be subject to a new harmonised classification or be prioritised for REACH Annex XIV. One possible option explored is nanocomposites but, under REACH, the status of nanoparticles is still somewhat uncertain and likely to be subject to further regulatory clarification in the next REACH review. There are also possible further limitations introduced under workplace exposure regulations for users of nanoparticles in the manufacture of products.

Finally, the hulls of naval ships are protected from corrosion with galvanic cathodic protection based on zinc. However, zinc may also be further regulated under REACH and other surveyed regulations.

It can be concluded that the impact of several regulations on the naval defence sector is cumulative. There is an intense effort (including for example the EDA coordinated ACWS and CCNS Projects, see outline in Annex E.1) to find suitable substitutes with minimal health and environmental impact profiles, but there are clear limitations and uncertainties in the process while the first generation and also second generation substitutes introduced may be subject to regulation themselves within only a few years (regrettable substitution). These problems are particularly affecting the long service life naval sector systems since it is increasingly hard for the naval experts to try to constantly find new technical solutions capable of delivering the required safety and performance in order to deal with new cumulative regulatory constraints becoming ever more restrictive over the long service life of the ship.

CONCLUSIONS

In addition to REACH and CLP, other EU regulations (e.g. BPR, ODS, POP) may each separately force substitution steps in rapid succession on military applications or upstream uses, leading to regrettable substitution and possible EU policy inconsistency, as some cases suggest. Furthermore, there is an inconsistent approach among the different EU regulations on how defence issues are handled (exemptions, exclusions, disapplications, etc.), which should be addressed in a forward-looking way as currently limitations on the use of one set of problematic substances often simply lead to a substantial increase in the use of another set of problematic substances. Overall, the stakeholder input on non-REACH related issues has been limited. However, it has been sufficient to show that there is a need for further clarification and work on overall regulatory consistency.

In relation to RoHS it is not clear today, whether its Article 2(4)(a) legally requires a MoD decision or whether MoD compliance demands with regard to RoHS are merely of voluntary nature.

8 SUMMARY OF FINDINGS OF THE IMPACT ASSESSMENT

The impact of the REACH Regulation on the European defence sector is fundamentally determined by its position within and at the end of **complex, international supply chains** – often shared with other sectors and involving many SMEs – that lead to the production of highly sophisticated defence systems (such as military aircraft, ships, tanks, munitions) and components.[213]

Generally, most defence sector stakeholders acknowledge the EU added value[214] of REACH and CLP as its complement. However, the impact assessment performed strongly suggests room for improvement with regard to regulatory effectiveness, efficiency and coherence and consistency.

More specifically, the analysis of the impact of REACH on the European defence sector, addressing also issues with CLP and other relevant EU chemicals regulations, has revealed a number of significant challenges and drawbacks (findings), which lead to some major risks perceived from an EU MoD perspective:

Impact on maintenance of cost effective military capabilities and operability of the Armed Forces

The cumulative impacts described create a significant risk to maintaining cost effective military capabilities. The increased through life cost is unavoidable. Defence exemptions will not guarantee the availability of chemicals necessary to maintain defence equipment. The import of chemicals and articles also poses a risk due to insecurities that a global supply chain may bring. As a result, some MoDs strongly believe that REACH may impact the actual operability of the Armed Forces.

More specifically, they see a strong risk of EU defence system development and maintenance becoming unsustainable because of the timeframe difference between REACH cycles and defence product lifecycles. Furthermore, reducing the European Defence Technological and Industrial Base (EDTIB) in favour of more imported equipment and maintenance outside of the EU to avoid REACH constraints could jeopardise independence and reliance on the EU economy as vital pillars of EU MoDs' defence strategies.

The detailed findings leading to these major risks perceived are summarised in Table 12 in the following order:

- General findings on REACH/CLP;
- Process/substance/domain-specific findings;
- Consequential/other findings (cost/benefit, future impacts, relocation risks).[215]
- Findings for other EU chemicals/product regulations impacting defence.

[213] See Section 3.2 for the list of REACH-relevant features of defence products.

[214] EC, Evaluation and Fitness Check (FC) Roadmap (18 May 2016), page 5.

[215] These findings generally support improvement proposals aiming at reduction of the administrative burden related to REACH implementation as well as the consistent and proportionate choice of regulatory Risk Management Options (see Chapter 9).

Table 12 Summary of findings of the impact assessment

GENERAL FINDINGS ON REACH
Finding 1 – Strong mismatch of timelines **There is a strong mismatch between the timelines of REACH authorisation (sunset dates of typically 3 years after Annex XIV inclusion and review periods for granted authorisations ranging from 4, 7 to 12 years) for Substances of Very High Concern (SVHCs) and the very long equipment lifecycles in the defence sector, which often requires the use of particular SVHC substances (up to several decades) for production and maintenance. This is causing defence companies, in some instances, to implement quick substitutes of mostly lower technical performance (short term substitution) to avoid the double resource-intensive effort of authorisation and replacement, dependence on a shrinking number of suppliers and uncertainties associated with the possible need for several authorisation renewals even if prospects to obtain authorisation may be good, if the argumentation is robust. This negatively affects the defence companies' competitiveness and innovation potential. – Section 3.2, 4.1.2.1, 4.1.2.2, 4.1.3, 4.2.3**
Finding 2 – Insufficient R&D funding for SVHC substitution **There is insufficient R&D funding for substitution at all levels: industry, Member States and EU. R&D policy makers at national (Member State, defence industry) or EU level often consider REACH related substitution as a regulatory cost issue and not as innovative R&D. At the same time there is a strong willingness, both within industry and MoDs, to perform substitution R&D in a collaborative approach, at least at low TRLs. Investing in substitution R&D is not generally seen as a competitive advantage by the industry (except perhaps for high TRL, quick replacements where finding a readily available alternative may confer an advantage), which is more concerned with ensuring long term commercial availability for the replacements. – Section 4.1.2.1 (for industry), Section 5.4 (for MoDs)** **A large majority of the defence industry (78.6%) have confirmed that substitution R&D activities have increased in their organisation or supply chain as a result of REACH. About half of *MoDs* surveyed (45.5%) are performing, financing or promoting R&D activities for SVHC substitution, including through the EDA and NATO. However, both defence industry and MoDs report that their budgets have not increased and that the R&D for substitution is performed to the detriment of other R&D activities. – Section 4.1.1 (for industry), Section 5.4 (for MoDs)**
Finding 3 – REACH obsolescence causes risks to Security of Supply (SoS) **Obsolescence / Security of Supply are a major concern for industry and MoDs, given the limited visibility towards chemicals and processes upstream in their very complex supply chains. Obsolescence from upstream suppliers has already resulted in significant product/process obsolescence within industry and MoDs. The issue is expected to worsen with REACH Registration in 2018 (1 - <100 tonnes/year) and the further evolution of Annex XIV. Supply chain communication to anticipate such risks is very challenging due to complexity, confidentiality and intellectual property considerations and differences in information quality. – Section 4.1.2.2, 4.1.3, 4.2.1, 4.2.4 (for industry), Section 5.2 (for MoDs), Annex H.6**

Finding 4 – Unpredictability of REACH SVHC regulation

The unpredictability surrounding the regulatory fate of SVHCs (i.e. whether, when and in which process(es) it will be further regulated under REACH) creates substantial uncertainties and risks for the defence industry and – as a consequence – the MoDs as the customer. The visibility of the authorisation listing process is not in line with the defence industries' development cycle; difficulties arise in anticipating what action will be taken against a substance and when. Substance-level tracking is, consequently, difficult. There is the further risk that one SVHC is substituted with an alternative substance which could transpire to be equally as harmful and subsequently be targeted by REACH during the long product service life ("regrettable substitution"). – Section 4.1.3, Annex H.3

Finding 5 – Possible EU policy conflicts with regard to REACH SVHC regulation

REACH impacts the military uses of many inorganic substances, including those linked to Critical Raw Materials which, according to the EC's related policy, are very hard to substitute (e.g. beryllium, borates, cobalt salts). New OELs under the EU workplace legislation (e.g. beryllium, hydrazine, refractory ceramic fibres) and Circular Economy are emerging as additional requirements, on top of existing ones (e.g. for lead and its compounds). The link between these EU laws and policies and REACH risk management options such as authorisation is not very clear today, leading to possible EU policy inconsistency. The case of chromates raises questions about the appropriateness of authorisation as a blanket risk management instrument for certain substances (like the aforementioned illustrative examples), which cannot be easily replaced; are broadly used in various sectors including high tech domains such as defence; and are also addressed by other EU policies – Chapter 6; Annex D, Annex N.3

Finding 6 – Are MoDs/Armed Forces addressees of REACH? – Legal uncertainty

It is not clear today whether government bodies/MoDs/Armed Forces may themselves have direct obligations according to REACH. According to a legal analysis by representatives of the German MoD this is not the case. However, some MoDs consulted have submitted pre-registrations and PPORD notification to ECHA. In one case defence exemptions have been granted to the benefit of national Armed Forces. With a view to the 2018 REACH registration deadline, and possible further Annex XIV inclusions, this legal uncertainty should be addressed. The EC has been asked for and is in the process of developing an official answer as an important first step. – Section 5.1; Annex I

Finding 7 – Collaboration within Member States on REACH/CLP may be enhanced

Based on the study consultation of MoDs and MSCAs there is generally a good level of collaboration with each other within the Member States. However, the limited awareness of most MSCAs consulted of defence sector specificities with regard to REACH/CLP as well as the expertise of some MoDs on substances, use needs and supply chain issues suggest that there is room for enhanced information exchange. The collaboration of MoDs with their National Enforcement Authorities has not been studied in detail. However, its benefit to better coordinate enforcement at the national level – where defence exemptions are granted – has been stressed. – Section 5.6

Finding 8 – Stakeholder calls for more EDA REACH/CLP support

Several MoDs and defence industry stakeholders have called for more EDA support on REACH/CLP or referred to the benefit of EDA's prior engagement (e.g. EDA/ECHA communication in 2015 has ensured decaBDE restriction tolerating use by civil aircraft has now been extended to military aircraft). Consultations with non-defence industry stakeholders also underlined the benefit of further clarifying the EDA's possible role with regard to REACH/CLP support in relation to the defence industry. – Annex H.10

PROCESS/SUBSTANCE/DOMAIN-SPECIFIC FINDINGS

Finding 9 – REACH Article 33 compliance challenges for complex defence equipment

According to the defence industry Article 33 compliance is very difficult for complex defence products. The efforts required to comply with it are considered by the defence industry as an excessive burden with regard to the added value to safe use of the article, especially by importers. It is feared that the situation will further deteriorate soon due to the "Complex Article" judgment of the CJEU and the updated ECHA Guidance for Articles. Different views persist about the minimum information to be provided, especially whether it should normally include the component article where the reportable SVHC is located (view of most MoDs). – Section 4.2.2.1, Annex N.5

Finding 10 – Military AfA not fully fit for purpose

Based on the defence industry survey and a dedicated analysis of AfAs by the Contractor the defence sector has already been strongly affected by the AfA process, e.g. phthalates, lead sulfochromate yellow, lead chromate and severely for Cr(VI) compounds. While the allowance of defence exemptions under REACH Article 2(3) is reserved for specific cases and does not cover civil applications of dual use substances, the AfA for military uses is often seen by defence industry stakeholders, but also some MoDs as customers and supporting the AfA, as disproportionate and not fully fit for purpose. Evidence of the large socio-economic benefit to European society and the control of the risks in using SVHC substances within the defence sector can be seen from past AfAs, in which military uses are identified; a simple average cost benefit analysis ratio for military specific or dual use, downstream user applications is approximately 1.77 million : 1. This raises questions of proportionality when having to go through such a burdensome process while the business case is generally clear, given the limited scope for substitution in defence equipment.

There is currently no dedicated defence sector-approach to authorisation. Non-air domains tend to be overlooked and a number of issues relating to military AfAs are unclear, such as the sufficiency of qualitative arguments (e.g. non-quantifiable impacts on the operational capabilities of the military and the ability to comply with international obligations as partner nations at EU level and wider field, e.g. with NATO) in lieu of economic quantification.

Authorisation costs, and through life maintenance activities using chemicals, are a particular concern, with the likely need for repeated renewals in high reliability sectors such as defence. Chemical supplier interest in supporting continued authorisation is also likely to diminish.

Decision uncertainty (review period/conditions) is a general concern, especially for upstream AfAs. However, generally, at the level of downstream user AfAs, ECHA considered that the

applicants have been able to make their case. – Section 4.2.3.1-4.2.3.4, Annex G.1-G.3

Finding 11 – Challenges for REACH defence exemption implementation across national borders

The so-called "defence exemption" in REACH Article 2(3) provides an important tool for EU Member States to mitigate negative impacts from the standard application of the REACH requirements in specific cases (only), in order to maintain a military capability. Most Member States consulted have set up a system for granting defence exemptions, but only 6 of the 27 EDA participating Member States, and Norway, are known to have granted defence exemptions to date. Based on national implementation of the EDA CoC 2015 by Member States, there is a gradual improvement in the overall harmonisation at European level with regard to defence exemptions. A major limitation of the REACH defence exemption is that it cannot cover the common civil applications of dual use substances. Also, national policies frequently foresee a conservative use of exemptions from health and environmental regulations.

Furthermore the REACH defence exemption process is often no option, or very difficult to manage, in cases in which defence industries in more than one Member State are involved in a transnational supply chain. This is especially true under the current, widely accepted restrictive (national only) interpretation of REACH Article 2(3). Given the challenges to apply REACH Article 2(3) across national borders, a clear majority of MoDs (73%) and defence industry (90%) responding would be in favour of an exclusion of defence from the REACH scope (fully or partly), whatever its form. – Section 3.3.3, Annex F

Finding 12 – Emerging security issues

It is not clear whether Article 2(3) may apply in the interest of Security. Several MoDs have raised this question. There is an increasingly blurred borderline between "defence" and "security" given the current global situation, especially with respect to newly emerging potential security (asymmetric) threats in the interior of the EU/Member States, to which MoDs may be called to play a supporting role at national level. – Section 3.3.2, Annex F.3

Finding 13 – Difficulties to establish general exemptions from authorisation

General exemptions from authorisation are often difficult to establish for the industry. Some key legal terms are undefined. Case-by-case clarifications are scattered in different places on the ECHA website. This may lead to needless spending of resources by having to take a conservative risk management approach. – Section 4.2.3.5, Annex G.4

Finding 14 – Cumulative impact for munitions

All defence domains; aerospace, munitions, land, naval, nuclear and electronics are heavily impacted by REACH, but domain-specific impacts may vary in subject. Munitions have a number of REACH & CLP issues. The REACH status of different ammunition types is difficult to determine (important for related obligations, e.g. registration by 31.5.2018). They contain a significant number of substances targeted by REACH, which are difficult to substitute. The CLP labelling requirements for military ammunition qualifying as explosive articles are difficult to apply and add little value (if any) to the trained user, as largely agreed by MoDs and industry. – Section 4.2.5, Chapter 6, Annex H.8, Annex K.2

CONSEQUENTIAL/OTHER FINDINGS

Finding 15 – Cumulative impacts of REACH and CLP processes on the defence sector

As an end user sector the defence industry is potentially affected by a high number of candidate list proposals. It "has all the issues" given also the plethora and sophistication of systems and components upon which defence relies, thus resulting in a multiplication of impacts. However, when comparing the different REACH processes, the largest impacts on the defence sector are caused by REACH authorisation (due to dependence on AfAs and resource-intensive substitution activities in parallel) and – for industry – REACH Article 33 compliance for very complex articles, while REACH registration is causing possible obsolescence and resulting in Security of Supply issues. Only the impact of REACH restrictions has been relatively limited and mostly indirect (commercial obsolescence, some issues for non-aerospace systems), because derogations are often foreseen for critical aerospace and defence applications (e.g. for cadmium and now also for decaBDE). – Section 3.2, Section 4.3, Section 5.7, Chapter 6

For CLP the labelling of ammunition (as "explosive articles"; currently no EU harmonised approach by EU MoDs) and the import of mixtures (lack of component info) have been identified as main issues. – Section 4.2.5

Finding 16 – High or hidden costs of REACH

Costs of REACH may be significant for both the defence industry and MoDs (as customer and end user), but could not always be quantified beyond direct compliance costs, due in part to the difficulties in determining indirect REACH related costs (e.g. price increases related to substitution and overall lifecycle cost; complexity of military procurement programmes; shorter maintenance intervals due to lower performing substitutes). Whether measurable or not, they are ultimately borne by the MoDs and, hence, the tax payer. Compliance costs for REACH (e.g. Article 33 and authorisation applications) are often considered as disproportionately high by industry when compared to the benefit. The largest cost occurs for SVHC substitution R&D and requalification tasks. Further cost analysis by industry and MoDs would be required for better quantification of the impact. – Section 4.1.2.3 and Annex H.7 (industry), Section 5.3 (MoDs)

Finding 17 – Limited health and environmental benefits of REACH to date

The better knowledge about chemical hazards, data quality and supply chain communication were frequently acknowledged. RMMs at the workplace have also improved as a result of REACH with a majority of MoDs, but less than half of the defence industry. However, this was explained by the fact that in a large number of cases the already existing strict national measures predating REACH, such as workplace safety laws, are considered as sufficient. The actual benefits to human health and the environment have been relatively limited, in cases when the use of substances is typically in low volumes and already well controlled and presents a low risk to users. It is largely felt by the defence industry that because of the RMMs already implemented, and monitored nationally, coupled with highly trained professional workers, these benefits are not commensurate with the efforts and costs. – Sections 3.2 ('safety relevant features') and 4.1.1 (for defence industry), Section 5.5 (for MoDs), Annex H.1

Finding 18 – Potential loss of competitiveness

There is an overall consensus from all surveyed defence stakeholders that REACH has not been

a driver for innovation to date due in part to timeline constraints resulting in quick substitution. Diminished innovative R&D could, therefore, potentially lead to a loss of future competitiveness. A large majority of the defence industry (70%) foresee a specific threat in this regard, while only 13% consider that REACH has already led to a gain on the company's global competitiveness. – Section 4.1.2. and 4.1.2.1, Annex H.2

Finding 19 – Future impacts expected to be significantly higher

Some MoDs and defence industry expect the future impact of REACH to be significantly higher than the impact that has been realised so far, particularly if REACH (and CLP) implementation continues as is. The main reasons given include: REACH Registration in 2018 for the 1 to <100 tonnage band, REACH Article 33 compliance, Cr(VI) authorisation decisions and sunset date in 2017, further additions to the candidate list and Annex XIV. The defence sector is already strongly impacted by the current authorisation list of only 31 SVHCs. The situation could become unmanageable if the addition of defence critical substances to Annex XIV would accelerate, causing a cumulative impact on the entire defence supply chain. – Chapters 4-6

Finding 20 – Relocation risks

REACH challenges the competitive position (level playing field) of EU defence companies in export markets and causes industry to consider relocation to avoid the REACH constraints for SVHCs used in article production and manufacturing processes. This is especially true for component suppliers (e.g. connectors) and surface treatment shops. Such relocation risks are seen as a major risk to SoS by most MoDs. This is because supply chains that reside outside the EU, resulting in the need for imports of products into the EU, are more difficult to control, manage and monitor (e.g. due to design restrictions as well as regulatory restrictions e.g. due to ITAR, if the production is moved to the US).

The reported impact for non-EU headquartered defence companies with operations in Europe is more or less similar to their EU competitors (see Annex C.1). However, the flexibility to move some hard-to-substitute processes or even the complete production out of the EU (e.g. to their home country) could be higher for non-EU companies. Some EU companies with operations outside EU may also have the option to relocate, but it is limited – for strategic and political reasons – to non-strategic components. – Annex L; Section 4.1.2.4.; Section 5.2

FINDINGS FOR OTHER EU CHEMICALS/PRODUCT REGULATIONS IMPACTING DEFENCE

Finding 21 – Inconsistent regulatory approach impacting defence

In addition to REACH and CLP, other EU regulations (e.g. BPR, ODS, POP) may each separately force substitution steps in rapid succession on military applications or upstream uses, leading to regrettable substitution – hence unnecessary cost and effort in wasted R&D activities – and possible EU policy inconsistency, as some cases suggest. Furthermore, there is an inconsistent approach among the different EU regulations on how defence issues are handled (exemptions, exclusions, disapplications, etc.). These should be addressed in a forward-looking way as currently limitations on the use of one set of problematic substances often simply lead to a substantial increase in the use of another set of problematic substances. Overall, the stakeholder input on non-REACH related issues has been limited, yet sufficient to show the need for further clarification and work on overall regulatory consistency. – Chapter 7, Annex M

In a nutshell, the key findings from the REACH & CLP impact analysis are given in Table 13.[216]

Table 13 Summary table of REACH & CLP impact analysis

Actor		Defence industry	MoDs/Armed Forces
	Main concern due to REACH	Competitiveness	Guarantee of military capabilities
General impacts	Protection of human health and the environment	Some improvements confirmed by a minority, in addition to strict pre-REACH measures	Some improvements confirmed by a majority, in addition to strict pre-REACH measures
	Innovation potential (i.e. better performance)	Negatively affected: timeline mismatch; lack of R&D funding for SVHC substitution	Possible future negative impact on capability due to less performing substitutes
	Costs	Actor-specific: often considered as disproportionate, especially for REACH Article 33, authorisation compliance and substitution R&D work; hidden costs (to be clarified)	Mainly as customer (final payer of REACH costs). Some MoDs do substitution funding; possible shorter maintenance intervals due to substitutes and hidden costs (to be clarified)
	Obsolescence/SoS	Major issue, especially with regard to registration (2018 deadline) and authorisation	
	Certainty and predictability	Major issue, especially for REACH SVHC regulation and authorisation. Possible EU policy conflicts, e.g. with EU Workplace Legislation, Critical Raw Materials Policy and Circular Economy	
Process-specific impacts	Registration	Mostly indirect (obsolescence); some own registration needs (e.g. for ammunition)	As final customer and capability guarantor (MoDs for their Armed Forces); to be clarified: Are MoDs/Armed Forces REACH addressees?
	REACH Article 33	Major issue for complex defence materiel, especially imports; impact of "Complex Article" judgment (CJEU, C-106/14)	
	Authorisation	Major issue, especially for long-term maintenance; process not fully fit for purpose (no dedicated defence sector approach)	
	Restrictions	Limited impact due to derogations	
	CLP	Main issues: Labelling of ammunition ("explosive articles"); mixtures import (lack of info)	As final customer and capability guarantor; currently no harmonised approach to CLP
Impact mitigation	REACH Article 2(3) ("defence exemption")	Overall limited experience (Note: exemption is applied by Member States in "specific cases" only, to maintain a military capability)	Increased impact for procedures and harmonisation work (EDA CoC 2015); to be clarified: Article 2(3) transnational use; Are MoDs/Armed Forces REACH addressees?
	Relocation	Limited possibility for EU headquartered companies (non-strategic activities)	As final customer and capability guarantor: reduced control over imported products

[216] Note: This table strictly reflects a summarised version of the impacts elaborated previously in Chapters 4-6, on the basis of stakeholder responses to the study survey. As such, any impact on MoDs/Armed Forces reflected does not in any way pre-empt the outcome of the examination of the issue "Are MoDs/Armed Forces addressees of REACH?" mentioned previously under Section 5.1, proposed to take place by EDA and Member States after the study is concluded, as described in Section 9.3.5.

9 PRACTICAL IMPROVEMENT PROPOSALS

The main objective of this study is to propose a way forward for the **REACH** Regulation to the European Commission, EU Member States MoDs and defence industry, aiming for a **win-win solution** achieving both goals as set out in **REACH Article 1(1)**:

1. to ensure a high level of protection of **human health** and the **environment**,
2. while enhancing **competitiveness** and **innovation**, here of the European defence industry.

As already pointed out in Chapter 1, it is important to see the study objectives in the light of the overarching goal to ensure the proper development of the European Defence Technological and Industrial Base (EDTIB) for the benefit of EU MoDs as EDA shareholders, as well as the preservation of capabilities, including sustainability of defence equipment maintenance processes performed by EU MoDs and related to equipment of EU or non-EU origin.

Therefore, this Chapter elaborates the practical proposals for improvements of the REACH and CLP Regulations and their current implementation regime, **based on the relevant findings** of the impact assessment (Chapter 8).[217]

OVERALL STRUCTURE OF IMPROVEMENT PROPOSALS

The proposals reflect a number of **general improvement objectives** that would contribute to a better REACH and associated EU regulatory and policy framework for defence (Table 14):

Table 14 General improvement objectives

Promotion of innovation for SVHC replacement	**Proportionality, with sector-tailored "fit-for-purpose" solutions**	**Best possible legal certainty and predictability**	**Coherence and consistency**
Transparency	**Collaboration**	**EU-level common approaches**	**Awareness of defence sector issues**

Based on these general objectives the key improvement proposals discussed in this Chapter may be broadly grouped into **three main improvement areas**:

- **More time and resources (Section 9.1)**
- **Consistency of REACH, other EU laws and policies (Section 9.2)**
- **EU-level solutions for defence under REACH (Section 9.3)**

These main improvement areas (even though not specifically regarding defence / one industry sector) are also broadly reflected in the discussions of the EU Member States, the EC and ECHA at the

[217] In addition, Annex N.8 contains a list of some other major stakeholder proposals made during the course of the study, where either the time constraints, study specifications and/or the gathered data from the impact assessment did not allow further debate with stakeholders and elaboration of formal improvement proposals.

policy conference *"REACH Forward"* (Brussels, 1 June 2016). It was noted[218] that the overarching goal of a non-toxic environment under the 7th Environment Action Programme could only be achieved by taking account of a broader context than just the REACH Regulation alone. The Occupational Health and Safety framework and the Circular Economy Package were highlighted. It was also considered important that the forthcoming REACH review 2017 seizes the opportunity to identify possibilities to enhance innovation and green growth; in this regard the need for active involvement of other policy fields, such as R&D and economic policy, was acknowledged. Furthermore the need for a reduction of administrative burdens, especially for SMEs, was recognised.

Table 15 below summarises - for each of the three main improvement areas - the key improvement proposals (together with the Section number where they are elaborated).

Table 15 Overview of key improvement proposals

Key Improvement proposals	**More time and resources**	• **R&D funding schemes for innovative substitution (9.1.1)** • **Collaborative R&T (9.1.2)** • **Prolonged Annex XIV timelines (9.1.3)**
	Consistency of REACH, other EU laws and policies	• **Risk Management Option Analysis (RMOA) guidelines (9.2.1)** • **Consistency of EU chemicals/product laws impacting defence (9.2.2)** • **Clarify REACH links with other EU laws and policies (9.2.3)**
	EU-level solutions for defence under REACH	• **Fit-for-purpose (F4P) military AfA (e.g. for long-term maintenance (9.3.1)** • **Simplified AfA: Specific cases (9.3.2)** • **REACH Art. 33 implementation: Common approach (9.3.3)** • **REACH Art. 33 revision (9.3.4)** • **EU-level clarification: Are MoDs/Armed Forces REACH addressees? (9.3.5)** • **REACH Art. 2(3) transnational use (9.3.6)** • **Stronger REACH/CLP role for EDA in defence matters (9.3.7)**

In addition to the key proposals listed above, other proposals for different addressees complete the picture. They are not necessarily less important but some of them – other than proposals to the EC and ECHA - may address issues of a more limited scope.

Other proposals are presented for:

- **EC, ECHA and MSCAs (Section 9.4)**
- **EU MoDs, EDA and defence industry (Section 9.5)**

[218] General Secretariat of the Council, Information Note for the Environment Council of 20 June 2016 (9 June 2016).

Finally, a proposal is introduced to

- **Address emerging issues of Security under REACH (Section 9.6)**.

A summary of improvement proposals including their **priority** in terms of expected impact (benefit for the EU defence sector) vs. implementation feasibility (difficulty) is given in Section 9.7.

Additional information / analysis on the proposals, which is not already part of the impact assessment, are included in Annex N.

DETAILED DISCUSSION OF EACH IMPROVEMENT PROPOSAL

The discussion of each improvement proposal in the following Sections contains its (1) full description with addressee, (2) rationale and (3) information about its implementation / feasibility issues.

Where several addressees are given, and one of them should take the lead for proposal implementation, this addressee is underlined.

Important Note: Proposals with an asterisk (*) are those for the EC REACH Review 2017, i.e. addressed to the EC, ECHA and/or the REACH MSCAs or necessitating their input for the proposal implementation.

To distinguish proposals that relate specifically to the defence sector, and non-defence "specific" (general) proposals that include defence but are also relevant for other sectors, the following colour scheme is applied in the proposal description (header):

Defence specific proposal	General proposal (including defence)

In the rationale of each proposal explicit **reference is made to the applicable Finding(s) in Chapter 8**, which contain further references to the applicable Section(s) and/or Annex(es) from which the findings are drawn.

For proposals dealing with **REACH process improvements**, the following types are distinguished based on the technical feasibility of their implementation, i.e. their difficulty to implement:

REACH process improvement - Difficulty to implement	**Easy** - Proposal could be implemented within existing processes
	Medium - Proposal for formalising existing but partially implemented processes / best practises
	Advanced - Proposal involving some rewriting of specific REACH annexes / implementing act (under EC remit, involving European Parliament and Council)
	Difficult - Proposal involving some rewriting of specific REACH articles (needs formal process of opening REACH text)

9.1 MORE TIME AND RESOURCES

The mismatch of timelines and insufficient R&D funding are key findings of this study. The defence sector, having products with long lifecycles, stringent performance standards and high reliability requirements, needs more time and resources for innovative SVHC substitution, ideally through an approach to "innovate first – regulate later".

Recital 12 of REACH supports that the Regulation should **"encourage"** substitution in the first place:

*"An important objective of the new system to be established by this Regulation is to **encourage and in certain cases to ensure** that substances of high concern are eventually replaced by less dangerous substances or technologies where suitable economically and technically viable alternatives are available."*

The objective of Authorisation is to *"ensure"* progressive substitution (REACH Article 55). But how is substitution *"encouraged"* in current REACH implementation? Improvements are recommended.

One means to encourage innovative substitution is to give more time for **voluntary** replacement or apply **less onerous RMOs** (such as tailored restrictions) first in order to manage imminent risks (see Section 9.2.1). A number of recent RMOA examples and significant statements in the REACH regulatory arena show that a **change of regulatory mindset** is happening after the initial automatism to use Annex XIV (see further information in Annex N.1).

This is also evident from the conclusions of the EU Member States, the EC and ECHA at the policy conference "REACH Forward", which highlighted: *"It was considered important that safe design of chemicals and products should become an integral part of EU innovation programmes and legislation. Incentives for substitution of chemicals should be embedded in innovation policies that support companies in their efforts to further a circular, green and low-carbon economy. Promoting greater awareness among the R&D communities about the challenges and opportunities created by REACH should help to **move from substance substitution to systemic innovation**."*[219]

Key improvement proposals that would further support such an approach to **"innovate first – regulate later"** are presented in this Section.

[219] General Secretariat of the Council, Information Note for the Environment Council of 20 June 2016 (9 June 2016).

9.1.1 R&D funding schemes for innovative substitution

R&D funding schemes for innovative substitution*	Addressee
Promote innovative substitution of SVHCs in defence applications through dedicated funding on **EU level**	EC
Promote innovative substitution of SVHCs in defence applications through dedicated funding on **national level**	MoDs

RATIONALE

Reference is made to Chapter 8, Finding 2 (Insufficient R&D funding for SVHC substitution).

59% of industry respondents are not aware of any public funding, national or EU, covering REACH related R&D but they unanimously (91%) support the idea that REACH related R&D should be part of EU funded R&D programmes. As it is also the case with MoDs (see Section 5.4), an overwhelming majority of companies responding would like to see more collaborative R&D/Substitution, preferably at European level with European funding if appropriate (see question 1.34 in Annex C). Performing internal R&D for substitution is not widely seen as a competitiveness-enhancing activity since developing new formulations is not a natural part of the defence industry activities.

The main thrust of this proposal is to encourage **medium/long term, low TRL, pro-active R&D leading to innovative substitution of SVHCs**. This R&D should take place at the European level within EU funded frameworks. It is also proposed that shorter term, high TRL R&T[220] for substitution is performed in a more collaborative approach at the European level. EDA could be a vehicle for this, with pooled funding coming from MoDs and possibly from industry (see Section 9.1.2).

This additional EU-level funding would thus have three important impacts:

- It would help preserve the competitiveness of industry since **less funding would be diverted from product improvement towards substitution**.
- It would enable collaboration which would result in substantial savings through **reduction of duplication**, which exists today since many companies are doing the same substitution R&D separately with internal funds.
- It would **help SMEs** which are considered very important in the defence innovation process, given their increased flexibility to exploit new technologies or combining existing ones.[221]

At the same time, potential EU funded defence-related R&D is not regarded as a future substitute to **national** R&D investments and activities which need to be continued and even enhanced.

PROPOSAL IMPLEMENTATION

As stated above, medium/long term, low TRL should be preferably channelled via the EU R&D programmes (like Horizon 2020 and the European Regional Development Fund – ERDF, within the European Structural and Investment Funds - ESIF). Shorter term, high TRL R&T is trickier to share since it may involve competition issues; however the less competitive part of the research could be coordinated via EDA (see Section 9.1.2). EDA involvement for this high TRL R&T could mirror ESA's

[220] In general, high TRL activities are difficult to promote via cooperation, compared to lower TRL.
[221] Me Frédéric MAURO, Professor Klaus THOMA, The future of EU defence research (March 2016), page 38.

role for the Space Sector where, for example, the evaluation of commercially available alternatives to chromium trioxide based surface treatment was performed in a cooperative approach by industry with part of the funding coming from ESA. As it is today, the EU channel is currently best suited to generic (i.e.: non-sector specific) R&D while EDA would be better suited for defence specific R&T. In both cases, an increased awareness of the need for REACH related substitution R&D from policy makers is certainly required. It seems odd that eliminating SVHCs being an important EU policy, the required R&D effort is not yet fully on the radar of EU funded R&D programmes.

A recent study[222] for the European Parliament recommends that: *"in anticipation of a full-fledged European Defence Research Programme (EDRP), the Commission should ensure that a relevant share of the Horizon 2020 programme is dedicated to test facilities and low Technology Readiness Levels (TRL) activities taking into account the specificities of defence constraints."* In this context REACH related substitution R&D should not be forgotten. Using a figure borrowed from the study,[223] REACH substitution R&D could be placed as follows:[224]

Figure 16 Possible EU level funding schemes for REACH substitution R&D

[222] Me Frédéric MAURO, Professor Klaus THOMA, The future of EU defence research (March 2016), page 9.

[223] See previous footnote, page 57. The bars for "European Regional Development Funds (ERDF)" and "REACH Substitution R&D" were added by the Contractor.

[224] Note: The sizes of the boxes / bars do not reflect the proportions of available funding.

9.1.2 Collaborative Research and Technology (R&T)

Collaborative Research and Technology (R&T)	Addressee
Promote innovative substitution of substances critical for defence which are impacted by REACH (SVHCs), through enhanced collaborative R&T projects under EDA CapTechs	EDA, with support from MoDs and defence industry (on expertise, funding), possibility of involvement of EU stakeholders (EC) for additional/or full funding project at EU level.

RATIONALE

Reference is made to Chapter 8, Finding 2 (Insufficient R&D funding for SVHC substitution) and Finding 3 (REACH obsolescence).

PROPOSAL IMPLEMENTATION

A number of substances or substances groups important for defence which are impacted by REACH have been highlighted in this study.[225] The **non-exhaustive illustrative examples listed in Table 9 (Chapter 6) may generally[226] be used as a starting point (only) for further review at EDA CapTechs level**, in accordance with their current REACH (Annex XIV listing) status and gathered information on ongoing activities for R&T/substitution either by MoDs or industry:

a) For those entries/substances where R&T/substitution activities are **ongoing**:[227] An **examination** at EDA level is recommended to gather more detailed[228] information on ongoing R&T activities, see if scattered R&T activities (in MoDs and industry) **can be joined** into EDA collaborative R&T projects, to increase efficiency, and if *additional* EDA R&T activities need to be initiated.

b) For those entries/substances where R&T/substitution activities are **not ongoing**: An **examination** at EDA level is recommended to see if and what EDA R&T activities need to be initiated.

c) For those entries/substances where R&T/substitution activities are **not known:**[229] An **examination** at EDA level is recommended to see if such activities currently exist or not, and depending on outcome to follow the proposed actions under a) (if activities finally exist) or b) (if activities finally do not exist) above.

Important note: Overall, the granularity required to decide which substances and uses to put forward for review by the CapTechs, and for which applications R&D is ongoing, is not available from the survey responses. Therefore the substance/use related information contained in this study report cannot be more than rough indicators, and a more detailed review by the EDA CapTechs would be required, in consultation with MoDs and defence industry.

[225] See especially Chapter 6 and Annex D.

[226] An exception would probably apply to petroleum substances (Annex D.19), because their treatment under REACH (including the identity of substances to be further analysed) is still too unclear, as well as to trichloroethylene (Annex D.3), because substitution appears to be already well advanced.

[227] It should be noted that the scope of ongoing R&T activities (substances and uses/applications covered) may differ.

[228] Further to potential information included in the study.

[229] I.e. related input was not provided by stakeholders during the study consultation.

9.1.3 Prolonged Annex XIV timelines

Prolonged Annex XIV timelines*	Addressee
Clarify prerequisites for military use specific sunset dates in Annex XIV based on REACH Article 58(1)(c) (*"production cycle specified for that use"*), especially whether it may apply to maintenance activities.	EC (with possible support of ECHA, MoDs and defence industry)

RATIONALE

Reference is made to Chapter 8, Finding 1 (Strong mismatch of timelines).

REACH Article 58(1)(c)(i) defines the **Annex XIV sunset date** as *"**the date(s)** from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted (hereinafter referred to as the sunset date) **which should take into account, where appropriate, the production cycle specified for that use**;"*

The Regulation is flexible in that it does not define a minimum timeframe between Annex XIV inclusion and sunset date.[230] Also, there may be more than one sunset date depending on the use.[231]

ECHA has been using a standard (first) latest application date of 18 months from the date of Annex XIV inclusion as well as a standard difference of 18 months between the application and sunset dates for its recommendations.[232] Hence, the recommended sunset date is **normally only 3 years** from the date of Annex XIV inclusion, while the substance may have been in use for a long time before and may still be required for decades rather than years ahead (e.g. hard chromium for some specific military applications; see more illustrative substance examples in Chapter 6 and Annex D).

Extended use-specific sunset dates are now proposed by the EC for the first time for the use of certain substances in the production of **legacy spare parts** and for repair **in order to avoid premature obsolescence** of articles and allow for the adoption of the rules on simplified authorisation.[233]

PROPOSAL IMPLEMENTATION

The proposed clarification can be provided by the EC, with possible support of ECHA, MoDs and defence industry (e.g. in relation to advice on production cycles). Sunset dates are defined in Annex XIV. Therefore the setting / change of sunset dates require a change of Annex XIV.

REACH process improvement - Difficulty to implement	**Easy** - Proposal could be implemented within existing processes

[230] Only the latest application date should be at least 18 months before the sunset date, REACH Article 58 (1) (c) (ii).
[231] The Regulation also allows to include in Annex XIV review periods for certain uses, if appropriate (REACH Art. 58(1)(d)). This possibility has not been used to date.
[232] ECHA, Preparation of Draft Annex XIV entries for substances recommended to be included in Annex XIV, General Approach (18 November 2015), page 4-5.
[233] See http://ec.europa.eu/growth/tools-databases/tbt/nview.cfm?p=EU_407_EN and also in Annex G.3.

9.2 CONSISTENCY OF REACH, OTHER EU LAWS AND POLICIES

It is important to see REACH and Risk Management Option Analysis (RMOA) in the context of other EU regulations and policies, in order for risk management approaches to be aligned and fitting in the global picture of the EU activities. To this end, a number of improvements are recommended in the interest of regulatory consistency, predictability and certainty.

9.2.1 Risk Management Option Analysis (RMOA) guidelines

Risk Management Option Analysis (RMOA) guidelines*	**Addressee**
Adopt EU-level guidelines for a Risk Management Option Analysis, especially regarding technical and socio-economic issues to be considered, stakeholder participation, RMOs/regulations, RMO selection criteria and deliverables, voluntary replacement and other "phased" approaches to enable fit-for-purpose REACH and related risk management. Enhanced assessment to conclude on candidate list for subsequent authorisation.	EC, together with ECHA, MSCAs, and other competent authorities (e.g. OSH) as appropriate; support by industry, e.g. Eurometaux, CII Initiative

RATIONALE

Reference is made to Chapter 8, including Finding 1 (Strong mismatch of timelines), Finding 3 (REACH obsolescence), Finding 4 (Unpredictability of REACH SVHC regulation) and Finding 5 (Possible EU policy conflicts with regard to REACH SVHC regulation).

Generally, the Risk Management Option Analysis (RMOA) approach is a very welcome development from a defence sector point of view. However, it has also brought to light new challenges, the major one being that there are **no EU-level common rules regarding the RMOA scope, process and criteria** (e.g. when to choose restriction or regard OSH legislation as sufficient). Essentially, an RMOA is seen by the authorities today as a voluntary[234] case-by-case exercise with varying information needs.

The development of a set of EU-level common rules for RMOA in the near future is seen as an important evolution of REACH helping to achieve all of its goals, for a number of significant reasons, which are elaborated in detail in Annex N.2. With regard to the defence sector in particular, the operational criticality of substances with SVHC properties and the shown tendency of short term substitutes in response to candidate list inclusion and authorisation (see Finding 1) highlight the need for a diligent and consistent choice of RMOs by ECHA and MSCAs.

PROPOSAL IMPLEMENTATION

The development of EU-harmonised guidelines for RMOAs would be done under the lead of the EC (*in continuation of the EC SVHC Roadmap to 2020*), in collaboration with ECHA, MSCAs and other competent authorities (e.g. OSH) as appropriate, and with the support of industry experts.

It is acknowledged that both development and application process for such harmonised RMOA guidelines will require resources and expertise. Therefore, a **collaborative approach** involving industry for additional information needs is important, while avoiding an information overflow.

[234] Because RMOA is not explicitly foreseen in the REACH legal text.

Harmonised RMOA guidelines should address the **purpose and scope, process and validity of RMOA**, as further detailed in Annex N.2. Importantly, the following contents should be covered in RMOA:

- **Confirmation of the risk(s) to be addressed and most relevant routes of exposure**;
- **Scoping and assessment of all available Risk Management Options (both REACH and non-REACH as well as voluntary measures) and defined criteria or indicators for their selection and cumulative/phased application**[235] - building on the EC SVHC Roadmap to 2020 - e.g. in which cases OSH legislation would be a sufficient risk management option and directions for different groups of substances (e.g. inorganic vs. organic substances);
- **The range of uses and industries impacted by the envisaged RMO** should **determine the depth of the RMO assessment and the documented RMOA conclusions**. **Therefore, an enhanced assessment to conclude on candidate list for subsequent authorisation is proposed** (see more details in Annex N.2 for the choice of candidate list and authorisation in particular).
- **Consistency with other EU laws and policies** (see Section 9.2.2 and 9.2.3).

Importantly, this approach is proposed to be applied also to those candidate list substances, for which no RMOA was performed prior to their inclusion at the beginning of authorisation implementation (**"post-candidate list inclusion RMOA"**), for example hydrazine and cadmium.[236]

A **web-based stakeholder consultation** - as already practised by some MSCAs today (see Annex N.2) - would be a recommended part of such a harmonised RMOA process.

An implementing act under REACH Article 132 or an explicit inclusion in the REACH legal text (should REACH be opened following the REACH review 2017) could also be considered for legal clarity reasons.[237]

REACH process improvement **- Difficulty to implement**	**Medium** - Proposal for formalising existing but partially implemented processes / best practises

[235] Some defined criteria where OSH legislation could be sufficient (as compared to REACH authorisation) were recently suggested by the REFIT Platform Government Group, see REFIT Platform Opinion on the submission by the Cross Industry Initiative on the interface between REACH and the EU Occupational Safety and Health (OSH) legislation (27/28 June 2016), page 6.

[236] One MoD made a comparable proposal for ECHA and industry to jointly undertake high quality risk assessments for all candidate list substances, see Annex N.2. More generally, several MoDs highlighted the need for a risk-based rather than a hazard-based approach to SVHC regulation under REACH.

[237] The voluntary nature of RMOA is sometimes used by REACH competent authorities to underline that this tool should not be too regulated.

9.2.2 Consistency of EU chemicals/product laws impacting defence

Consistency of EU chemicals/product laws impacting defence	Addressee
Consistent approach in EU legislation for chemicals and products (such as BPR, F-GAS, ODS, POP, RoHS) • to address defence specificities (exemptions/exclusions/etc.) • to avoid undesired regulatory outcomes impacting defence in multiregulation situations (e.g. regrettable substitution) *In-depth analysis of issues and recommendations for improvement*	EDA with MoDs, supported by defence industry and the EC *A dedicated study is proposed*
Specific issue: Work towards a common understanding regarding the prerequisites for the application of RoHS Article 2(4)(a)[238] 1) National examination and legal position (*MoDs to consult their legal teams*) 2) Further discussion in EDA framework with a view to reach a common understanding	1) MoDs 2) EDA with MoDs (supported by the EC)

RATIONALE

Reference is made to Chapter 8, Finding 21 (Inconsistent regulatory approach impacting defence).

PROPOSAL IMPLEMENTATION

Further analysis regarding these complex multiregulation issues is required, as suggested by the EC, to identify issues and provide recommendations for improvement of the situation. It is proposed that a dedicated study is launched to this end, which is supported by EDA and MoDs (working together in the REACH Task Force) and the EC similarly to the present REACH-centric analysis.

The study could serve as an important first step towards the definition of a more global, systematic strategy to ensure consistency of EU laws for chemicals and products impacting defence. Further key elements of such a strategy addressed to the regulators, which could be confirmed as part of the study, may include:

- **Prior impact analysis of possible consequences of substitution**: It appears important that regulators, with the support of expert stakeholders, are taking a more forward-looking approach and take into consideration the possible consequences of imposing substitution requirements, including further prior analysis of possible cumulative impacts with other regulations on maintenance of defence capabilities and regrettable substitution issues. One suitable point of entry for such analysis is the Risk Management Option Analysis for substances of concern (see Section 9.2.1).
- **Common system of regulations review**: As there is currently no periodic review comparable to "REACH review" under BPR, ODS and POP, a common system of review could be established also for these related regulations to keep better track of in many cases

[238] RoHS Article 2(4)(a) states: *"4. This Directive does not apply to: (a) equipment which is necessary for the protection of the essential interests of the security of Member States, including arms, munitions and war material intended for specifically military purposes;"*

unintended but highly detrimental cumulative effects of these regulations on the maintenance of long service life defence systems.

- **Harmonisation of defence-related provisions**: During any future regulatory harmonisation exercise focusing on these reviewed regulations to form a singular regulatory regime covering multiple related substance groups, the harmonisation exercise could also include the harmonisation of the current defence-related provisions to protect the interests of defence in a more uniform manner than today, as far as possible.

See also Annex N.7 regarding the stakeholder proposal of a full integration of EU chemicals legislation into REACH (REACH as a single “mother regulation”).

9.2.3 Clarify REACH links with other EU laws and policies

Clarify REACH links with other EU laws and policies*	Addressee
Clarify REACH links and relationship with key relevant EU policies, especially EU OSH legislation (OELs), CRM policy, Circular Economy	EC

RATIONALE

Reference is made to Chapter 8, including Finding 3 (REACH obsolescence), Finding 4 (Unpredictability of REACH SVHC regulation) and especially Finding 5 (Possible EU policy conflicts with regard to SVHC regulation).

Defence stakeholders' reports that the authorisation process may lead to regrettable substitution, R&D resources have also been diverted from other activities leading to capability enhancements, e.g. targeting noise and fuel burn reductions or reduction in greenhouse gases,[239] as well as the claim that the use of a given SVHC may have significant benefits in areas such as clean air, resource efficiency and circular economy.[240] This suggests that there are **potential conflicts of the REACH authorisation process with other EU policies.** Indeed, there is already a number of REACH provisions addressing its relationship with other pieces of EU legislation (see especially REACH Article 2). But recent developments under other EC policies have highlighted even more the need to **look beyond REACH** when conducting RMOA or promoting candidate list substances for Annex XIV. Topical examples[241] include:

- **EU OSH legislation**, with the introduction of new EU bOELs for a number of SVHCs;
- **Critical Raw Materials (CRM)** policy of the EC, with an increasing list of CRMs being identified;
- **Circular Economy Package** of the EC.

A more detailed discussion of the interface and potential conflicts of REACH and these three policies with a specific focus on defence sector issues can be found in Annex N.3.

PROPOSAL IMPLEMENTATION

It is recommended that the EC enhances its important work on clarifying REACH links and relationship with key relevant EU policies, especially EU OSH legislation (OELs), CRM policy and circular economy. The main issues to be clarified can be summarised as follows:

REACH vs. OSH legislation

- Definition of criteria under which EU OSH legislation can be sufficient, and promotion of the substance to Annex XIV may not be necessary, or an exemption under REACH Art. 58(2) viable.

REACH vs. CRM policy

- Examination of supply chain risks for defence-critical CRMs as a consequence of assumed REACH regulatory scenarios (such as Annex XIV inclusion).

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[239] See Section 4.1.2.1, info box "Consequences of re-prioritising R&D".

[240] See the example of nickel compounds in Chapter 6 and under https://nickelinstitute.org/~/media/Files/Sustainability/RMOAsSection/Economic%20and%20strategic%20importance%20of%20nickel%20compounds.ashx?la=en.

[241] Other examples were also mentioned during the study, such as the requirements for end of life vehicles.

REACH vs. Circular Economy

- Determine, how provisions / decisions under REACH (e.g. for RMOA) are to be interpreted / made in the light of the Circular Economy objectives, and how SVHCs are to be addressed in this context, especially if the use serves to ensure longevity of defence equipment and can be made safely (low risk), as is typically the case for defence equipment.

As far as the clarification is / will be achieved, it is important that it will be properly communicated to those experts in charge of relevant implementation processes (e.g. RMOA under REACH), and they will be enabled (e.g. through training) to apply the suggested principles.

REACH process improvement **- Difficulty to implement**	**Easy** - Proposal could be implemented within existing processes

9.3 EU-LEVEL SOLUTIONS FOR DEFENCE UNDER REACH

REACH calls for EU-level solutions to ensure efficient implementation and a level playing field for industry. The defence sector, like many other sectors today, is highly reliant on cross-border activities. The EDA CoC 2015 has been an important first step towards a harmonised approach to REACH implementation in this sector. The impact analysis has shown that further work is recommended to address key challenges for defence due to REACH – preferably on an EU level.

9.3.1 Fit-for-purpose (F4P) military AfA (e.g. for long-term maintenance)

Fit-for-purpose (F4P) military AfA (e.g. for long-term maintenance)*	**Addressee**
Discuss a fit-for-purpose application for authorisation (template / modules) for military uses, taking into account their frequent dual use nature and identifying special cases, e.g. maintenance and ammunition.	EDA with MoDs and defence industry, supported by ECHA, MSCAs and the EC (AfA Task Force)

RATIONALE

Reference is made to Chapter 8, including Finding 1 (Strong mismatch of timelines) and Finding 10 (Military AfA not fully fit for purpose).

The continued use of an Annex XIV substance ultimately ensures the reliability, quality, and longevity of important defence equipment. As a result, the defence sector supports simplification of the authorisation process. The pending EC rules for low volumes and legacy spare parts are generally welcome, but appear not sufficient to cover defence sector needs (for example maintenance is not covered and quantities used for defence may sometimes be as little as 100ml per year). Of the authorisation applications covering military uses presented in Annex G.1, only **16%** would have qualified for the proposed simplification process (based on the proposed 100kg tonnage threshold).

It is therefore proposed that a sector-level approach to REACH authorisation be put in place for defence, in order to streamline and simplify defence-specific AfAs - which may need to be renewed several times - and mitigate the "overshadowing risk" for defence applications as niche uses.

PROPOSAL IMPLEMENTATION

The key proposal is for defence industry and MS MoDs – and with EDA as facilitator – to elaborate an accepted application form to enable fit-for-purpose authorisation for military uses by industry and MoDs (if they consider themselves/their Armed Forces as "downstream user"), and have it reviewed by ECHA and other participants through the AfA Task Force (MSCAs, EC).

The template would not need to start from scratch, as relevant input documents are available:

- **EDA CoC 2015**;
- **ECHA-EASA paper 2014** on authorisation in the context of *aviation* industry;[242]
- **EC template(s) for simplified authorisation for low volumes and spare parts** (once available);
- **Previous defence-specific applications for authorisation** (see e.g. in Annex G.1).

[242] ECHA, EASA, An elaboration of key aspects of the authorisation process in the context of aviation industry (April 2014).

A simplification is proposed for all elements of the authorisation dossier, i.e. Chemical Safety Report (**CSR**), Analysis of Alternatives (**AoA**) and Socio-Economic Analysis (**SEA**). The development of tailored justifications for appropriate **review periods** (e.g. for long-term maintenance) should also be considered. Initial suggestions for the fit-for-purpose authorisation for military uses can be found in Annex N.4.

It may be that some/many of the arguments can already be made based on the existing ECHA guidance for authorisation applications. However, there is uncertainty what is acceptable and how/where the argument is made properly. A tailor-made template (or guidance) would greatly ease the authorisation process for the defence sector and enhance predictability.

The issue how to cover **dual use** should also be addressed. It is understood that civil applications should have a strong economic case for authorisation if the chemical processing of non-defence parts and defence parts is performed on the same factory line.

Such a simplification of the authorisation process would not necessarily require formal changes of REACH, and retain the safety review by ECHA and the EC. As long as a tailored form is not available, certain defence-specific elements mentioned in Annex N.4 are proposed to be clarified *ad hoc* by ECHA, e.g. in Questions & Answers (e.g. how to consider risks during substitution activities for ammunition/explosives).

REACH process improvement **- Difficulty to implement**	**Medium** - Proposal for formalising existing but partially implemented processes / best practises

9.3.2 Simplified AfA: Specific cases

Simplified AfA: Specific cases*	Addressee
Explore further specific cases for simplified application for authorisation	EC, with the support of ECHA and MSCAs (AfA Task Force)

RATIONALE

Reference is made to Chapter 8, including Finding 1 (Strong mismatch of timelines) and Finding 9 (Military AfA not fully fit for purpose).

Defence sector stakeholders support the EC initiative to streamline and simplify authorisation for "low volumes" and look forward to soonest adoption of the rules, in order to be effective for the next amendment of Annex XIV (expected in 2017). However, it was expressed both by MoDs and defence industry, that the volume threshold of 100kg may not be sufficient[243] given the volatile needs to maintain military capabilities, while the use-related risk is considered as low as explained in Sections 3.2 and 4.1.1. Also, **maintenance** does not fall under the envisaged "legacy spare parts" rule.[244]

PROPOSAL IMPLEMENTATION

It is understood that the EC, together with ECHA and the MSCAs, have been working on further specific cases for simplified authorisation in the REFIT framework (AfA Task Force). It is recommended that the work is extended to discuss further specific cases, for example if compliance with a binding EU-wide Occupational Exposure Limit can be demonstrated.

Title VII of REACH ("Authorisation") does not explicitly provide for the introduction of a simplified authorisation process in deviation from the general requirements via the annexes of REACH. For example, amending Annex XVI on Socio-Economic Analysis may be a possible avenue (via REACH Articles 62(5)(a), 131 and 133(4), "Committee procedure"[245]). If no solution via the REACH annexes nor Article 132 (implementing legislation to put the REACH provisions efficiently into effect, as done for the first time for the Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing) is possible and the simplified rules would deviate from the provisions in Title VII, a change of the REACH legal text (Title VII) could be required. A further analysis of the related implementation issues is not possible in the frame of this study and without the required definition of the specific cases.

REACH process improvement **- Difficulty to implement**	**Advanced** - Proposal involving some rewriting of specific REACH annexes / implementing act (under EC remit, involving European Parliament and Council)

[243] See also Section 9.3.1 above regarding the low percentage of AfAs analysed that meet the proposed 100kg threshold.
[244] Only "repair" is included, see Annex G.3, info box "Ongoing EC initiative for low volumes and legacy spare parts".
[245] here: "regulatory procedure with scrutiny".

9.3.3 REACH Art. 33 implementation: Common approach

REACH Art. 33 implementation: Common approach*	Addressee
(1) Legal clarification - following the O5A judgment of the CJEU of 10 September 2016 in case C-106/14: a. whether the component article in a (very) complex article (e.g. aircraft, tank, ship) containing the SVHC above 0.1% needs to be reported under Article 33 "by default", i.e. regardless of necessity for safe use ("localisation information"), or whether the provision of this localisation information is rather subject to information availability / the supplier's risk assessment (i.e. case by case). b. what are the boundaries of "safe use" communication in terms of Article 33, notably whether decommissioning of equipment and disposal activities are covered as well (given that REACH does not apply to waste).	EC
(2) After (1) is available: Work towards a common understanding of the MSCAs and ECHA on the localisation issue	EC, together with ECHA and MSCAs (CARACAL)
(3) Update ECHA Guidance for Articles in accordance with the legal clarification and common understanding reached. The guidance should also address the case of very complex articles, such as airplanes, ships or cars.	ECHA
(4) When (1)-(3) are achieved:[246] Work together towards the practical implementation of Article 33 communication, possibly through a sector-level approach, based on the latest ECHA Guidance for Articles and considering specific proposals made by some MoDs (e.g. ES, FR)	EDA with MoDs and defence industry

RATIONALE

Reference is made to Chapter 8, Finding 9 (REACH Article 33 compliance challenges).

It is considered very important to work on the clarification with regard to REACH Article 33 implementation, following the CJEU judgment of 10 September 2015 in case C-106/14 ("O5A").

The main open question is to what extent REACH Article 33 communication for (very) complex articles containing a candidate list substance above 0.1% should identify the component article(s) where it is present, regardless of the necessity for safe use ("localisation information").

Today, different views of defence industry and authorities persist on this important question, thus creating major uncertainties with regard to interpretation and implementation of REACH Article 33. A review of the different opinions and proposed solutions is included in Annex N.5.

Therefore, given that the key question of the localisation requirement is

[246] **Important Note**: **In case the final ECHA Guidance for Articles in response to the CJEU "Complex Article" judgment (adoption expected in the first half of 2017) should eventually satisfy the needs of MoDs and defence industry**, the work on a sector-level approach could start directly (i.e. without steps (1)-(3)).

- subject to differing MSCA (and MoD) opinions, which may lead to a continuation of different interpretations and enforcement actions across EU in relation to Article 33,[247] that led to the CJEU judgment - a situation which is not compatible with today's transnational/global supply chains, also for defence products;
- ECHA has not taken a clear stand in the draft Guidance for Articles for PEG;
- a question of legal interpretation of Article 33, taking into account the CJEU judgment;[248]
- of high importance to complex article producers in the defence industry (as well as in other high-tech sectors) and the proportionality of implementation of the provision;

a legal clarification by the EC is recommended, followed by the harmonisation of ECHA and MSCA positions and corresponding technical guidance, including the cases of very complex articles.

PROPOSAL IMPLEMENTATION

It is recommended that the EC's legal services provide a legal **clarification** on the questions of localisation requirement and of the boundaries Article 33 communication (see proposal description).

Following such clarification

- the EC would work in a second step towards a common understanding of the MSCAs and ECHA in relation to this question, e.g. in the frame of CARACAL (**harmonisation**).
- ECHA would update its **technical guidance** in accordance with the legal clarification and common understanding reached. The guidance should also **address** the case of **very complex articles**, such as airplanes, ships or cars.[249]

Only when such clarification, harmonisation and technical guidance development is achieved, it will be possible for MoDs and defence industry to work together – with EDA as a facilitator – towards the practical implementation of Article 33 communication within the boundaries set, possibly through a sector-level approach.

REACH process improvement **- Difficulty to implement**	**Medium** - Proposal for formalising existing but partially implemented processes / best practises

[247] As an example, the German MSCA BauA has already published an updated article guidance following the O5A ruling, while the update of the ECHA Guidance for Articles to align with the ruling is still ongoing.

[248] According to REACH Article 77(2) ECHA's tasks include *"(g) providing technical and scientific guidance and tools"* and *"(k) preparing explanatory information on this Regulation for other stakeholders".*

[249] In this context ECHA has stated during the study consultation that complex sector-specific examples would be more appropriate in **individual industry sectors' own guidelines**, which ECHA could potentially be involved in reviewing.

9.3.4 REACH Art. 33 revision

REACH Art. 33 revision*	Addressee
Should REACH be opened following the 2017 review: Revise Article 33 to address (very) complex articles, review its objective, usefulness (return of experience), requirements and feasibility	EC

RATIONALE

Reference is made to the proposal in Section 9.3.3 and Chapter 8, Finding 9 (REACH Article 33 compliance challenges). A revision of REACH Article 33 to address (very) complex articles would be the clearest way to achieve a **manageable** (supplier perspective) and **meaningful** (customer perspective) communication on SVHCs, which cannot be subject to major interpretation differences as is the case today (see Annex N.5).

The EC and ECHA have also recognised the persisting issues with REACH Article 33 implementation:

A recent study done for the EC[250] recommends that *"The treatment of **imported articles that contain SVHCs** under the Regulation should be reviewed.* […] *If appropriate, amendments should be made to the legislation."* ECHA considers that *"The current legal requirement for information on substances in articles is not working well enough. A **fundamental review of these obligations** would be helpful and could usefully form part of work on the circular economy and the drive towards a non-toxic environment."*[251] Indeed the EC is pursuing a dedicated action on **chemicals tracking in products** under the Circular Economy Package for 2017:[252] *"Analysis and policy options to address the interface between chemicals, products and waste legislation, including how to reduce the presence **and improve the tracking of chemicals of concern in products**"*. As a way forward in this regard the idea of an "EU product passport" building on SDS for substances and mixtures, Article 33 of REACH and voluntary tracking systems (for electric and electronic equipment and vehicles) was expressed.[253]

PROPOSAL IMPLEMENTATION

The amendment of REACH Article 33 would likely require a co-decision by the European Parliament and the Council of the European Union. Apart from addressing (very) complex articles, a legislative revision is proposed to include more generally a review of different objectives (safe use advice, anticipation of obsolescence, end of life objectives, etc.), usefulness (return of experience), requirements and feasibility of Article 33 (e.g. detection threshold instead of 0.1%?, how to show localisation for complex articles if required). The practical experience on the challenges gained so far by industry as well as input from MoDs would be very useful to find an appropriate solution.

REACH process improvement **- Difficulty to implement**	**Difficult** - Proposal involving some rewriting of specific REACH articles (needs formal process of opening REACH text)

[250] EC, Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs (December 2015), page viii.
[251] ECHA, Report on the Operation of REACH and CLP 2016 (May 2016), page 13, 18.
[252] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52015DC0614; last accessed: 11.12.2016.
[253] Bjørn HANSEN, Head of the Chemicals Unit, DG Environment, European Commission, Chemicals legislation and the circular economy, slide 12.

9.3.5 EU-level clarification: Are MoDs/Armed Forces REACH addressees?

EU-level clarification: Are MoDs/Armed Forces REACH addressees?*	Addressee
(1) Obtain EC legal view: Are MoDs/Armed Forces addressees of REACH?[254]	EC (with ECHA)
(2) After (1): National examination and legal position *MoDs to consult their legal teams.* Additionally, *if* REACH applies to MoDs/Armed Forces: Evaluate in relation to the EDA CoC 2015, whether the concept of sovereign state can be considered a sufficient reason for a MoD to decide to use defence exemptions for its own benefit and not consider authorisation	MoDs (with MSCAs)
(3) After (2): Further discussion on the overall picture, including on potential inconsistencies, as well as possible future harmonisation of MoDs legal positions	EDA with MoDs

RATIONALE

Reference is made to Chapter 8, Finding 6 (Are MoDs/Armed Forces addressees of REACH? – Legal uncertainty). Knowledge of the EC legal view as a first step is considered important. It may also impact related assessments for governmental bodies vs. REACH in general.

PROPOSAL IMPLEMENTATION

Reference is made to the proposal description. Eventually, a common understanding of the status of MoDs and Armed Forces under REACH is preferred. It could be achieved through discussions by MoDs in the EDA framework. Given the possibility of MoD REACH registrations for 2018 and the fact that defence exemptions to the benefit of MoDs/Armed Forces have already been filed or are under examination by some MoDs, the EC view is proposed to be provided as early as possible in 2017.

Note: *It should be made sure that the views are formed based on a full understanding of the different business cases at hand (e.g. how to treat the case that a substance or mixture is given by the MoD to private companies). The main business cases are introduced in Section 5.1 of this report.* ***For any further factual clarifications the EC is advised to turn to MoDs via the EDA.***

REACH process improvement **- Difficulty to implement**	**Easy** - Proposal could be implemented within existing processes

[254] Question asked to the EC as part of the study survey: *Would the Commission disagree that REACH lays down specific duties and obligations on the industry; however governmental bodies – in contrast to the industry – (e. g. national MoDs/Armed Forces) are not to be subsumed under the legal definitions of REACH Article 3, like* ***Importers/Downstream Users/Suppliers or Recipients of Articles/Substances/Mixtures,*** *when procuring, using or re-selling defence equipment or chemicals, and can merely be regarded as* ***end users (or even: "consumers")****?*

9.3.6 REACH Art. 2(3) transnational use

REACH Art. 2(3) transnational use	Addressee
(1) Legal clarification of REACH Article 2(3): Do exemptions *"from the REACH Regulation"* granted by individual MS *"in the interests of defence"* apply automatically in other EU Member States (thus rendering the need for reciprocal acknowledgment redundant)? (a) National examination and legal position *MoDs to consult their legal teams* (b) Discuss way forward in the EDA REACH Task Force, with a view to determine the feasibility of an EU-level common approach	(a) MoDs (with MSCAs) (b) EDA with MoDs, supported by the EC and the defence industry
(2) (Further) examine possibilities of a joint defence exemption process	EDA with MoDs, supported by the defence industry
(3) (Further) promote (reciprocal) acknowledgment / consideration of other EU MS defence interests in the procedure of each MS through enhanced information exchange on defence exemptions	EDA with MoDs
*Important note: These three separate tasks require a **clear identification and understanding of the different business cases**.*	

RATIONALE

Reference is made to Chapter 8, Finding 11 (REACH defence exemption implementation). REACH defence exemptions are granted by the EU MS. There is no EU-level harmonised approach of EU MS today, whether / under which conditions exemptions (from REACH) in the interests of defence granted by one MS are valid in other EU MS, thus posing specific challenges in transnational supply chains and EU multinational projects.

Overall, little is clear today as regards the transnational use of defence exemptions.

PROPOSAL IMPLEMENTATION

As described in the proposal, there are three proposed ways to clarify, or if necessary facilitate, the applicability of the exemptions from REACH in the interests of defence across EU-borders within the existing legal framework of REACH Article 2(3):

1) **Legal interpretation of REACH Article 2(3)**: Reference is made to Section 3.3.3 and one MoD's proposal elaborated there to re-examine whether the validity of "defence exemptions" granted by individual MS is indeed restricted to that MS, thus creating the possible need for acknowledgment in other EU Member States, or whether a "defence exemption" granted by one MS does apply abroad, i.e. in other EU Member States. It should be noted that this interpretation may[255] be connected to the sensitive **interpretation of *"interests of defence"*,** which is therefore proposed to be part of the national examination step. MS that have already

[255] Not however according to the MoD proposing this examination, see also Section 3.3.3.

completed this examination and/or have national legislation in place that clarifies the national position are invited to review it at their discretion.

Sometimes it is also not clear, whether an additional "defence exemption" or (reciprocal) acknowledgment is **at all required** (e.g. if there is no substance use in the MS to which the defence product is supplied, and hence, no REACH obligation to exempt from in that MS).

Therefore, a clear identification and understanding of the different business cases is critical.
In case the Member States would conclude on such a "pan-European" interpretation of REACH Article 2(3), changing their previous positions, the EDA CoC could be updated as seen fit by the MS MoDs to reflect this (see proposal "CoC evolutions" in Section 9.5.7).

2) **Joint exemption process**: For business cases involving the use of a given substance in several EU MS (e.g. where two or more MS buy the same equipment and/or surface treatment using an Annex XIV substance takes place at multiple sites, here the defence exemption would relate to REACH authorisation[256]) the idea of a "joint exemption" process has been contemplated by some MoDs. The defence exemption would relate to REACH authorisation. If feasible, it could save MS resources for multiple procedures. The EDA could be well placed to coordinate the process. It is proposed that interested MoDs will further discuss the possibilities of a joint defence exemption process via EDA as facilitator. If agreed, the EDA CoC could be updated to include such a process (see Section 9.5.7).

3) **(Reciprocal) Acknowledgment / consideration of other EU MS defence interests in the procedure of each MS**: Today, EU MS MoDs mostly state that they consider foreign defence exemption decisions, however, their own exemption decision will be based on a case-by-case assessment according to national procedure. Reciprocal acknowledgment of foreign defence exemptions and/or consideration of other EU MS defence interests in the procedure of each MS is proposed to be further promoted via the EDA, based on the information provided by the MSs, e.g. through sharing of more detailed information related to exemptions (e.g. requests, decisions), experiences and good practices; a database could be created to this end.

Overall, for the success of enabling transnational use of defence exemptions granted under REACH Article 2(3) **enhanced information exchange** between MS interested parties (MoDs and defence industry) is of paramount importance.

Furthermore, as mentioned above, a clear identification and understanding of the different **business cases** (some examples have been mentioned above) is required. This will serve to determine where

- a defence exemption granted by one MS can be valid or of benefit in another Member State, with or without the need for (reciprocal) acknowledgment; or
- a joint exemption process would be feasible and useful.

Further elaboration on the different business cases cannot be done within the scope of this study and needs to follow as part of the proposal implementation.

[256] Another possible area of joint application is the CLP defence exemption, where there is lack of information with regards to imported maintenance chemicals (mixtures).

9.3.7 Stronger REACH/CLP role for EDA in defence matters

Stronger REACH/CLP role for EDA in defence matters	Addressee
EDA to assume stronger role for EU-level REACH & CLP support in defence matters Tasks: • Follow relevant discussions at EU level (EC, ECHA, industry) • Interface/channel between ECHA and MoDs & industry for REACH issues related to defence • Participation in ECHA public consultations on REACH & CLP (based on MoD and/or defence industry input) • Advice to ECHA bodies on defence-specific issues • Raise awareness with stakeholders on REACH/CLP impacts on defence, including through participation in relevant events • Establish links with REACH functions in other European agencies • Report to CARACAL on behalf of MoDs on issues already agreed (e.g. CoC, results of the study) on the EC's invitation • Future technical support to Member States (not in current remit)	EDA with MoDs

RATIONALE

Reference is made to Chapter 8, including Finding 2 (Insufficient R&D funding for SVHC substitution), Finding 8 (Stakeholder calls for more EDA REACH/CLP support) and Finding 11 (REACH defence exemption implementation).

In his State of the Union 2016 speech[257] the President of the EC has reinforced his Commission's political intent for a stronger cooperation in defence matters on the EU level and move towards common military assets: *"The business case is clear. The lack of cooperation in defence matters costs Europe between €25 billion and €100 billion per year, depending on the areas concerned. […]"*

Background: EDA's role towards EU stakeholders on wider EU policies, such as REACH

As an **intergovernmental body**, EDA is working in support of its shareholders, i.e. the Member States.

The main aspects of the agency's role towards EU stakeholders (such as the European Commission or ECHA) on wider EU policies, such as REACH, are threefold:

- First, to **ensure that defence specificities are taken into account in wider EU policies**. Here the main objective is to prevent or at least minimise any negative impact on defence;
- The second aspect of EDA's role is to **explore how EU initiatives can benefit defence**, e.g. by facilitating access to EU funding instruments;

[257] Jean-Claude JUNCKER, President of the European Commission, State of the Union 2016 (14 September 2016).

- The third aspect is to **support Member States in complying with EU regulation**; but also, making sure that the Commission is aware about certain problems.

During the past years the EDA has worked successfully as an independent platform to the benefit of its MoD shareholders and the defence industry on REACH-related issues through among others:

- administration of the **EDA REACH Task Force**, with the EDA REACH portal and adoption of the EDA CoC on REACH defence exemptions in March 2015 as major milestones achieved;
- its **CapTechs'** R&D activities relevant for REACH SVHC substitution, chiefly through its CapTech *"Materials and Structures"*, which selected the *"REACH Compliant Materials"* as one of the relevant material categories for the R&D work of the group (see Section 5.4 and Annex E.1).

The study consultation of both *MoDs* and *industry* has shown that both would like to see a stronger role for the EDA, both for increased collaborative R&T in relation to SVHC substitution (see Section 9.1.2) and for technical REACH & CLP related support, in addition to administrative support functions.[258] Today, the EDA's **technical expertise on REACH is limited** due to the lack of human resources. Thus it relies mainly on expertise from MS MoDs, currently participating in the REACH Task Force. It would further increase the overall work efficiency if the EDA could support the REACH-related work also as a **technical expert**. Such expertise would also enable the EDA to establish closer links with other relevant stakeholders and communicate both ways between themselves, with the MoDs, and the defence industry. It would further help raise the needed awareness of defence sector issues with EU chemical regulations. A stronger role for EDA on EU regulations such as REACH and CLP avoids the multiplication of efforts at the national level and thus saves costs. It would thus benefit all stakeholders.

The study consultation of the EC, ECHA and the MSCAs has shown that **defence related issues have been typically a relatively minor topic during REACH-related discussions** (e.g. based on the views provided by industry). This appears to be in contradiction with the findings of this study, which suggests a strong impact of REACH on the EU defence sector. Therefore, enabling the EDA to assume a stronger role for REACH and CLP support could help raise EU MoD and general defence sector views and concerns on the EU level to the EC and ECHA, including during public consultations foreseen in REACH. The EDA's successful intervention in case of decaBDE[259] has shown the usefulness of channelling REACH-related issues at inter-Agency level to ECHA.

PROPOSAL IMPLEMENTATION

Enabling the EDA to assume a stronger role for EU-level REACH & CLP support requires corresponding funding commitments from the MoDs as EDA's shareholders. Suggested tasks are given in the proposal description.

[258] Regarding the possibility of functioning as an independent arbiter and verifier of claims made by industry, where needed by the ECHA Committees during the AfA opinion-making process (model discussed for EASA), see Annex N.4.
[259] See Annex F.3, info box "Omission of military aircraft in the restriction exemption proposal for decaBDE".

9.4 ADDITIONAL IMPROVEMENT PROPOSALS FOR THE EC, ECHA AND MSCAs

9.4.1 "Super" Downstream User (DU) platform

"Super" Downstream User (DU) platform*	Addressee
Establish a dedicated communication platform for "super" downstream users (such as the aerospace, defence and electronics industries) to discuss REACH, CLP and related regulatory issues, e.g. in the form of an annual stakeholders' day	EC with ECHA and MSCAs

RATIONALE

The list of findings (Chapter 8, e.g. Finding 15 (Cumulative impacts of REACH processes on the defence sector) shows the breadth and complexities of the regulatory impact of REACH, as well as other EU laws and policies, on the EU defence sector. The defence industry and MoDs as their customers are located at the end of long and complex international supply chains that are often shared with other high-tech sectors. The defence sector is thus typically far away from substance manufacturers and mixture formulators, but still strongly impacted by the use of substances in the components or manufacturing processes it is using, as an end user or "super" downstream user (DU). It would be mutually beneficial to discuss the related issues and possible solutions with ECHA, the EC and MSCAs on a dedicated communication platform for "super" DUs.

PROPOSAL IMPLEMENTATION

Because the scope of the issues extends beyond REACH (though it remains the main impacting piece of EU chemicals legislation for sectors like defence), it is proposed that the EC would be in the lead of establishing such a platform. An annual "super" downstream user stakeholders' day could for example be annexed to the CARACAL meetings of the EC, ECHA and MSCAs. However, non-REACH authorities (e.g. those responsible for OSH) would also be invited to contribute.

REACH process improvement **- Difficulty to implement**	**Easy** - Proposal could be implemented within existing processes

9.4.2 Substance tracking tool

Substance tracking tool*	Addressee
Provide a practical tool for industry to facilitate monitoring of substances in the "pipeline" for regulatory risk management under REACH and CLP *"from cradle to grave"* (e.g. from RMOA to Annex XIV), e.g. by providing a possibility to sign-up for substance-specific alerts	ECHA (with EC support)

RATIONALE

Reference is made to Chapter 8, Finding 4 (Unpredictability of REACH SVHC regulation) and Annex N.7 ("*ECHA webpage – rationale for a regulatory substance tracking tool")*.

A regulatory substance tracker, to which the user can sign-up, is proposed to highlight in particular:

- implications of the current process step (e.g. the meaning of inclusion in the candidate list);
- substances which will not be promoted to a given list in the foreseeable future - unless new information comes to the light - and why (e.g. no Annex XIV inclusion of a candidate list substance for the time being because restriction route has been taken).[260]

Overall, it is expected that the provision of such a tool for a substance-specific regulation will be a natural evolution of REACH and its implementation would only be a question of time.

PROPOSAL IMPLEMENTATION

The development of a substance- and process-specific tracking tool is expected to be resource-intensive and requires multi-disciplinary competence (mainly IT and regulatory). It would be driven by ECHA, but rely on the strong support from the EC. On the other hand, the benefits for industry and SMEs in particular are expected to be high. Questions and misunderstandings about the regulatory status of a substance will also be reduced, which will benefit ECHA, who is understood to be often confronted with related issues. The "pipeline" to Annex XIV could be an important pilot case.

REACH process improvement **- Difficulty to implement**	**Easy** - Proposal could be implemented within existing processes

See also Annex N.8 regarding the wider idea of a tool covering all EU substance regulations.

[260] In this respect ECHA itself has also recommended to the EC to provide further transparency: ECHA, Report on the Operation of REACH and CLP 2016 (May 2016), page 17, Recommendation R30: *"The Commission is invited to provide further transparency on the follow up of those substances recommended by ECHA for inclusion in the Authorisation List, but not finally included."*

9.4.3 EC REACH/CLP single web hub

EC REACH/CLP single web hub*	Addressee
A single webpage ("hub") and regular newsletter for easy access by industry to Commission activities on REACH and CLP, especially information on • REACH Committee and CARACAL meetings • (Draft / final) amendments of REACH (e.g. Annex XIV and XVII) • List of REACH authorisation decisions • Explanation of procedural steps for different REACH decisions	EC (ECHA to provide an easily accessible link to such page)

RATIONALE

Reference is made to Chapter 8, Finding 4 (Unpredictability of REACH SVHC regulation) and Annex N.7 (*"EC webpages"*).

PROPOSAL IMPLEMENTATION

As outlined in the description of proposal. Resources required depend on the level of information provided on the webpage. It could be fairly simple by providing short descriptions with links for further information, including how to obtain automatic notifications about certain activities (e.g. for CARACAL meetings documents). The webpage could be combined with a regular newsletter, which informs in a nutshell about the key evolutions.

ECHA on its webpage would provide an easily accessible link to such a Commission page.

REACH process improvement **- Difficulty to implement**	**Easy** - Proposal could be implemented within existing processes

9.4.4 Authorisation exemption guidance

Authorisation exemption guidance*	**Addressee**
Guidance / practical guide on exemptions from authorisation	ECHA (with EC support)

RATIONALE

Reference is made to Chapter 8, Finding 13 (Difficulties to establish general exemptions from authorisation). There is still a lot of confusion within the industry today about the prerequisites of exemptions, e.g. whether they may / have to be included in Annex XIV or what industry should do to confirm their applicability. It would be very helpful for industry to have easy access to a single ECHA document that clarifies (available) exemptions from authorisation, their boundaries and what industry needs to do to use them.

PROPOSAL IMPLEMENTATION

The ECHA document can be a guidance[261] or practical guide. Since it would only collect and present available interpretations (including also for REACH Articles 2(3) with reference to the EDA CoC and REACH 58(2) prerequisites) in a structured way and provide general advice to industry about the different types of clauses and what needs to be done to apply them, the overall administrative effort does not seem to be significant, while there would be a strong benefit of transparency for industry, and in particular for SMEs.

REACH process improvement **- Difficulty to implement**	**Easy** - Proposal could be implemented within existing processes

[261] For exemptions from registration according to REACH Art. 2(7)(b) there is already a Guidance for Annex V.

9.5 ADDITIONAL IMPROVEMENT PROPOSALS FOR EU MODS, EDA AND DEFENCE INDUSTRY

The present Section provides additional improvement proposals to EU defence sector stakeholders, i.e. EU MoDs, EDA and the defence industry.

9.5.1 Transparency of REACH Art. 2(3) procedures and decisions

Transparency of REACH Art. 2(3) procedures and decisions	Addressee
Publish national defence exemption application forms (in English) on the EDA REACH Portal (if necessary with limited access)	EDA with support of MoDs (provide translated forms)
Categorise REACH (and possibly CLP) defence exemptions (esp. exempted REACH requirement and the underlying business case)	EDA with support of MoDs and the EC
Complete information on defence exemption procedures for remaining MoDs on the EDA REACH Portal	EDA with support of MoDs (provide MS information)

RATIONALE

Reference is made to Chapter 8, Finding 11 (REACH defence exemption implementation).

The information on the EDA REACH Portal (https://reach.eda.europa.eu/home) gives a structured and useful overview of the questions around the REACH defence exemption, the EDA Code of Conduct 2015 and information on national defence exemption procedures.

In the study consultation some suggestions were made by stakeholders, which could further enhance transparency, and indirectly also reciprocal acknowledgment of defence exemptions. The categorisation of REACH (and possibly CLP[262]) defence exemptions (e.g. based on the exempted requirement and the underlying business case) would also improve the comparability of national defence exemptions.

PROPOSAL IMPLEMENTATION

As given in the description of proposal. The EDA is in the driving seat for all proposed tasks, relying however on the technical input from the MoDs.

[262] CLP is not part of the EDA CoC 2015 at present.

9.5.2 Collaboration within Member States on REACH/CLP defence matters

Collaboration within Member States on REACH/CLP defence matters	Addressee
Strengthen collaboration among Member State administrations on defence and REACH/CLP	MoDs with their MSCAs MoDs with their NEAs

RATIONALE

Reference is made to Chapter 8, Finding 7 (Collaboration within Member States on REACH/CLP).

Collaboration between Member State administrations is particularly important in the area of defence because of the concurring REACH responsibilities of MoDs (defence exemptions), MSCAs (general REACH) and National Enforcement Authorities (NEAs).[263]

- **MoD-NEAs**: NEAs should be aware of defence exemptions granted to a company in their area of jurisdiction, and have more details about its scope, especially the exempted REACH requirement and validity.
- **MoD-MSCAs**: Overall, MoDs and MSCAs consulted have already reported a good level of collaboration with each other within the Member States. In some cases MSCAs have responsibilities in the **defence exemption** procedure, and related EU-level discussions may take place in CARACAL. It is advised that such discussions are coordinated with the MoD. Beyond the defence exemption process, MoDs may also discuss with their MSCAs before or during the **policy making process on RMOA, Annex XV proposals and discussion relating to amendments of the candidate list, Annex XIV and Annex XVII**. The study has shown that a number of MoDs have significant expertise on substances, use needs and supply chain issues. This MoD expertise can be very beneficial for their MSCAs when considering regulatory action for specific substances. Generally, it is advised that there is a clear division of REACH-related tasks between the MoD and MSCAs in defence matters and coordination as regards EU-level activities.

PROPOSAL IMPLEMENTATION

It is proposed that MoDs assess whether and how the information exchange and collaboration with their MSCAs and NEAs can be strengthened, in order to ensure full awareness of defence exemptions (NEAs), coordination / division of REACH-related tasks on defence matters and appropriate regulatory action for substances of concern (MSCAs). This may be realised for example through

- regular information to REACH enforcement authorities on exemptions provided by MoD, unless there are grounds for the MoD to not disclose this information;
- regular meetings with MSCAs and MoDs to discuss REACH and CLP defence-related issues.

[263] See Annex P for Definitions of Member State Competent Authority and National Enforcement Authority.

9.5.3 Align procurement contract terms with REACH

Align procurement contract terms with REACH	Addressee
Standardise defence procurement contract terms around appropriate EU MoD and supply chain best practices and return of experience to align with REACH	MoDs, with the support of EDA and the defence industry (as required)

RATIONALE

This issue has been raised after completion of the study consultation. It is therefore not related to a specific finding in Chapter 8.

The defence industry has expressed concerns regarding the wording of some contract clauses in defence procurement contracts. Such clauses are sometimes not aligned with REACH terminology[264] and provisions regarding the communication of information in the supply chain.[265] For example, they may refer to "hazardous materials", "goods" or "products" when requiring the delivery of safety data sheets (which are only required under REACH Article 31 for hazardous "substances" and "mixtures" in the sense of REACH, but not for "articles" which are subject to REACH Article 33 in relation to candidate list substances).

This leads to confusion with defence contractors on what documentation / information is required.

PROPOSAL IMPLEMENTATION

Clauses addressing compliance with "environmental" legislation, such as REACH, should be aligned with the corresponding legal terminology and provisions. Standardisation of relevant contract terms around appropriate EU MoD and supply chain best practices and return of experience would be mutually beneficial, and perhaps this could be achieved through the applicable working groups of EDA (REACH Task Force) and ASD.

It is proposed that MoDs when implementing this proposal, include a review of national procurement clauses for commercial contracts (e.g. DefCon 0068 (for UK) was mentioned), clauses embedded in LoR requests to the US Government for FMS agreements (considering also US DSCA Policy 15-19), procurement clauses of international organisations that Member States have established e.g. OCCAR/OMP6, as well as clauses/requirements used by MoDs when submitting requests for procurements through other international organisations, such as the NSPA.

[264] Mainly REACH Article 3(1)-(3) defining "substance", "mixture" and "article".
[265] Mainly REACH Articles 31-33.

9.5.4 REACH cost analysis

REACH cost analysis	Addressee
(1) Implement internal mechanisms to track REACH-related costs	MoDs, defence industry
(2) (After 2018): Analyse economic impact of REACH on EU MoDs and defence industry	EDA with the support of MoDs and defence industry

RATIONALE

Reference is made to Chapter 8, Finding 16 (High or hidden costs of REACH).

PROPOSAL IMPLEMENTATION

A two-step approach is recommended, as outlined in the description of the proposal.

A further study on the economic impact does not appear reasonable, until major timelines have passed such as the upcoming 2018 registration deadline. Sufficient time should be given for such a study and the related consultation (e.g. one year project time at minimum), in order for the consultees to get the required data from their company organisation and supply chain.

It is important that this study would extend beyond direct costs for REACH compliance to include also indirect costs (see also Annex H.7).

9.5.5 Ammunition REACH status

Ammunition REACH status	Addressee
Finalise ongoing work titled "Ammunition Classification" on the clarification of REACH status of ammunition types (article / mixture / substance or combinations) as soon as possible in 2017 (with a view to REACH Registration by 2018)	EDA with MoDs, with the support of the EC, ECHA and the defence industry

RATIONALE

Reference is made to Chapter 8, Finding 14 (Cumulative impact for munitions)) and to Annex H.8.

PROPOSAL IMPLEMENTATION

Through the conclusion of the ongoing work as soon as possible in 2017, given the possible necessity of REACH registrations by 2018.

9.5.6 Ammunition CLP labelling

Ammunition CLP labelling	Addressee
(1) National examination and position on the approach to ammunition labelling under CLP - *MoDs to consult their legal teams*	MoDs (with MSCAs)
(2) After (1): Further discussion on the overall picture, including on potential inconsistencies, aiming at a common understanding of MoDs on how to apply CLP to ammunition (or use of CLP defence exemption)	EDA with MoDs, supported by the EC
References: *ASD paper on CLP and ammunition of 9 May 2016, list of suggestions A) - F) on page 3); available positions of EC, UK MSCA, DE, FR and SE MoD provided during the study*	

RATIONALE

Reference is made to Chapter 8, Finding 14 (Cumulative impact for munitions) and Finding 15 (Cumulative impacts of REACH and CLP processes on the defence sector). ASD has proposed EDA and MoDs to act on the issue of CLP labelling of military ammunition to the effect of achieving a **common understanding of EU MoDs on how to apply CLP to ammunition**.[266]

PROPOSAL IMPLEMENTATION

Already available EC, MSCA and MoD opinions can be found in Annex K.2. If CLP defence exemption is agreed to be the right way forward, discussions on the extension of the EDA CoC could take place (see Section 9.5.7). In the longer term[267] a dedicated action on ammunition safety could be considered, as supported by several MoDs (see Annex N.6).

[266] See ASD paper on CLP and ammunition of 9 May 2016, list of suggestions A) - F) on page 3.

[267] The CLP defence exemption was rather not foreseen to be used to exempt from a requirement that does not add value in the first place.

9.5.7 EDA Code of Conduct (CoC) evolutions

EDA Code of Conduct (CoC) evolutions	Addressee
Discuss REACH/CLP update needs for EDA CoC 2015 • EU-transnational use of REACH defence exemptions • Addition of CLP: common business cases (e.g. labelling of ammunition/military explosives, lack of information for imported maintenance formulations) • Joint exemption process (for REACH, CLP) • *If* REACH applies to MoDs/Armed Forces: Evaluate whether the concept of sovereign state be considered a sufficient reason for a MoD to decide to use defence exemptions for its own benefit and not apply for authorisation	EDA with MoDs, supported by the EC
Review and analyse Member States approaches for the national implementation of the EDA CoC 2015, including in cases where same substances have been examined previously by more than one Member State, in order to identify best practices and lessons learned, to be shared with all Member States	EDA with MoDs

RATIONALE

Reference is made to Chapter 8, Finding 11 (REACH defence exemption implementation).

The proposal is made to (further) strengthen the EU-level harmonisation of REACH / CLP defence in the interest of a level playing field for EU defence industry and a better effectiveness and efficiency of defence exemptions in transnational scenarios.

PROPOSAL IMPLEMENTATION

The implementation may depend on the outcome (discussions, clarifications, etc.) under other study proposals (see Sections 9.3.5, 9.3.6, 9.5.6).

9.5.8 Exclusion for defence

Exclusion for defence	Addressee
(1) National examination of the necessity to include an exclusion (from the REACH Regulation) for defence – whatever its form – in the legal text, should REACH be opened following the 2017 review *Consider coverage of dual use cases and Security interests.*	MoDs, in consultation with MSCAs and their national defence industries
(2) If national review is completed and a wide number of Member States support further examination: Further discussion of such an exclusion in the EDA framework	EDA with MoDs
(3) If based on this examination all stakeholders agree that there are strong arguments: Pass on this proposal to the EC for possible action	EDA

RATIONALE

Reference is made to Chapter 8, Finding 11 (REACH defence exemption implementation). An exclusion for defence (not requiring MS approval on a case-by-case basis) is supported by a clear majority of MoDs and defence industry consulted. However, the proposal, including all related factors, need to be thoroughly examined first before proceeding in raising the issue to the EC; the proposal in Section 9.3.6 (REACH Article 2(3) transnational use) also serves this purpose.

PROPOSAL IMPLEMENTATION

Following national examination, further discussion of such an exclusion and its scope can be carried out within the EDA framework, with the support of the EDA REACH Task Force. As part of it, it could also be examined if it is not possible to include exempted uses covering defence activities (among others) into Annex XIV. A sufficient legal basis in REACH allowing this may be that existing EU OSH legislation could qualify as "specific Community legislation" in the sense of REACH Article 58(2)[268] (see also related proposal under Section 9.2.3).

If eventually considered necessary by all defence stakeholders involved, the implementation of an exclusion for military uses across different substances, which does not require national case-by-case exemptions, may require a change of the REACH text amending REACH Article 2(3),[269] and hence a co-decision by the European Parliament and the Council of the European Union. Such an exclusion could be limited, if appropriate, to the authorisation process (Annex XIV substances) or be subject to a time limit / review period to encourage substitution.

REACH process improvement **- Difficulty to implement**	**Difficult** – Proposal involving some rewriting of specific REACH articles (needs formal process of opening REACH text)

[268] Exemptions in Annex XIV may be based only on REACH Article 58(2) ("existing specific Union legislation") and PPORD.

[269] To highlight the relationship with an exclusion. It was also proposed during the study by one MoD to clarify the wording of REACH Article 2(3) with regard to the "interests of defence", see Annex N.8.

9.6 ADDRESS SECURITY: FOR AUTHORITIES IN CHARGE OF INTERNAL AFFAIRS

Address Security*	**Addressee**
Consider national security issues vs. REACH – Discuss the way forward in the Member States (including with MoDs)	Member State authorities for internal affairs / DG Home

RATIONALE

Reference is made to Chapter 8, Finding 12 (Emerging security issues).

Potential issues (such as the ones mentioned in this study) relate purely to the issue of security aspects for which at the same time defence considerations have already been adequately covered in REACH (under Article 2(3)). Therefore the responsibility to address the issue would be with stakeholders dealing with internal security matters. It is recommended that the issue of national security vs. REACH is further investigated by the competent authorities, in particular whether the REACH defence exemption may apply. Otherwise there may be an additional exemption need.

PROPOSAL IMPLEMENTATION

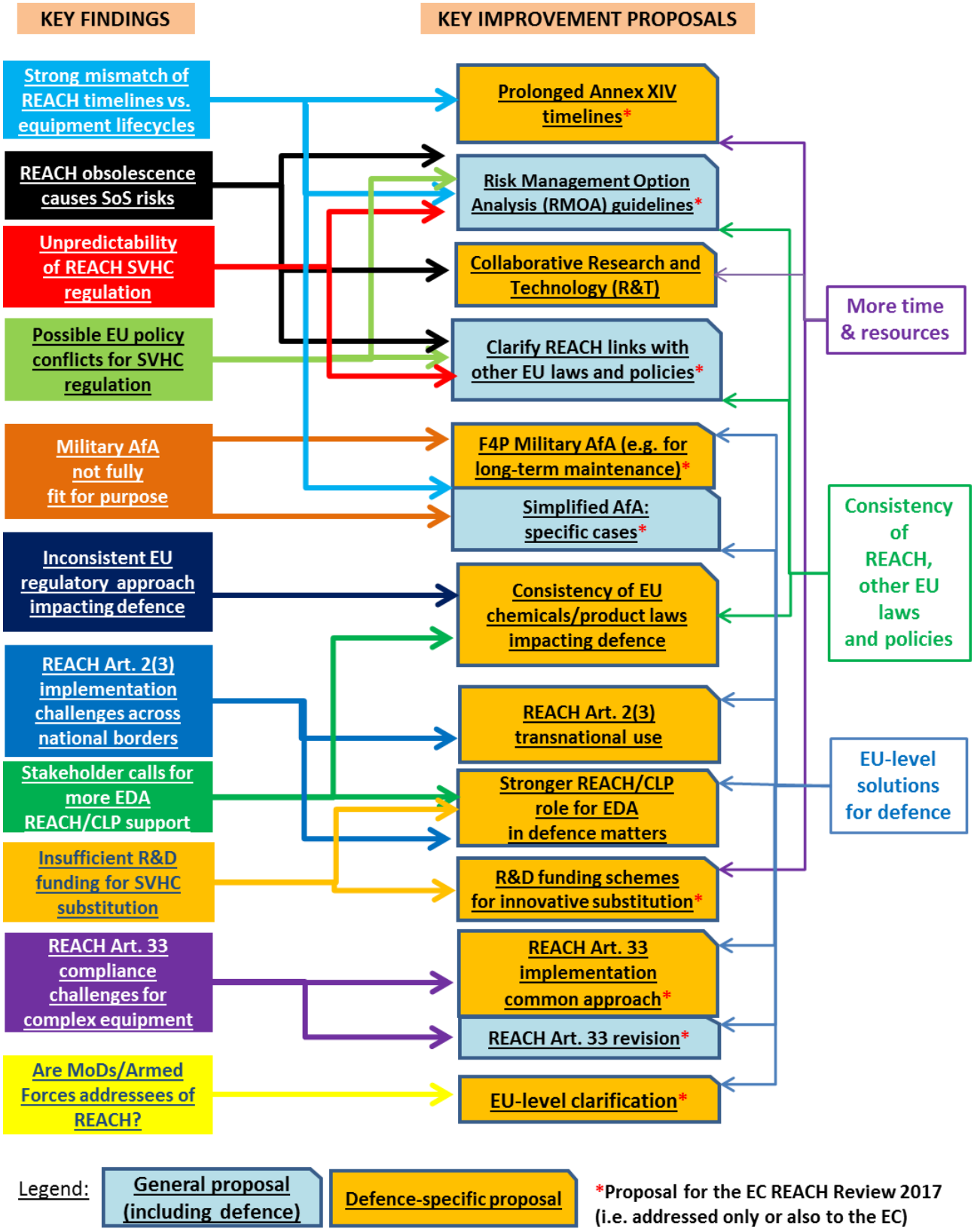
The issue of national security vs. REACH and the way forward is proposed to be discussed by the MS Authorities for internal affairs and DG Home. To this end, relevant participants in this study and supporting this proposal will inform their counterparts (i.e. DG Grow informs DG Home and MoDs inform their MS Authorities for internal affairs) and discuss the issue further with them as needed.

Depending on the outcome of the discussions, and if it is concluded that the defence exemption cannot be used, the need for an additional exemption possibility by means of opening the REACH text should be investigated by the EC.

9.7 SUMMARY OF IMPROVEMENT PROPOSALS ACCORDING TO THEIR PRIORITY

Figure 17 provides a schematic summary of the key findings, improvement proposals and their link.

Figure 17 Summary of key findings and key improvement proposals



PRIORITY OF IMPROVEMENT PROPOSALS

The priority of the improvement proposals is determined as a function of their **implementation feasibility (difficulty) vs. the expected benefit (impact)** for the European defence sector, as illustrated in a merely indicative way in Figure 18 below.

The difficulty mainly takes into account the expected technical challenges[270] to implement a given proposal (e.g. additional tasks for a given stakeholder within its given remit or a legal clarification/view is easier to achieve than the definition of a common approach involving a number of different stakeholders or a change of the legal text). Other elements (such as the required human and financial resources) are also important parameters determining the practical difficulty, but could not be finally assessed within the scope of this study.

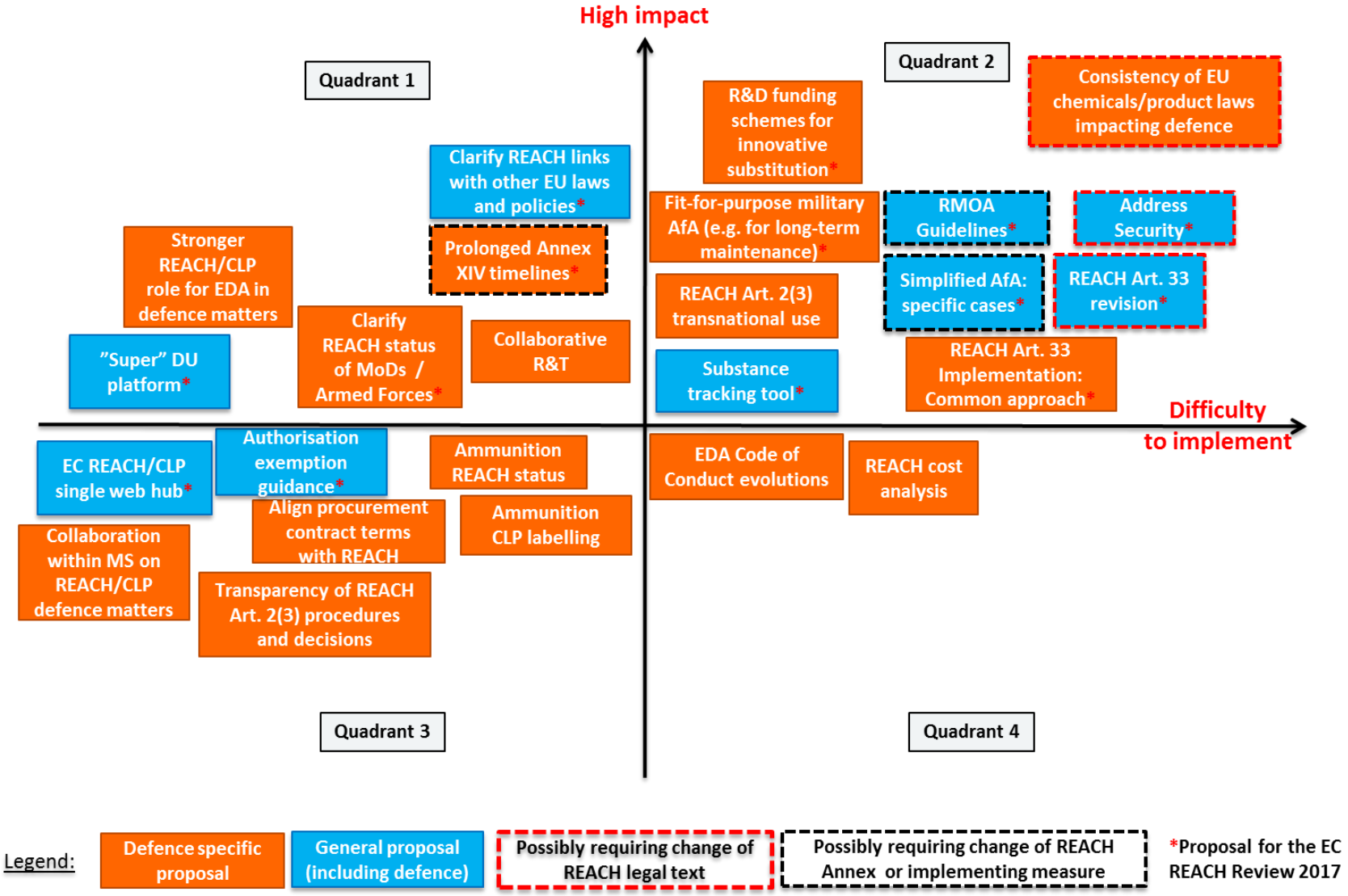
When looking at the figure, some relevant conclusions can be drawn:

- In a nutshell, one could say that all proposals in quadrant 1 and 2 could make a real difference with regard to the **enhancement of competitiveness and innovation** in the European defence sector, whereas those in quadrant 3 and 4 are strongly recommended evolutions of REACH and CLP to ensure a better workability for defence.
- All **key improvement proposals** presented in Sections 9.1 – 9.3 are considered as being of relatively **high impact** (quadrant 1 and 2) and hence high priority, together with those proposals for the EC, ECHA and MSCAs presented in Section 9.4.1 ("Super" DU Platform), Section 9.4.2 (Substance Tracking Tool) and Section 9.6 (Address Security).
- The remaining improvement proposals (see Sections 9.4.3, 9.4.4 and 9.5) are below the horizontal line (in quadrant 3 and 4) and could be considered of somewhat lower impact.
- Non-defence "specific" (general) proposals are by no means less important for the defence sector, because defence is part most of the time of a global supply chain where it is a small actor, but with the highest performance needs, together with a few high reliability sectors. The defence sector does not operate in a bubble, with no exposure to external influences.
- The figure also shows that some key **defence-specific** improvements with expected high impact could be more realistically achieved in the shorter term, while the non-defence specific (**general)** proposals of high impact are more difficult to achieve, also with regard to the necessity of changing the REACH text for some of them (e.g. Article 33 revision).[271]
- The relatively lower priority of proposals concerning the **REACH defence exemption** reflects the realities of transnational supply chains with frequent "dual use" technologies and its application as a last resort only, based on the EDA CoC 2015. However, successful collaborative work to enable transnational use of REACH Article 2(3) (Section 9.3.6) could have a relatively high positive impact for the European defence sector.
- Most proposals could be implemented without a change of the REACH legal text, a REACH Annex or implementing measure.

[270] Based on the previous Sections of Chapter 9, where the technical difficulty to implement was highlighted for REACH process improvements.

[271] The proposal related to an "exclusion for defence" (Section 9.5.8) is not displayed as it will require further examination to evaluate the necessity.

Figure 18 Priority of improvement proposals



ANNEXES

A. DESCRIPTION OF STUDY ACTIVITIES

The study scope was complex, i.e. multi-dimensional in terms of regulations and defence stakeholders to be covered, with differences in the required depth of the impact assessment. Similarly, different types of practical improvement proposals were to be distinguished. Therefore the proper understanding of the study scope and the interconnections of its contents was important for activities to be carried out effectively and efficiently.

A.1 Overview of study scope

The detailed description of the study scope according to the study specifications can be found at https://etendering.ted.europa.eu/cft/cft-display.html?cftId=1329, under "Document Library", 16.ESI.OP.038 Tender Specifications.

In summary the core study deliverables of the study were:

1. **Impact analysis** of REACH and CLP Regulations on EU defence sector in order to identify critical provisions, issues and differences, including for EU and non-EU defence industries and MoDs. It provided the necessary input for the subsequent work.
2. **Practical proposals on improvements** for the REACH and CLP Regulations and their current implementation regime, to serve as basis for EDA and its participating Member States' (pMS) input to the European Commission for the next REACH Regulation review in 2017 and as suggestions for REACH evolutions beyond 2018. This deliverable built on the REACH and CLP impact analysis.
3. **Synthesis of information on impacts of other EU chemical regulations** on EU Member States MoDs and defence sector (notably BPR, POP, ODS), interactions with REACH and CLP, and a strategy (draft as a minimum) & proposals for improvements, thus completing the study.

The study was underpinned by extensive consultations of relevant stakeholders from industry and authorities, as well as in-depth literature review. A focus of the study was placed on the discussion of a significant panel of important (potential) SVHCs[272] at different stages of the REACH/CLP processes that were identified as critical for the European defence industry, in order to illustrate the regulatory impacts and justify practical improvement proposals.

It is **important to highlight** that it was not the purpose of the present study to provide the Contractor's legal opinions on certain controversial issues. If those existed and they influence the extent of the regulatory impact, this was highlighted in the report and harmonisation of views / clarification was suggested in the frame of an improvement proposal, as necessary.

[272] See Chapter 6 and Annex D.

Key study priority areas included:

- ***in-depth REACH* impact analysis**, incl. identification of relevant differences among stakeholders, as a main study focus.
- ***practical* improvement proposals** for REACH (and CLP), comprising both regulation and implementation: Consideration was given to how efficiently a proposal can be realised.
- **looking at the bigger picture**: REACH has to be seen in the context of other relevant EU chemicals and environmental regulations impacting defence (notably BPR, ODS, POP) and directives (e.g. worker protection legislation) as well as EC policies (e.g. critical raw materials).
- **a significant panel of important (potential) SVHCs** for military applications to illustrate impacts and justify improvement proposals. Account was taken of the **type of technology**, i.e. whether it is purely for defence (**military use**) or also civil (**dual use**).
- ***specific* issues** for each of the main types of defence materiel (systems and components) were identified - in addition to global challenges for the defence sector - since a main peculiarity for defence is indeed that it comprises a wide range of product sectors, rather than a product sector in its own right.

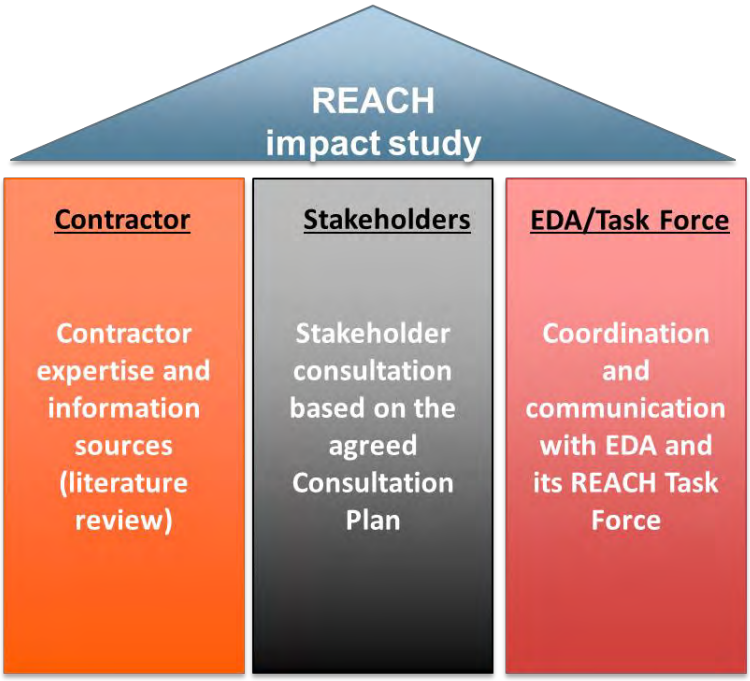
A.2 EDA study support letter

A.3 Summary of actions undertaken

This section summarizes the actions undertaken by the Contractor (collection of study input, analysis and reporting).

The study input to address its scope[273] has been obtained through the combined use of (1) the Contractor's expertise and literature review, (2) close coordination and communication with the EDA and its REACH Task Force comprising experts from participating MoDs and – last but not least – (3) consultation of relevant stakeholders (see Figure 19 below). Considering the tight study time frame (May – November 2016) efficient delivery was of critical importance.

Figure 19 Three pillars for the study input



The Contractor's[274] nominated team members covered relevant multi-disciplinary skills and expertise, combined with extensive industrial and consulting experience in complex multi-stakeholder REACH projects, including impact assessments and the aerospace sector as central elements for this study:

- Tim BECKER (MA Law) as Project Manager and Senior Legal Expert (REACH, CLP, other EU Chemicals Regulations, REACH Impact Studies);
- Philip A. CAPEL (Master in Chemical Engineering) as Industry Expert;
- Agustin COELLO-VERA (PhD Electrical Engineering) as Industry Expert (REACH, RoHS, Aerospace & Defence);
- Tero KOSKI (Master of Social Science in Economics) as Expert for (Socio-/)Economic Analysis;
- Ruaidrí MacDOMHNAILL (PhD Organic Chemistry) as Senior Expert (REACH & Chemistry);
- Riku RINTA-JOUPPI (MA Law, MSc Bioinformatics) as Senior Legal Expert (REACH and other EU Chemicals Regulations).

[273] Annex A.1.
[274] www.reachlaw.fi.

Starting with the kick-off meeting on 11 May 2016 the monthly face-to-face meetings between the Contractor and the EDA REACH Task Force were of key importance to ensure that the deliverables suit the needs of EDA and the pMS. The EDA and REACH Task Force experts were providing valuable input especially to the Contractor's project management plan, consultation plan and questionnaires, substance list and study report, further to their actual participation in the study. MoDs of the EDA pMS also acted as interface with their Member State REACH Competent Authorities (MSCAs), in order to request their answer to the study questionnaire for MSCAs. The role of the EC (DG GROW) through provision of general support/comments, participation in study meetings and communication with CARACAL members was also very helpful.

The fruitful **stakeholder consultation** was paramount for the proper impact assessment and preparation of improvement proposals. Consequently the EDA called on relevant stakeholders in a dedicated letter of 11 May 2016 to support the study.[275]

STUDY QUESTIONNAIRES

With the support of the EDA and REACH Task Force experts[276] the Contractor prepared dedicated detailed study questionnaires for the following stakeholder groups:

- EU MoDs
- Defence industry, both EU and non-EU (with operations in EU)
- EC (DG GROW and DG ENV)
- ECHA
- REACH MSCAs.

STAKEHOLDER CONTACT LIST

For the stakeholder contact list the Contractor identified relevant major defence companies with the support of the ASD RIWG chair for EU industry (fifteen in total) and the US Aerospace Industries Association (AIA) for non-EU companies (five in total). Furthermore, the Contractor identified another major non-EU company and added all other individual EU industry contacts that had responded to the *EDA Questionnaire for Industry on REACH Defence related Issues* in 2015; these included also smaller companies. All other contacts for the above stakeholder groups were provided / available through the EDA and the EC DG GROW (for REACH MSCAs part of CARACAL).

In addition to the stakeholder groups listed above, the following stakeholders were targeted for the study consultation:

- the EDA
- Other defence international organisations: OCCAR, relevant NATO AVT RTGs
- Associations of manufacturers for which the defence sector is an important customer/their member companies
- Five trade union experts nominated by *industriAll European Trade Union*[277]

[275] See Annex A.2.
[276] Comments on the draft questionnaires were also provided by the ASD RIWG chair (for the industry questionnaire), the representative from the EC DG GROW attending the EDA REACH Task Force, and ECHA (for the ECHA questionnaire).
[277] http://www.industriall-europe.eu.

- Other industries: Industry REACH representatives for substances / substance groups of concern (points of contact were kindly provided by *Eurometaux*)
- a consultant.

The complete list of stakeholders that responded to the consultation by written response and/or interview – or contributed to defence association-level responses - is given in Annex B.

GATHERING OF RESPONSES

The stakeholder consultation through questionnaires and interviews was launched in the beginning of June 2016, and supported by web alerts to reach the widest possible audience.[278] The consultation of key stakeholders, such as the ASD RIWG, was prioritised. To enable individual responses, non-disclosure agreements were concluded between the Contractor and some defence companies upon their request.

All stakeholder requests for interviews were accepted by the Contractor and corresponding interviews were scheduled and performed. During June and July 2016 the Contractor held bilateral interviews (either face-to-face or by online meeting / teleconference) with the EDA, MoDs[279] and several defence industry stakeholders.[280]

The Contractor also contacted the identified *industry representatives for substances / substance groups of concern* in order to obtain relevant information, in particular about substance-specific military-related applications, as well as the REACH and Annex XIV status. Their input has been received by written response and/or phone interviews.

Table 16 in Annex A.4 below provides a detailed overview of the consultation feedback received.

LITERATURE REVIEW

In addition to the collection of study input from stakeholders, EDA and its REACH Task Force the Contractor engaged intensely in the identification and analysis of relevant reports, previous REACH impact assessments and other publications on REACH and other related topics for this study.[281] The list of main study references used can be found in Annex O.

ANALYSIS AND REPORTING

The analysis of responses for the impact assessment and elaboration of improvement proposals was facilitated by tick box-type questions in the questionnaires for defence industry and MoDs.

The report presents the information collected in an **aggregated / globalised** way, thereby ensuring the due protection of input covered by non-disclosure agreements. Reference is made to stakeholder groups (e.g. MoDs, EU and non-EU defence industry) rather than individual organisations. Where the Contractor considered it necessary or useful to link reported information to individual stakeholders

[278] On the websites of the Contractor and the EDA (EDA news alert).

[279] EL, ES, FI, FR, IT, NL, SE, UK. DE responded in writing, a follow-up phone call with the Contractor was held on 8.7.2016.

[280] An online meeting with the ASD RIWG chair and several ASD member company representatives was conducted on 13.7.2016.

[281] Key sources included the websites of ECHA, the European Commission, the EDA and the Court of Justice of the European Union (CJEU).

(e.g. when they make certain claims or suggestions), the prior stakeholder approval was obtained or the information was publicly available.

A major part of the analysis was dedicated to the identification of potential discrepancies among the different stakeholders consulted, particularly between the defence industry and MoDs, but also within the same stakeholder group (e.g. between large defence system integrators and smaller component/ammunition manufacturers).

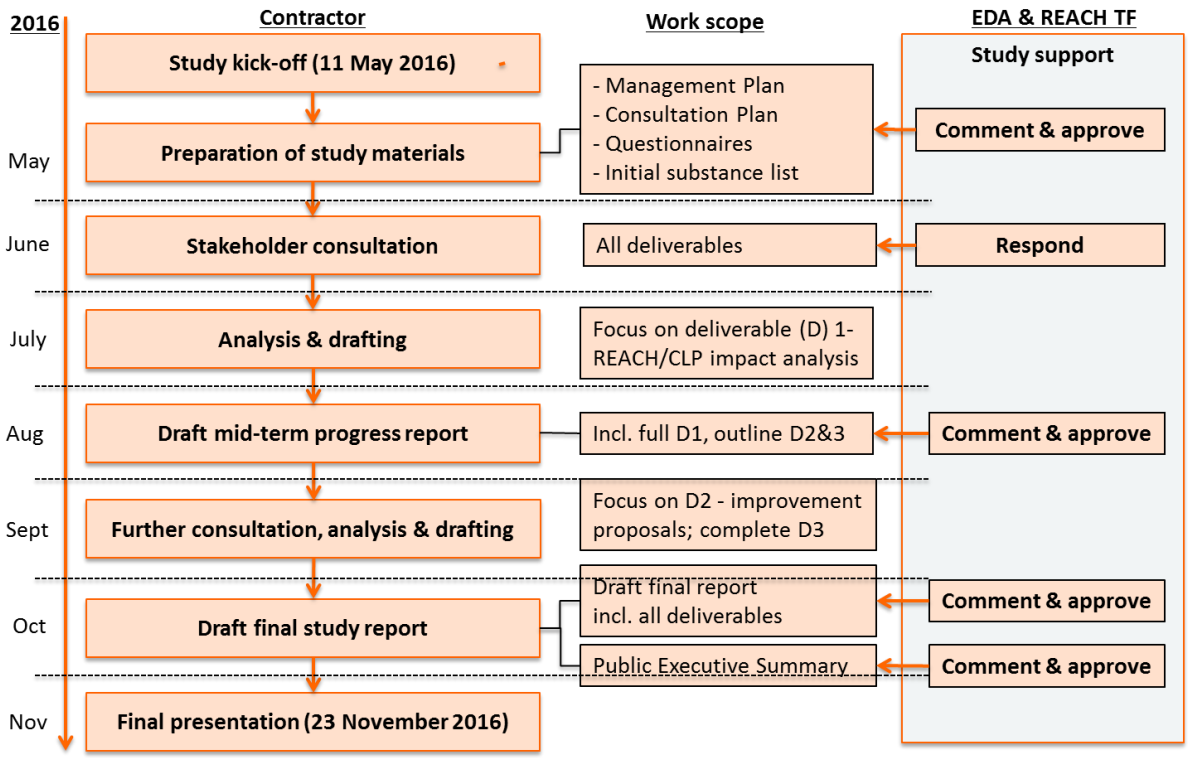
Where differences of views between stakeholders were identified, they are brought to light through this study report, and improvement proposals were made to resolve them rather than taking a stand in the frame of this study.

The Contractor also reviewed the defence industry input from the *EDA Questionnaire for Industry on REACH Defence related Issues* in 2015.

SUMMARY OF OVERALL STUDY WORKFLOW

The following workflow (Figure 20) summarises the key steps of the study project.

Figure 20 Overall study workflow and support by EDA / REACH Task Force



A.4 Overview of consultation feedback

Table 16 Overview of consultation feedback

Stakeholder	Minimum Requirements (acc. to study specifications /consultation plan)	Consultation Method Used	Consultation Addressees	Written Responses	Interviews
MoDs	LoI countries: DE, ES, FR, IT, SE, UK Non-LoI to be selected with the support of EDA and Task Force	Questionnaire for *Ministries of Defence*	All EDA pMS MoDs + NO (Directly by the Contractor and through EDA)	6 LoI: DE, ES, FR, IT, SE, UK 7 non-LoI: EL, FI, NL, BE, CZ (substance-specific questions only), PT + NO Total 13	8: ES, FI, FR, EL, IT, NL, SE, UK
EDA	YES	Tailored questions	EDA	YES	YES (7.6.)
Other defence international organisations	Not mentioned in study specifications	-	Invitation by EDA to participate in the study consultation to: NATO, OCCAR	None; OCCAR responded through EDA: currently no REACH expertise	2: NATO AVT-293/RTG-103 (25.10.) and NATO AVT-247/RTG-084 (28.11.), see Annex E.2
EC	YES	Questionnaire for EC	EC/DG GROW and DG ENV (Directly by the Contractor)	Yes (jointly by DG GROW and DG ENV)	- Active participation by DG GROW in study progress meetings
ECHA	YES	Questionnaire for ECHA	ECHA (Directly by the Contractor)	Yes	-
REACH MSCAs	LoI countries: DE, ES, FR, IT, SE, UK Non-LoI to be selected with the support of EDA and Task Force	Questionnaire for REACH MSCAs	All MSCAs (through EC DG GROW. Also by EDA through MoDs)	5 LoI: DE, ES, IT, SE, UK 11 non-LoIs: AT, BE, BG, DK, EE, EL, HU, NL, NO, PL, RO Total: 16	FR (22.8.) NL (12.7.) Total: 2
ASD RIWG	YES	Questionnaire for *defence industry* Tailored questions by the Contractor (based on Questionnaire for *defence industry*)	ASD (through EDA) ASD RIWG (Directly by the Contractor)	NO. ASD RIWG were interviewed and provided a verbal response/answers to the questionnaire.	YES (13.6.) Approved minutes of interview of 13.6.2016

Stakeholder	Minimum Requirements (acc. to study specifications /consultation plan)	Consultation Method Used	Consultation Addressees	Written Responses	Interviews
NDIAs	LoI countries: DE, ES, FR, IT, SE, UK 10 non-ASD members	Questionnaire for *defence industry*	All EDA pMS NDIAs (Directly and through EDA)	3 LoI: AIAD (IT), BDSV (DE), GIFAS (FR) Negative response: SOFF (SE) [covered by company answers], NiDV (NL)	-
EU defence companies	Appropriately selected	Questionnaire for *defence industry*	~ 60 companies (selected based on: ASD RIWG input and EDA *Survey for Industry on REACH Defence related Issues 2015* contacts)	27 companies from 10 countries: - 6 LoI: DE, ES, FR, IT, SE, UK - 4 non-LoI: CZ, EL, NO, PL as follows: AIM INFRAROT-MODULE GmbH, Airbus Defence and Space, Aqeri AB, Avio SpA, BAE Systems Land (UK), BAE Systems Bofors AB, BAE Systems Hägglunds, BAE Systems Military Air & Information, EAS (Hellenic Defence Systems SA), Etienne Lacroix Group, EURENCO, GDELS SBS, MBDA (France), INDRA SISTEMAS S.A., INDUSTRIA DE TURBO PROPULSORES, SA, Leonardo-Finmeccanica S.p.A., Meggitt, Metallwerk Elisenhütte GmbH, Nammo Raufoss AS, Nexter Munitions, Pratt&Whitney Rzeszów, Rheinmetall Waffe Munition GmbH, Rolls-Royce, Roxel (UK Rocket Motors) Limited, RUAG Ammotec GmbH, Saab, Sellier Bellot J.S.C. Those not responding individually mostly referred to the ASD/NDIA answer (for additional information see Annex B)	3: Aqeri AB, Avio SpA, Meggitt

Stakeholder	Minimum Requirements (acc. to study specifications /consultation plan)	Consultation Method Used	Consultation Addressees	Written Responses	Interviews
Major non-EU defence companies with business in EU	5	Questionnaire for *defence industry*	6 US companies (5 proposed by AIA (GE Aviation, Harris Corporation, Lockheed Martin, Pratt & Whitney, Raytheon Company) + Boeing)[282]	5: Boeing, GE Aviation, Lockheed Martin, Pratt & Whitney, Raytheon Company. Negative response: Harris Corporation	2: Pratt & Whitney, Raytheon Company
Associations of manufacturers for which the defence sector is an important customer	Not mentioned in study specifications	Questionnaire for *defence industry*	Directly by the Contractor to ACSIEL ("Alliance Electronique") and SFEPA (explosives) (Selected with the support of EDA and Task Force)	Through their members: - 5 ACSIEL: Amphenol Socapex, éolane Les Ulis Sainte Savine, Esterline Souriau, Sofradir, STMicroelectronics - 1 SFEPA: Pyroalliance	5: Esterline Souriau, éolane Les Ulis Sainte Savine, CEPE - aerospace coating group, Akzo Nobel N.V., Indestructable Paint Ltd.
Other industries	Not mentioned in study specifications	Tailored questions	Selected organisations known to the Contractor with REACH-related activities for substances of interest for defence (some PoCs were identified with the support of Eurometaux) or made known by the EDA	**14:** ADCA Task Force, ASD-Eurospace (for Space REACH Task Forces), Cadmium consortium, CRM Alliance, Cross-industry initiative (CII), ECFIA consortium, EPMF (Precious Metals & Rhenium Consortium - PMC), Freiberger Compound Materials GmbH (FCM), FuelsEurope & Concawe, Hydrazine Registration Consortium, International Lead Association/Lead REACH Consortium, Nickel Institute, The Beryllium Science & Technology Association (BeST), The Cobalt Development Institute (CDI)	**12**: ADCA Task Force, Cadmium consortium, CSM, EUROMETAUX, Freiberger Compound Materials GmbH (FCM), FuelsEurope & Concawe, International Lead Association/Lead REACH Consortium, International Zinc Association, Nickel Institute, PlasticsEurope, The Beryllium Science & Technology Association (BeST), The Cobalt Development Institute (CDI)

[282] Only US-headquartered companies have been identified, given that they are the largest of all non-EU defence industries companies impacted by REACH and therefore representative of all the potential issues experienced.

Stakeholder	Minimum Requirements (acc. to study specifications /consultation plan)	Consultation Method Used	Consultation Addressees	Written Responses	Interviews
Trade unions	Not mentioned in study specifications	Questionnaire for *defence industry*	IndustriAll European Trade Union nominated 5 trade union experts in DE, ES and FR Contractor contacted all trade union experts directly in their local language	1 CCOO de Industria (Spain) answered as trade union; 3 experts referred to their REACH point of contact (who responded through GIFAS and BDSV)	Krauss-Maffei Wegmann (answer for company)
Consultants	Not mentioned in study specifications	Tailored questions	Selected by the Contractor based on ECHA advice to obtain relevant study input based on the consultant's experience with military-related applications for authorisation		Ecomundo
			Total responses:	**88**	**38**

B. LIST OF CONSULTEES

The following list (Table 17) shows the stakeholders that provided a response to the study consultation, either on their own or via their National Defence Industry Association (NDIA).

"x" stands for "Yes".

Table 17 List of consultees

No.	Organisation	Country	Stakeholder type	Written response	Interview
1	**European Commission (DG GROW and DG ENV)**	EU	EU Institution	Questionnaire	
2	**European Chemicals Agency (ECHA)**	EU	EU Agency	Questionnaire	
3	**European Defence Agency (EDA)**	EU	EU Agency	x	x
4	**Belgian Defence**	Belgium	MoD	Questionnaire	
5	**Defence Ministry of the Czech Republic**	Czech Republic	MoD	Questionnaire	
6	**Ministry of Defence of Finland**	Finland	MoD	Questionnaire	x
7	**Direction technique de la Direction Générale de l'Armement (DGA/DT)**	France	MoD	Questionnaire	x
8	**Bundesministerium der Verteidigung / Federal Ministry of Defence**	Germany	MoD	Questionnaire	
9	**Hellenic Ministry of National Defence (HMoD)**	Greece	MoD	Questionnaire	x
10	**SECRETARIAT GENERAL OF DEFENCE/NATIONAL ARMAMENTS DIRECTORATE**	Italy	MoD	Questionnaire	x
11	**Netherlands Defence Meteriel Organization**	Netherlands	MoD	Questionnaire	x
12	**Norwegian Defence Logistic Organisation and Defence Materiel Agency**	Norway	MoD	Questionnaire	
13	**Directorate-General for National Defence Resources of the Ministry of Defence of Portugal**	Portugal	MoD	Questionnaire	
14	**SDGINREID-DGAM (MINISTERIO DE DEFENSA)**	Spain	MoD	Questionnaire	x
15	**Swedish Defence Materiel Administration (FMV)**	Sweden	MoD	Questionnaire	x
16	**Defence Equipment and Support (DE&S) - Quality Safety and Environmental Protection (QSEP) office**	United Kingdom	MoD	Questionnaire	x
17	**BMLFUW (Federal ministry for Agriculture, Forestry, Environment and Water Management)**	Austria	REACH MSCA	Questionnaire	
18	**FPS Health , Food chain safety and Environnement**	Belgium	REACH MSCA	Questionnaire	
19	**Ministry of Environment and Water**	Bulgaria	REACH MSCA	Questionnaire	
20	**Danish Environmental Protection Agency**	Denmark	REACH MSCA	Questionnaire	
21	**HEALTH BOARD - Department of Chemical Safety**	Estonia	REACH MSCA	Questionnaire	

No.	Organisation	Country	Stakeholder type	Written response	Interview
22	**Ministry of Environment, Energy and Sea (MEEM)**	France	REACH MSCA		x
23	**Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA)**	Germany	REACH MSCA	Questionnaire	
24	**Ministry of Finance - Directorate of Energy, Industrial and Chemical Products - Section B'**	Greece	REACH MSCA	Questionnaire	
25	**National Public Health Center**	Hungary	REACH MSCA	Questionnaire	
26	**Ministry of Health**	Italy	REACH MSCA	Questionnaire	
27	**Ministerie van Infrastructuur en Milieu**	Netherlands	REACH MSCA	Questionnaire	x
28	**Norwegian Environment Agency**	Norway	REACH MSCA	Questionnaire	
29	**Bureau for Chemical Substances**	Poland	REACH MSCA	Questionnaire	
30	**Ministry of Environment, Waters and Forests**	Romania	REACH MSCA	Questionnaire	
31	**Ministry of Health Social Services and Equality and Ministry of Agriculture, Food and Environment**	Spain	REACH MSCA	Questionnaire	
32	**Swedish Chemicals Agency (KEMI)**	Sweden	REACH MSCA	Questionnaire	
33	**UK Competent Authority for REACH and CLP Chemicals Regulation Divison HEALTH & SAFETY EXECUTIVE (HSE)**	United Kingdom	REACH MSCA	Questionnaire	
34	**ASD RIWG**[283]	International	EDIA	Interview minutes	x
35	**GIFAS**	France	NDIA	Questionnaire	
36	**BDSV (Federation of German Defence Industries)**	Germany	NDIA	Questionnaire	
37	**Federation AIAD (Italian Industries Federation for Aerospace, Defence and Security)**	Italy	NDIA	Questionnaire	
38	**Sellier Bellot J.S.C.**	Czech Republic	EU company	Questionnaire	
39	**Airbus Helicopters**	France	EU company	via GIFAS	
40	**Dassault Aviation**	France	EU company	via GIFAS	
41	**Safran**	France	EU company	via GIFAS	
42	**Thales**	France	EU company	via GIFAS	

[283] The members of ASD consist of 14 European Aerospace and Defence Companies and 26 National Associations in 19 countries. These are: AAI - Austrian Aeronautics Industries Group, ADIG- Austrian Defence Industry Association, ADS - Advancing UK Aerospace, Defence & Security Industries, AED Portugal (DANOTEC), AFDA - Association of Finnish Defence and Aerospace Industries, Agoria, AIAD - Italian Industries Federation for Aerospace Systems & Defence, Airbus, Airbus Defence & Space, Airbus Group, Airbus Helicopters, ALV CR – Association of Aviation Manufacturers of the Czech Republic, AOBP - Defence and Security Industry Association of the Czech Republic, APAI - Association of Polish Aviation Industry, BAE Systems, BDIA - Bulgarian Defence Industry Association, BDLI - German Aerospace Industries Association, BDSV - Federal Association of the German Security and Defence Industry, BSDI - Belgian Security & Defence Industry, CIDEF, Dassault Aviation, FAD - Defence & Aerospace Industries Association in Denmark, Fokker, FSI -Norwegian Defence and Security Industries Association, GIFAS - French Aerospace Industries Association, HASDIG - Hellenic Aerospace & Defence Industries Group, Indra, Leonardo, MBDA, NAI - NAG - Netherlands Aerospace Group, NIDV - Netherlands Defence Manufacturers Association, Rolls-Royce, SAAB, Safran, SAI - Swedish Aerospace Industries, SAIG - Swiss Aeronautical Industries Group, SASAD - Turkish Defence Industry Manufacturers Association, SOFF - Swedish Security and Defence Industry, TEDAE - Spanish Association for Defence, Security and Space Technology Companies and Thales.

No.	Organisation	Country	Stakeholder type	Written response	Interview
43	**Airbus Safran Launchers**	France	EU company	via GIFAS	
44	**Amphenol Socapex**	France	EU company	Questionnaire	
45	**éolane Les Ulis Sainte Savine**	France	EU company	Questionnaire	x
46	**ESTERLINE SOURIAU**	France	EU company	Questionnaire	x
47	**Etienne Lacroix Group**	France	EU company	Questionnaire	
48	**EURENCO**	France	EU company	Questionnaire	
49	**MBDA (France)**	France	EU company	Questionnaire	
50	**Nexter Munitions**	France	EU company	Questionnaire	
51	**PYROALLIANCE - SAFRAN**	France	EU company	Questionnaire	
52	**SOFRADIR**	France	EU company	Questionnaire	
53	**STMicroelectronics**	France	EU company	Questionnaire	
54	**Airbus Defence and Space**	Germany	EU company	Questionnaire	
55	**Diehl (BGT) - Defence**	Germany	EU company	via BDSV	
56	**Metallwerk Elisenhütte GmbH**	Germany	EU company	Questionnaire	
57	**Rheinmetall Waffe Munition GmbH**	Germany	EU company	Questionnaire	
58	**AIM INFRAROT-MODULE GmbH**	Germany	EU company	Questionnaire	
59	**Airbus Helicopter Deutschland GmbH**	Germany	EU company	via BDSV	
60	**Krauss-Maffei Wegmann (KMW)**	Germany	EU company	-	x
61	**MBDA Deutschland GmbH**	Germany	EU company	via BDSV	
62	**MTU Aero Engines AG**	Germany	EU company	via BDSV	
63	**RUAG Ammotec GmbH**	Germany	EU company	Questionnaire	
64	**thyssenkrupp Marine Systems GmbH**	Germany	EU company	via BDSV	
65	**EAS (Hellenic Defence Systems SA)**	Greece	EU company	Questionnaire	
66	**Avio SpA**	Italy	EU company	Questionnaire	x
67	**Leonardo-Finmeccanica S.p.A.**	Italy	EU company	Questionnaire	
68	**Akzo Nobel N.V.**	Netherlands	EU company		x
69	**Nammo Raufoss AS**	Norway	EU company	Questionnaire	
70	**Pratt&Whitney Rzeszów**	Poland	EU company	Questionnaire	
71	**Airbus Operations S.L.**	Spain	EU company	via ASD RIWG	
72	**GDELS SBS**	Spain	EU company	Questionnaire	
73	**INDRA SISTEMAS S.A.**	Spain	EU company	Questionnaire	
74	**INDUSTRIA DE TURBO PROPULSORES, SA**	Spain	EU company	Questionnaire	
75	**BAE Systems Bofors AB**	Sweden	EU company	Questionnaire	
76	**BAE Systems Hägglunds**	Sweden	EU company	Questionnaire	
77	**Saab**	Sweden	EU company	Questionnaire	
78	**Aqeri AB**	Sweden	EU company	Questionnaire	x
79	**BAE Systems Land (UK)**	United Kingdom	EU company	Questionnaire	
80	**BAE Systems Military Air & Information**	United Kingdom	EU company	Questionnaire	
81	**Indestructible Paint Ltd**	United Kingdom	EU company		x
82	**Meggitt**	United Kingdom	EU company	Questionnaire	x
83	**Rolls-Royce**	United Kingdom	EU company	Questionnaire	
84	**Roxel (UK Rocket Motors) Limited**	United Kingdom	EU company	Questionnaire	

No.	Organisation	Country	Stakeholder type	Written response	Interview
85	**Boeing**	US	Non-EU company	Questionnaire	
86	**General Electric Company: GE Aviation**	US	Non-EU company	Questionnaire	
87	**Lockheed Martin**	US	Non-EU company	Questionnaire	
88	**Pratt & Whitney**	US	Non-EU company	Questionnaire	x
89	**Raytheon Company**	US	Non-EU company	Questionnaire	x
90	**NATO AVT-247/RTG-084**[284]	International	Other defence international organisations		x
91	**NATO AVT-293/RTG-103**[285]	International	Other defence international organisations		x
92	**ACSIEL – ALLIANCE ELECTRONIQUE**	France	Other industries	via its members	
93	**Freiberger Compound Materials GmbH (FCM)**	Germany	Other industries	x	x
94	**Centro Sviluppo Materiali S.p.A. (CSM)**	Italy	Other industries		x
95	**CEPE**	International	Other industries		x
96	**ADCA Task Force**	International	Other industries	x	x
97	**ASD-Eurospace (for Space REACH Task Forces)**	International	Other industries	x	
98	**Cadmium consortium**	International	Other industries	x	x
99	**CRM Alliance**	International	Other industries	x	
100	**Cross-industry initiative (CII)**	International	Other industries	x	
101	**ECFIA consortium**	International	Other industries	x	
102	**EPMF (Precious Metals & Rhenium Consortium - PMC)**	International	Other industries	x	
103	**EUROMETAUX**	International	Other industries		x
104	**FuelsEurope & Concawe**	International	Other industries	x	x
105	**Hydrazine Registration Consortium**	International	Other industries	x	
106	**International Lead Association/Lead REACH Consortium**	International	Other industries	x	x
107	**International Zinc Association**	International	Other industries		x
108	**Nickel Institute**	International	Other industries	x	x
109	**PlasticsEurope**	International	Other industries		x
110	**The Beryllium Science & Technology Association: BeST**	International	Other industries	x	x
111	**The Cobalt Development Institute (CDI)**	International	Other industries	x	x
112	**CCOO de Industria**	Spain	Trade Union	Questionnaire	
113	**Ecomundo**	France	REACH Consultant		x

[284] See Annex E.2.
[285] See Annex E.2.

C. SURVEY RESULTS

Table 18 Defence industry survey results

1. Defence industry survey results		Overall (EU + Non-EU)			EU			Non-EU			Response rate
		Yes	No	Don't know	Yes	No	Don't know	Yes	No	Don't know	
1.1.	Have you already tracked any price increases from your suppliers attributable to REACH compliance?	**38 %**	27 %	35 %	**39.4 %**	27.3 %	33.3 %	**25 %**	25 %	50 %	**88 %**
1.2.	Do you believe that these prices will increase / further increase in the future due to REACH?	**85 %**	2.5 %	12.5 %	**83 %**	3 %	14 %	**100 %**	0 %	0 %	**95 %**
1.3.	Have you raised your prices due to REACH compliance?	**26 %**	47 %	26 %	**26.6 %**	46.8 %	26.6 %	**25 %**	50 %	25 %	**81 %**
1.4.	Have you incurred additional development or R&D costs due to REACH?	**87 %**	10.5 %	2.5 %	**85 %**	12 %	3 %	**100 %**	0 %	0 %	**90 %**
1.5.	Have any substances, mixtures or articles become unavailable for supply to you as a result of one of the REACH processes?	**77.5 %**	17.5 %	5 %	**74 %**	20 %	6 %	**100 %**	0 %	0 %	**95 %**
1.6.	Has this resulted in some process/product obsolescence in your operations?	**69 %**	31 %	n/a	**68 %**	32 %	n/a	**80 %**	20 %	n/a	**86 %**
1.7.	Has this obsolescence resulted in a loss of business?	**8 %**	73 %	19 %	**9 %**	72 %	19 %	**0 %**	80 %	20 %	**88 %**
1.8.	Is obsolescence due to REACH captured by your company's normal obsolescence management process?	**68.6 %**	25.7 %	5.7 %	**67 %**	26 %	7 %	**80 %**	20 %	0 %	**83 %**
1.9.	Has REACH had any impact on the selection of your suppliers (e.g. EU vs. non-EU) or your procurement strategy in general?	**56 %**	27 %	17 %	**55.5 %**	27.8 %	16.7 %	**60 %**	20 %	20 %	**98 %**

1. Defence industry survey results		Overall (EU + Non-EU)			EU			Non-EU			Response rate
		Yes	No	Don't know	Yes	No	Don't know	Yes	No	Don't know	
1.10.	Would you say that R&D activities have increased in your organization/supply chain as a result of REACH?	**78.6 %**	16.7 %	4.7 %	**76 %**	19 %	5 %	**100 %**	0 %	0 %	**100 %**
1.11.	Do you agree that REACH induced obsolescence does not always imply advancement of the state-of-the-art of your products, e.g. has the focus shifted from advancement to maintenance of current technology?	**70.3 %**	5.4 %	24.3 %	**69 %**	6 %	25 %	**80 %**	0 %	20 %	**88 %**
1.12.	Has your companies R&D budget increased to cover REACH related R&D?	**41 %**	51 %	8 %	**43 %**	48.5 %	8.5 %	**25 %**	75 %	0 %	**93 %**
1.13.	Have you implemented new Risk Management Measures as a result of a REACH process?	**41 %**	59 %	n/a	**44 %**	56 %	n/a	**20 %**	80 %	n/a	**98 %**
1.14.	Have you implemented new Environmental Release Monitoring measures as a result of a REACH process?	**21 %**	74 %	5 %	**24.3 %**	70.3 %	5.4 %	**0 %**	100 %	0 %	**100 %**
1.15.	Do you believe that the above measures delivered actual benefits to health, safety and environment?	**42 %**	33 %	25 %	**42 %**	32 %	26 %	**40 %**	40 %	20 %	**86 %**
1.16.	Do you consider or have experience that you may re-use REACH information (e.g. registration data) for compliance with similar chemicals regulations outside EEA?	**27.5 %**	37.5 %	35 %	**17 %**	43 %	40 %	**100 %**	0 %	0 %	**95 %**
1.17.	Do you consider any other direct benefits that REACH has brought about?	**39 %**	61 %	n/a	**36 %**	64 %	n/a	**60 %**	40 %	n/a	**90 %**
1.18.	Do you consider that the EDA CODE OF CONDUCT ON REACH DEFENCE EXEMPTIONS (2015) creates a workable and sufficient solution for the defence sector to mitigate REACH impacts?	**9 %**	14 %	77 %	**10 %**	17 %	73 %	**0 %**	0 %	100 %	**83 %**

1. Defence industry survey results		Overall (EU + Non-EU)			EU			Non-EU			Response rate
		Yes	No	Don't know	Yes	No	Don't know	Yes	No	Don't know	
1.19.	Have you been audited for REACH compliance by a national authority?	**29 %**	71 %	n/a	**28 %**	72 %	n/a	**40 %**	60 %	n/a	**98 %**
1.20.	Where your company is operating in more than one EEA Member State: Were there any difficulties/challenges due to different approaches by different Member States?	**16 %**	43 %	41 %	**15.6 %**	43.8 %	40.6 %	**20 %**	40 %	40 %	**88 %**
1.21.	Do you consider that the REACH Regulation has already impacted on your business in terms of loss of your global competitiveness?	**49 %**	51 %	n/a	**50 %**	50 %	n/a	**33 %**	67 %	n/a	**93 %**
1.22.	Do you foresee a soon to come specific threat in this regard?	**70 %**	30 %	n/a	**70 %**	30 %	n/a	**75 %**	25 %	n/a	**88 %**
1.23.	Do you consider that the REACH Regulation has already impacted on your business in terms of gain of your global competitiveness?	**13 %**	87 %	n/a	**14 %**	86 %	n/a	**0 %**	100 %	n/a	**90 %**
1.24.	Have your company, or any of your suppliers that you may know of, considered relocation of manufacturing facilities to non-EEA countries due to REACH?	**45 %**	55 %	n/a	**37 %**	63 %	n/a	**100 %**	0 %	n/a	**95 %**
1.25.	Do you foresee a soon to come specific threat in this regard?	**42 %**	58 %	n/a	**35 %**	65 %	n/a	**100 %**	0 %	n/a	**90 %**
1.26.	Are you aware of any past/current examples of relocation to non-EEA countries to continue using the substance?	**33 %**	67 %	n/a	**29 %**	71 %	n/a	**60 %**	40 %	n/a	**93 %**

1. Defence industry survey results		Overall (EU + Non-EU)			EU			Non-EU			Response rate
		Yes	No	Don't know	Yes	No	Don't know	Yes	No	Don't know	
1.27.	Do you expect that the regulatory burden under these non-EEA chemicals regulations affecting your business is going to increase in the foreseeable future (e.g. TSCA reform)?	**42 %**	3 %	55 %	**36 %**	3 %	61 %	**80 %**	0 %	20 %	**90 %**
1.28.	Looking towards the REACH Registration Deadline in 2018 and given that the defence sector is small compared to other industries, have you received assurances that substances critical for your products will be registered and therefore available for your use after the deadline?	**11 %**	58 %	31 %	**13 %**	55 %	32 %	**0 %**	80 %	20 %	**86 %**
1.29.	Are any of your products dependent on the use of specific SVHC substances to meet customer requirements?	**90 %**	10 %	n/a	**89 %**	11 %	n/a	**100 %**	0 %	n/a	**98 %**
1.30.	Is this dependency due to: Contractual obligation	**79 %**	21 %	n/a	**79 %**	21 %	n/a	**80 %**	20 %	n/a	**81 %**
1.31.	Is this dependency due to: Necessity in order to achieve performance/quality	**95 %**	5 %	n/a	**94 %**	6 %	n/a	**100 %**	0 %	n/a	**93 %**
1.32.	Do your customers impose other contractual constraints (e.g. ban or avoid use of certain substances, or notify further) beyond REACH or other chemical regulations legal requirements?	**79 %**	21 %	n/a	**76 %**	24 %	n/a	**100 %**	0 %	n/a	**90 %**
1.33.	Are you aware of any public funding/other support by your national MoD/government or on EU level for R&D for alternatives to SVHC substances like the ones on the REACH candidate list for authorisation?	**41 %**	59 %	n/a	**38 %**	62 %	n/a	**60 %**	40 %	n/a	**93 %**
1.34.	Do you consider that more funding for R&D for alternatives to SVHC substances like the ones on the REACH candidate list for authorisation should be made available by the EU?	**91 %**	9 %	n/a	**90 %**	10 %	n/a	**100 %**	0 %	n/a	**81 %**

Table 19 MoD survey results

2. MoDs survey results		YES	NO	Don't know	Response rate
2.1.	Are your MoD/Armed Forces contractually requiring the use of certain substances in order to maintain specific standards / performance requirements that you are expecting?	**60 %**	40 %	n/a	**83 %**
2.2.	Are your MoD/Armed Forces contractually requiring the ban or avoidance of certain substances?	**56 %**	44 %	n/a	**75 %**
2.3.	REACH challenges the Security of Supply to maintain / improve your country's defence capabilities	**67 %**	8 %	25 %	**100 %**
2.4.	REACH has impacts on your suppliers' (industry) competitiveness (positive or negative)	**50 %**	8 %	42 %	**100 %**
2.5.	REACH Article 2(3) has impacts on our MoD (e.g. financial and human resources, liability risks, etc.)	**92 %**	0 %	8 %	**100 %**
2.6.	Direct obligations as addressee of REACH according to the definitions of Article 3 REACH (e. g. importer / downstream user / re-seller of (e.g. surplus) defence equipment (REACH article supplier, etc.))	**75 %**	17 %	8 %	**100 %**
2.7.	Loss of skills due to the risk of some industry relocating to a non EEA country	**42 %**	16 %	42 %	**100 %**
2.8.	Loss of understanding and control of the supply chain	**27 %**	36.5 %	36.5 %	**92 %**
2.9.	REACH has also other significant impacts	**70 %**	0 %	30 %	**83 %**
2.10.	Has the cost of purchasing defence hardware / industrial chemicals already increased as a result of suppliers' REACH compliance?	**33 %**	17 %	50 %	**100 %**
2.11.	Do you believe that the procurement cost will increase / further increase in the future due to REACH?	**82 %**	9 %	9 %	**92 %**

2. MoDs survey results		YES	NO	Don't know	Response rate
2.12.	Have you had costs for dedicated R&D or development of alternative solutions to banned / ready to be banned or commercially obsolete substances due to REACH or other hazmat regulations, in order to allow continued procurement or internal or external maintenance of defence hardware?	**45.5 %**	9 %	45.5 %	**92 %**
2.13.	Have you had additional human resource costs in your MoD's procurement or maintenance activities in order to comply with REACH or manage its risks and impacts?	**64 %**	18 %	18 %	**92 %**
2.14.	Reformulation resulting in reduced performance and reliability.	**73 %**	9 %	18 %	**92 %**
2.15.	Obsolescence due to market decision to stop manufacturing a substance or not registering it for defence-relevant uses, and therefore not supplying it to the defence industry anymore	**45 %**	0 %	55 %	**92 %**
2.16.	Obsolescence due to non-registration (issue of SMEs for 2018)	**58 %**	0 %	42 %	**100 %**
2.17.	Obsolescence due to non-authorisation for SVHC	**64 %**	0 %	36 %	**92 %**
2.18.	Other risks	**43 %**	14 %	43 %	**58 %**
2.19.	Are you carrying out or coordinate own R&D projects for SVHC substitution?	**55 %**	36 %	9 %	**92 %**
2.20.	Is your government providing public funding to support your industry's R&D and replacement for SVHC substitution?	**45.5 %**	18 %	36. 5 %	**92 %**
2.21.	Do you consider that the EU should make available more public funding to support the substitution of SVHC? Which existing programme/scheme could be used? Or do you have any new ideas?	**64 %**	0 %	36 %	**92 %**
2.22.	Have you implemented new Risk Management Measures as a result of a REACH process	**75 %**	25 %	0 %	**100 %**
2.23.	Have you implemented new Environmental Release Monitoring measures as a result of a REACH process	**30 %**	50 %	20 %	**83 %**
2.24.	Do you consider any other benefits that REACH has brought about?	**100 %**	0 %	0 %	**17 %**
2.25.	Do you believe that the above measures delivered actual benefits to health, safety and environment?	**62.5 %**	25 %	12.5 %	**67 %**

3. EC, ECHA and MSCAs survey results

A statistical analysis of responses - similar to survey results for the defence industry and MoDs - was not performed for EC, ECHA and MSCAs, due to the different objective of their consultation based on the study specifications.[286]

OBJECTIVES OF EC, ECHA and MSCAs CONSULTATION

One of the most important goals of the study was to provide practical proposals on REACH process improvement, including the coordination and intrinsic consistency (in terms of risk management priorities) of the EC, ECHA and MSCA proposals on substances to be regulated by REACH and CLP, as well as the consistency with other Commission policy and strategy considerations (e.g. policy and strategy on strategic (raw) materials). Against this background the Contractor gathered information – via dedicated questionnaires to the EC, ECHA and MSCAs on their

- experience with the selection of substances for SVHC identification proposals and related Risk Management Option Analysis, including the coordination amongst themselves;
- experience with the national MoD and defence industry stakeholders for the implementation of REACH and CLP, as well as their consideration of specific concerns for the defence sector;
- views on possible improvements based on this experience.

Furthermore, some additional questions reflecting their specific roles for the REACH implementation were asked to ECHA (e.g. with regard to relevant guidance) and the EC (e.g. with regard to the genesis of certain REACH provisions and questions of REACH and CLP legal interpretations).

METHODOLOGY

Given the mentioned objectives of the EC, ECHA and MSCAs consultation, the Contractor performed a qualitative survey with mostly open questions and a corresponding qualitative assessment of the answers to support the elaboration of improvement proposals rather than a statistical evaluation (as an important element required for the MoD and defence industry impact assessment). Consequently, the EC (DG GROW and DG ENV) and ECHA were also given the opportunity to review the draft improvement proposals. One MSCA also commented on the Contractor's Mid-Term Progress Report, providing valuable information for the further work.

USE OF SURVEY RESPONSES

The EC, ECHA and MSCAs survey responses have provided important qualitative input for various sections of the study report. Reference is made in particular to:

- Section 4.2.3.2 (ECHA comment on downstream user AfAs related to defence);
- Section 4.2.3.3 (MSCA comment on shortcomings in some defence-related AfAs);
- Section 5.6 (Collaboration within the Member States);
- Chapter 9 (Practical Improvement Proposals);
- Annex K.2 (Available authority views concerning CLP labelling of ammunition);

[286] The description of the study scope according to the study specifications can be found at https://etendering.ted.europa.eu/cft/cft-display.html?cftId=1329, under "Document Library", 16.ESI.OP.038 Tender Specifications.

- Annex N.1 (Illustrative recent examples of “phased” approaches instead of straight authorisation);
- Annex N.2 (Additional information on RMOA);
- Annex N.3 (REACH links with EU OSH legislation, CRM policy and circular economy);
- Annex N.4 (Possible elements of a fit-for-purpose simplified authorisation for military uses);
- Annex N.5 (Review of opinions on Article 33 interpretation / implementation).

D. CRITICAL SUBSTANCES FOR DEFENCE: ADDITIONAL INFORMATION

This Annex contains additional information of illustrative examples of substances (or groups thereof) critical for the defence sector, for which regulatory action was undertaken under REACH/CLP, in the order of their status with regard to REACH Annex XIV. These substances examples are also listed in Chapter 6 (Table 9), together with an outline of their defence system impact.

Each substance / substance group was analysed with regard to:

- Criticality for defence;
- REACH Risk Management Option (RMO) status;
- Industry initiative(s) for the substance(s).

In addition, case studies have been included in some instances to illustrate specific impacts.

D.1 Phthalates

CRITICALITY FOR DEFENCE

According to the defence stakeholders consulted bis(2-ethylhexyl)phthalate (DEHP) (CAS 117-81-7) and dibutyl phthalate (DBP) (CAS 84-74-2) have been used in the following domains, not limited to military applications (dual use):

- Propellant formulation;
- Some coatings and bonding stop-off;
- As plasticisers for jointing compounds and polymer insulations, for cables, wiring and plastics.

The use informed in ejection seat explosive cartridge is a military use only.

Whereas substitution has occurred to a large extent until now, continued use is still mandatory to some extent for munitions and air domains.

RMO STATUS

Annex XIV sunset dates for DEHP and DBP have passed on 21.02.2015.

Authorisation applications of relevance for defence have been submitted by Rolls-Royce (consultation number 0001-01), Deza (0005-02) and Roxel-Rocket Motors (0007-01 and 0007-02).[287] In the meantime authorisations have been granted by the EC in all cases, with review periods ranging from 4-12 years.[288]

REACH defence exemptions are not known. One exemption request was under examination in 2015 for DBP in propellant (powders for small calibre cartridges), but then it was withdrawn following change to a DBP supplier inside the EU covered by a REACH authorisation.

Some MoDs have pointed out the continued importance of DBP in propellants and the risk of supply chain disruption due to Annex XIV listing, which puts the security of military procurement at risk.

[287] See Annex G.1.

[288] See EC list of REACH Authorisation Decisions, available at https://ec.europa.eu/growth/sectors/chemicals/reach/authorisation_fi.

Since in the case of DBP there is today only one (authorised) supplier left, **a monopolisation of the market has occurred due to REACH authorisation**.

On 1 April 2016 ECHA - in collaboration with the Danish CA - has submitted an Annex XVII restriction proposal under REACH Article 69(2) for the use of the four phthalates (DEHP, BBP, DBP, DIBP) in articles.[289] A tangible impact of this proposal for the defence sector has not yet been identified.

INDUSTRY INITIATIVE(S) FOR THE SUBSTANCE(S)

Industry initiatives for the substance(s) were not identified and consulted by the Contractor on appropriate regulatory risk management, since Annex XIV inclusion has already occurred.

D.2 Lead chromate (CAS 7758-97-6)

CRITICALITY FOR DEFENCE

Lead chromate is still used in the defence sector today as igniting pellet and ignition retarder. It is a military use only.

RMO STATUS

The Annex XIV sunset date for lead chromate has passed on 21.05.2015.

In one MS an authorisation application for continued industrial use of lead chromate in manufacture of pyrotechnical delay devices contained into ammunition for naval self-protection (consultation number 0028-01) has been submitted in November 2014.[290] On 11 September 2015 the compiled RAC and SEAC opinions suggesting a review period of 7 years (SEAC) and additional conditions / monitoring arrangements were issued.[291] The final EC decision is still pending.

In another MS a number of defence exemptions were granted for continued use of lead chromate in ammunition after the sunset date. The exemption is used to cover the time until the targeted replacement is available.

The reasons for the different MS approaches could not be investigated during the limited course of the study and need to be examined further after the study is concluded (see Section 9.5.7).

[289] ECHA, Annex XV Restriction Report Proposal for a Restriction for Four Phthalates (DEHP, BBP, DBP, DIBP) (1 April 2016).
[290] See Annex G.1.
[291] To be downloaded at https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation-previous-consultations/-/substance-rev/5601/del/50/col/synonymDynamicField_302/type/asc/pre/2/view.

INFO BOX: Risks associated with substitution of Annex XIV substances in ammunition

Ammunition manufacturers have highlighted the aspect of safety of (well-known) military applications, while the search for substitutes can cause more risks to human health than the continued use of a known SVHC, due to the physical dangers related to explosives.

In ammunition manufacturing, the chemical compositions have been used for a very long time and are therefore well-known in their behaviour and relatively "safe" to handle (because one knows what to expect). However, when trying to substitute a certain substance in this mixture, unforeseen behaviour is very likely and has occurred in several occasions.

For example, when trying to find substitutes for lead chromate one explosive composition turned out to be unstable under light pressure and exploded which lead to destruction of an entire laboratory with minor injuries to one employee. Besides from the financial loss related to this accident, it highlights that handling explosives and "randomly altering the composition" in the hope to find a SVHC-free formulation implies great risks due to the physical hazards related to these compositions.

In such conditions, the risk related to finding a new explosive composition may be seen as disproportionate to the benefit of having SVHC-free ammunition; especially since long-term behaviour of such "new" compositions cannot be verified. Given that ammunition is sometimes used after several years of storage, the risk of unwanted behaviour of a new composition is striking; with possible deadly consequences for the soldiers.

Ammunition manufacturers in the EU defence industry suggest, that this special aspect of safety of (well-known) military applications is duly reflected in the ECHA guidance on authorisation.

INDUSTRY INITIATIVE(S) FOR THE SUBSTANCE(S)

Industry initiatives for the substance(s) were not identified and consulted by the Contractor on appropriate regulatory risk management, since Annex XIV inclusion has already occurred.

D.3 Trichloroethylene (CAS 79-01-6)

CRITICALITY FOR DEFENCE

Defence stakeholders have reported the following uses of trichloroethylene in different domains (air, naval, land, munitions and explosives, other):

- heat exchangers (cooling systems) for military applications. Here it was reported that the substance was substituted as heat exchanger, but the substitution was not successful. Research for a suitable alternative is ongoing.
- manufacture of energetic materials;
- degreaser for the surface cleaning of some metallic components;
- gas turbine engines.

Based on failed substitution efforts mentioned at least in one case there is understood to be continued dependence on the substance in the defence industry.

RMO STATUS

The substance is listed in Annex XIV. The sunset date passed on 21 April 2016. Hence, continued uses as a substance in EU for military applications require a REACH authorisation or defence exemption.

INDUSTRY INITIATIVE(S) FOR THE SUBSTANCE(S)

Industry initiatives for the substance(s) were not identified and consulted by the Contractor on appropriate regulatory risk management, since Annex XIV inclusion has already occurred.

D.4 Cr(VI) compounds

CRITICALITY FOR DEFENCE

Chromium trioxide (CAS 1333-82-0) and other Cr(VI) compounds[292] have been used for many decades for metal surface treatment (corrosion protection, electrical continuity, equipotential bonding) in a very wide range of sectors such as airplanes, launchers and spacecraft, ships, land vehicles, cannons or connectors.

Continued use in the foreseeable future is considered critical by more or less all defence stakeholders consulted. The use is typically dual use, i.e. comprising both military and civil applications.

Whereas R&D activities aiming at the substitution of Cr(VI) substances have been going on within the A&D sector for many years and supported by some national MoDs, including through joint projects at the EDA (see Annex E.1, "ECOCOAT"), successful substitution in all applications will take time.

Defence sector stakeholders expect most new solutions to be less durable than the very efficient and "one-size-fits-all in terms of performance" of existing Cr(VI) solutions for many kinds of surface treatments.[293] For example presently a tank barrel coated with Cr(VI) resist 100 shots, one nickel coated only 10 shots. Also airplanes or ship corrosion resistance is noted to be lower due to changed coating. Therefore, if Cr(VI) has to be replaced, shorter maintenance intervals are expected resulting in higher maintenance costs and putting into question the capability of the MRO sector to cope with significant reductions in inspection periods.

INFO BOX: Addition of maintenance centres for Zn and Ni-based surface treatment processes[294]

When new surface treatment processes are put in place, new buildings have to be built with new containers (in the range of 50,000 to 100,000 litres, according to the processes) inside them in order to continue the maintenance processes with Cr(VI) and Cd in the old buildings and move to the Zn and Ni salts based processes in the new buildings, and new control measures have to be put in place.

RMO STATUS

The latest application date for chromium trioxide and some other Cr(VI) compounds has passed on 21.03.2016. The sunset date for these compounds will be on 21.09.2017.

A significant number of applications for authorisation have been submitted to ECHA in 2015 and the first half of 2016 for chromium trioxide and other Cr(VI) substances.[295]

[292] For lead chromate see above Annex D.2.

[293] The same applies to cadmium (see Annex D.12).

[294] Source: MoD of a MS with a strong Defence Technology and Industrial Base.

The important joint upstream application for authorisation for chromium trioxide by the CTACSub Consortium has different uses applied for surface treatment for applications in the aeronautics and aerospace industries (dossier number 0032-04) and various other industry sectors namely architectural, automotive, metal manufacturing and finishing, and general engineering (dossier number 0032-05). This could potentially result in different **review periods** for **aerospace, land and other** defence systems and components. The EC decision is expected in 2017.

According to defence industry stakeholders consulted the non-availability of Cr(VI) would significantly affect the availability of qualified surface treatment systems on military airframes and electrical connectors. The effectiveness of these protective treatment systems has been proven. The effectiveness of the available alternatives is known to be inferior in many cases.

On 13 May 2016 the European Commission (DG EMPL) has proposed the introduction of an EU-wide binding Occupational Exposure Limit (bOEL) of 0,025 mg/m^3 for chromium (VI) compounds which are carcinogens under the Carcinogens or Mutagens Directive 2004/37/EC (CMD).[296] If agreed by the European Parliament and the Council, the bOEL has to be implemented by the Member States not later than two years after the date of entry into force of the Directive.[297]

The EC proposal points out that CMD and REACH are legally complementary. This means that industry would have to comply both with the DNEL (REACH authorisation) and bOEL limits, whichever is lower.

The judgment of the CJEU of 25 September 2015 in case T-360/13 (VECCO) on the possible application of REACH Article 58(2) (exemption from authorisation to be included in Annex XIV) when OELs are set, should be noted.[298] The judgment is currently under appeal.

INDUSTRY INITIATIVE(S) FOR THE SUBSTANCE(S)

Industry initiatives for the substance(s) were not consulted by the Contractor on appropriate regulatory risk management, since Annex XIV inclusion has already occurred.

CASE STUDY: AUTHORISATION IMPACT ON CHROMATES

The Annex XIV inclusion of Cr(VI) compounds has **affected a plethora of industries throughout the EU, including the defence sector**. The defence-related impacts were on all areas of the defence sector; land, sea, air, space systems as well as munitions.

Defence products are strictly regulated against international standards and are subject to rigorous product safety and quality requirements. This limits the scope of what can be used and in turn the suitability of alternative products and processes. Cr(VI) substances are one of many SVHCs that some defence systems depend upon. These substances are used primarily because they provide high levels of corrosion resistance, in combination with hardness and wear resistance for many decades. The use can sometimes be mandated by the defence prime contractor, e.g. fighter aircraft manufacturers, and any deviation would require prohibitive requalification of the system.

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[295] See also Annex G.1 and G.2.

[296] Proposal COM(2016) 248 final for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

[297] For France it has been noted that the EC proposal will have no impact because the French OEL is already much lower: 0,005 mg/m^3 for OEL "15minutes" and 0,001 mg/m^3 for OEL "8hours" [Art. R4412-149 (M) and decree number 2012-746 of 9 May 2012].

[298] See summary of judgment in Annex J.

Unavailability of these substances will significantly impact the **supply of many defence systems** compliant with current performance and reliability requirements. **Maintenance activities** for defence hardware are also impacted by Annex XIV listing. Indeed there have been issues within e.g. the maintenance of vehicles where previously specified maintenance and repair materials have become unavailable, like sealants containing Cr(VI).

The **costs** of preparing an authorisation dossier are considered high even with the collaboration between formulators and downstream users in preparing dossiers. From questionnaire responses, the average amount of money spent by those companies who were involved in seeking authorisation themselves, or were in a consortium for a Cr (VI) substance was € 345,448. Examples of these costs are preparing and/or reviewing the dossiers submissions with in-house experts, payment to consultants, consortium management, information gathering, in-house staff to deliver technical inputs, contributions to submission groups to pay ECHA fees including technical advocacy and trade association activities.

Difficulties experienced by defence industry stakeholders that contributed to the preparation of Cr(VI) dossiers, and that were consulted during this study were that the **RAC and SEAC committees** appeared to be applying the same standards and expectation for upstream and downstream applications. It was noted that the defence industry believed that the level of detail for a downstream application cannot be replicated for upstream applications in such complex supply chains.

Many companies that responded noted that the experience of the chromate authorisation process demonstrated that the **preparation of an authorisation dossier is extremely demanding** requiring experts in several fields, and high monetary and manpower investment – even when a company did not apply for authorisation itself but were rather members of a consortium whose upstream actors applied. Indeed many companies that responded were in several Cr(VI) authorisation consortia for different uses and Cr(VI) containing substances, e.g. CTAC, CCST, STF, etc. and incurring associated costs. Involvement in consortia was described as being complex, expensive and time consuming challenges defence companies had experienced during the course of Cr(VI) authorisation activities.

Preparing and/or reviewing the dossiers submissions with in-house experts, payment to consultants, consortium management, information gathering, in-house staff to deliver technical inputs, contributions to submission groups to pay ECHA fees including technical advocacy and trade association activities were all cited as complex, costly and time consuming challenges defence companies had experienced during the course of Cr(VI) authorisation activities.

D.5 Cobalt salts

CRITICALITY FOR DEFENCE

Uses of cobalt salts are exceptionally broad, they are used in over 25 sectors.

In the defence sector cobalt salts are used in processes for nickel-based corrosion protection and in wear coatings (dual use). These could include ‘super-alloys’ for wrought alloy parts used in aerospace (where it is usually used in jet engines and landing gear as cobalt confers very good properties of resistance to temperature extremes and to wear). The uses are considered as critical by some defence stakeholders. Replacement activities are not known.

Furthermore, according to the Cobalt Development Institute (see below) reliable sources indicate that there is a very specific military application as a **humidity indicator** which is either a part of or used to protect the integrity of weapon systems. This humidity indicator requirement is indicated in

multiple military specifications. This is where also Co dichloride is used as there is no known alternative[299] in an application to protect hydraulic braking systems. Humidity indicator cells that contain Co salts listed on the Candidate List are only manufactured outside the EU. The manufacturer estimates that it supplies the majority of the defence market worldwide and 75% of the EU market, which uses less than 100kg cobalt salt per annum.

Cobalt is listed by the EC as **Critical Raw Material** (CRM).[300]

RMO STATUS

Five cobalt salts were recommended by ECHA for Annex XIV inclusion in 2011. However, following inputs by the cobalt industry highlighting the disproportionality and lack of regulatory effectiveness of the proposal, as well as the unintended socio-economic impact of Annex XIV inclusion the EC referred the case back to ECHA for further analysis of the uses. Final ECHA conclusions were expected to be sent to the EC in autumn 2016 who will decide on the most appropriate recommendation. The regulatory outcome is uncertain at this stage.

The Netherlands is now also preparing a CLH proposal for *cobalt metal* as Carc. 1B. The cobalt industry has already self-classified cobalt metal since 2013 but the current CLH proposal could unintentionally affect many alloys including most stainless steels as the level of cobalt (present as an impurity in nickel and other base metals or intentionally added in alloys, including super-alloys) is higher than the proposed over-stringent Specific Concentration Limit (SCL) of 0.01%.

An EU-wide OEL has been under consideration. It would contribute to harmonise national OELs, which are still very different today.

INDUSTRY INITIATIVE(S) FOR THE SUBSTANCE(S)

The Contractor has gathered information from the Cobalt Development Institute (CDI)[301] / Cobalt REACH Consortium Ltd (CoRC).[302][303] The cobalt industry supports very strongly the Cross-Industry Initiative. It advocates for the RMOA to be performed earlier and for the consideration of the other RMOs (than Authorisation or Restriction) mentioned by the SVHC Roadmap 2020, such as an EU-wide harmonised OEL in the case of industrial substances (as are the five cobalt salts) or voluntary industry measures. Inclusion in Annex XIV is considered disproportionate for the five cobalt salts.

The CDI, who is also a member of the CRMs Alliance, would like to see a more balanced approach (based on RMOA) for CRMs in the EU policies and regulations.

D.6 ADCA (CAS 123-77-3)

CRITICALITY FOR DEFENCE

C,C'-azodi(formamide)) (ADCA) is used in the munitions domain as “smoke” in various smoke ammunition types or IR illumination products. According to some MoDs this use is critical. Information on R&D is not available.

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[299] Other alternatives/chemistries do not have the required performance (of 90% RH) that only Co can deliver.

[300] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52014DC0297.

[301] http://www.thecdi.com/reach-consortium.

[302] http://www.cobaltreachconsortium.org.

[303] Interview on 20 July 2016.

RMO STATUS

ADCA was included in the candidate list as respiratory sensitizer following proposal from Austria and recommended for inclusion in Annex XIV by ECHA in 2014. The decision is now with the EC.

An EU-wide bOEL does not exist at the moment. An OEL exists in the UK. By contrast, in Germany it was decided recently, that no national bOEL can be determined for ADCA, because sufficient information from experience with humans and animal testing is lacking.[304]

INDUSTRY INITIATIVE(S) FOR THE SUBSTANCE(S)

The Contractor has contacted the ADCA Task Force for REACH in the frame of the study. The military use is known to them. It is understood that inclusion in candidate list and Annex XIV are considered disproportionate to the risk when handling this highly important chemical. An OEL similar to the UK one is considered to be the best way to efficiently control the risk potentially coming from ADCA, which is only used at the workplace. The ADCA Task Force participates in the Cross-Industry Initiative.[305]

D.7 Refractory Ceramic Fibres

CRITICALITY FOR DEFENCE

Refractory Ceramic Fibres (RCF)[306] are used as heat protection insulator used in a flight safety-critical recording system, used on all military and civil aircraft. Any replacement material would need to afford similar insulation protection. Continued use is considered as critical, as there is no known validated alternative. RCF material is available from only a small range of suppliers. According to the consultation of the defence industry production could be switched to existing facilities outside EU, should RCF material eventually migrate to Annex XIV.

RMO STATUS

RCF were recommended for inclusion in Annex XIV by ECHA in 2014. The decision is now with the European Commission and the Article 133 REACH Committee of Member State representatives.

On the point of potentially regrettable substitution, it should be noted that – while not specifically developed for that purpose - RCF was once the replacement for asbestos in a few niche applications. It has itself been subject to substitution requirements since its classification as carcinogen in 1997.

With its proposal of 13 May 2016 the European Commission (DG EMPL) has also proposed the introduction of a bOEL for RCF which are carcinogens (0,3 f/ml) under Directive 2004/37/EC (CMD).[307] The aerospace and defence sector and the aforementioned use of RCF were not explicitly mentioned in the EC's impact assessment for the proposal of 13 May 2016.[308] For the possible implications of this EC proposal in case of its adoption reference is made to Annex D.4 above for Cr(VI) compounds.

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[304] http://www.dfg.de/dfg_profil/gremien/senat/gesundheitsschaedliche_arbeitsstoffe.

[305] http://www.cii-reach-osh.eu.

[306] Aluminosilicate Refractory Ceramic Fibres (Al-RCF), Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF), Index number in CLP Annex VI: 650-017-00-8.

[307] Proposal COM(2016) 248 final for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

[308] See Commission Staff Working Document (SWD(2016) 152 final of 13.5.2016, Table 1, column *"relevant sectors"*, p15: *"Manufacturing (fibre production, finishing, installation, removal, assembly operations, mixing/forming)"*.

INDUSTRY INITIATIVE(S) FOR THE SUBSTANCE(S)

The Contractor has contacted ECFIA, the association representing the "High Temperature Insulation Wool Industry" in the frame of the study. ECFIA supports the Cross-Industry Initiative. It advocates an EU-wide bOEL for RCF.[309] Inclusion in Annex XIV is considered as disproportionate for this substance.

For the aerospace and defence domain, an Annex XVII restriction with derogation for aerospace with appropriate, more severe, health and safety requirements has been suggested by the UK's NDIA, ADS, as an alternative Risk Management Option.

D.8 Boric Acid (CAS 10043-35-3)

CRITICALITY FOR DEFENCE

Boric acid has very critical uses (typically both civil and military use) in the following areas:

- electrolytic deposition of metals such as Ni, SnPb, Co, Cd; CCC; cleaning/descaling /biocide; acidity regulators; anodising, metal working fluids, soldering / brazing fluxes and flux solutions;
- control and emergency stop of nuclear reactions;
- submarine propulsion.

According to the defence stakeholders consulted R&D related activities for substitution have not started yet, with only few exceptions. It was also expressed that the expectation would be on the process suppliers to provide process alternatives for use in their treatments.

Borates are listed by the EC as Critical Raw Materials (CRM).[310]

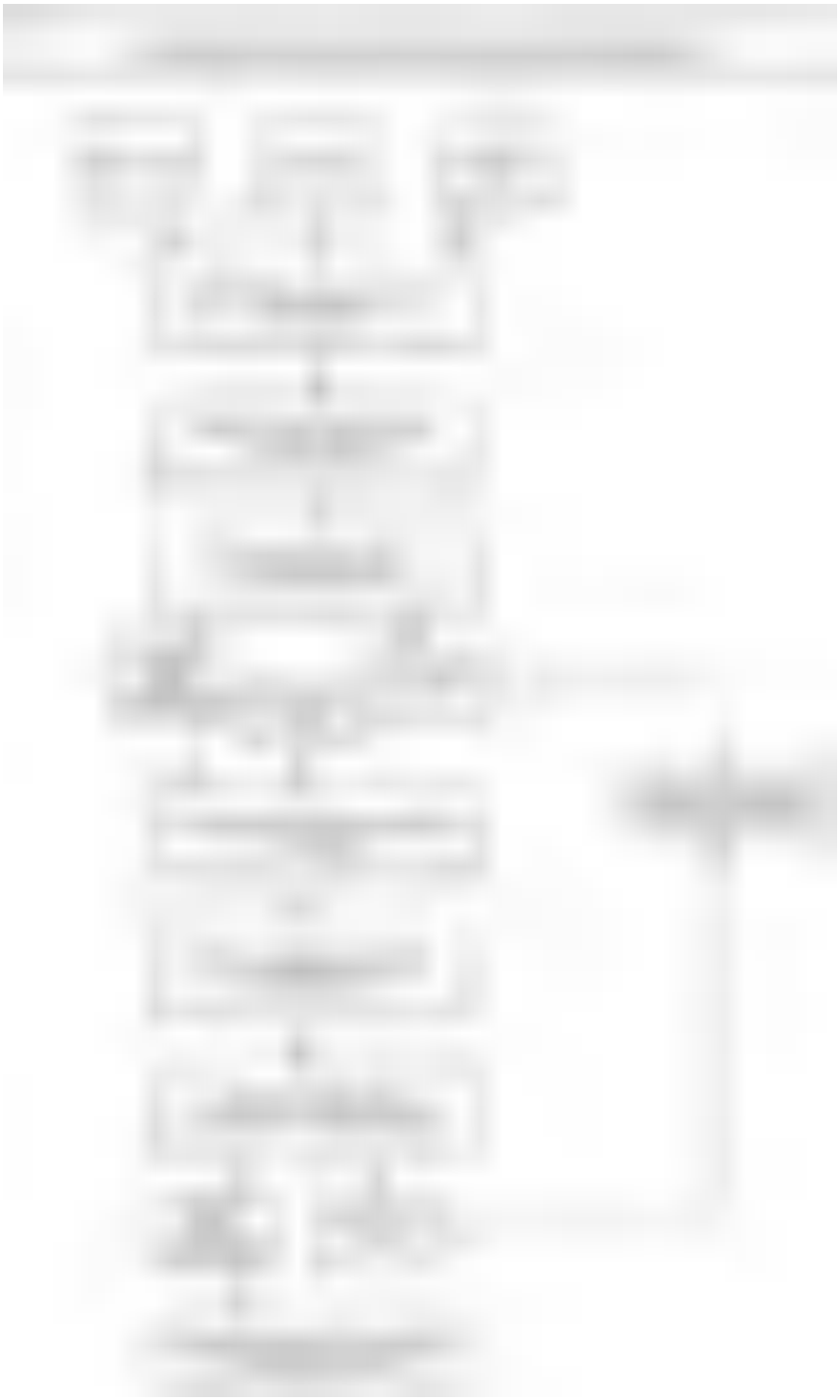
CASE STUDY: GALLIUM ARSENIDE (GaAs) SEMI-CONDUCTORS' RELIANCE ON BORON OXIDE; HIDDEN OBSOLESCENCE FOR PROCESS CHEMICALS

Boron substances may illustrate well the issue of hidden obsolescence risks with regard to process chemicals. For example, the substance diboron trioxide (EC 215-125-8) is used as a process chemical in the manufacture of GaAs (for GaAs see Annex D.17 below). Just like boric acid, diboron trioxide has been prioritised by ECHA for Annex XIV inclusion in 2015. Annex XIV inclusion would have a major impact on the main EU manufacturer of GaAs, because the non-EU supplier does not wish to apply and would stop supply on that case, while the substance is not available from within EU in the quality required for semiconductors.

GaAs is synthesised by the reaction of gallium and arsenic to form polycrystalline GaAs. This material is then melted and regrown using a highly controlled process to form single crystal ingots which can be processed into wafers using boron oxide (Figure 21).

[309] www.ecfia.eu/has_reach_asw.htm
[310] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52014DC0297.

Figure 21 Use of Boron Oxide during manufacturing of Gallium Arsenide



The process occurs at high temperatures and pressures and is highly reliant on liquid boron oxide to avoid arsenic loss during the heating period of the synthesis. At the end of synthesis the crucible is taken out of the vessel and the GaAs ingot is separated from the boron oxide. After etching the material is ready for single crystal growth.

Further, the GaAs so produced is further processed in several steps to produce mono-crystalline GaAs and further into GaAs wafers. Boron oxide is an essential reagent in these processes.

There are no alternatives available to fulfil this use.

RMO STATUS

Boric acid was recommended for inclusion in Annex XIV by ECHA in 2015. The decision is now with the EC. Annex XIV inclusion would have a major impact for the defence sector.

INDUSTRY INITIATIVE(S) FOR THE SUBSTANCE(S)

The Contractor has contacted the International Minerals Association for further information. Since the expert in charge left the association in August 2016, it was not possible to get feedback during the course of this study.

D.9 Lead and its compounds

CRITICALITY FOR DEFENCE

Lead and its compounds are widely used and considered as very critical for the defence sector in several domains including munitions, lead batteries, soldering for EEE and others (dual use). The main applications of lead metal and its compounds in the EU defence sector are given in Table 20 below.

Table 20 Overview of applications of lead and its compounds in the European defence sector

Domain	Substances
Primer caps and detonators; in ammunition and explosives	lead styphnate (CAS 15245-44-0)* lead tetroxide (orange lead) (CAS 1314-41-6)* lead diazide (CAS 13424-46-9)* lead monoxide (CAS 1317-36-8) - *used in manufacture of lead diazide i.e. as an intermediate* other lead salts **affects a very high munitions group*
corn of bullet ammunition	lead (CAS 7439-92-1)[311]
lead batteries	lead (CAS 7439-92-1) lead monoxide (CAS 1317-36-8) lead diazide (CAS 13424-46-9)
solder material for EEE dry lubricant coating babbitt alloys in bearings lead-containing alloys such as brass and leaded-steels	lead (CAS 7439-92-1)

[311] Info from Lead REACH Consortium on 2 August 2016: The CSR excludes military use from the 'professional use of lead ammunition' exposure assessment (which is really article service life), but the production of ammo and lead shot is currently covered by the generic exposure scenario 'Use of Lead metal in production of a range of lead articles (e.g. cast, rolled and extruded production, ammunition and lead shot) (IU6)'."

antigallants anti-fret Additional uses of *possible* relevance, informed by the Lead REACH Consortium: lead-containing articles such as anchors, weights, counterweights etc. lead sheet used for radiation screening	
Additional uses of *possible* relevance, informed by the Lead REACH Consortium: "red lead paints" – rust-inhibiting priming paints applied directly to iron and steel (mainly ships)	lead tetroxide (orange lead) (CAS 1314-41-6)
Ingredient of PZT[312] in manufacture of sensor ceramics	lead monoxide (CAS 1317-36-8)

INFO BOX: Substitution of lead (Pb) based primary explosives

Lead salts are considered as **the pillar of the ignition in a munition**. Whilst they are toxic to humans, these materials have been used for over a hundred years as initiatory explosives in various caps and detonators. From an explosives viewpoint, the safety and reliability characteristics of these materials, over a wide temperature range is well known, and as such proposed alternatives do not have the range of historical data to confirm their safety and reliability.

There is a degree of uncertainty in the supply chain. Some lead salts could become commercially obsolete because the pyrotechnical use is specific and for small quantities (e.g. in the range of only a few tens of kilos each year for a company). In case of Annex XIV listing the producer may refrain from authorisation due to the high costs in regard of the market.

Generally - according to defence stakeholders consulted - it is very difficult to find alternatives to heavy metals in primary explosives since MoDs need them to be as small as possible in terms of volume so the best candidates to provide the necessary power for sufficient length in a small volume end up being heavy (i.e. high density) metals like lead salts. There are a number of alternatives under proposal, and R&D work. If alternatives offering the same level of small volume (to avoid complete redesign of ammunition, which is not acceptable for that constraint only) are found someday, there will be a need to fully qualify these alternative materials, possibly even requiring system qualification to ensure safety and reliability. The supply chain is working on lead free alternatives, but it is known that there are concerns with some materials and their reliability, especially at low temperatures. Defence industry stakeholders have and will continue to discuss alternatives with the supply chain.

The of alternatives to lead salts is also an issue, e.g. the cost of silver azide for replacing lead azide has been reported to be at least four times higher.

[312] For lead titanium zirconium oxide (PZT) (CAS 12626-81-2) see Annex D.11 below.

RMO STATUS

Lead and its compounds are advanced to a different level in the REACH authorisation process, as shown in Table 21 below.

Table 21 REACH Annex XIV status of lead and its compounds

Lead and its compounds	REACH status
lead tetroxide (orange lead) (CAS 1314-41-6)	Annex XIV recommendation (2016)
lead monoxide (CAS 1317-36-8)	Annex XIV recommendation (2016)
lead styphnate (CAS 15245-44-0)	Candidate list (Score in 2015: 17)
lead diazide (CAS 13424-46-9)	Candidate list (Score in 2015: 14)
lead (CAS 7439-92-1)	CLP Annex VI Repr. 1A; RMOA underway (SE)

Lead and its compounds have a binding European OEL of 0.15 mg/m^3 and a binding European Biological Limit Value.[313]

INDUSTRY INITIATIVE(S) FOR THE SUBSTANCE(S)

The Contractor has contacted the International Lead Association (ILA), managing the Lead REACH Consortium, in the frame of the study. Of the lead substances shortlisted by defence stakeholders (see above) members of the Lead REACH Consortium have registered and are engaging in regulatory defence (including dossier updates, advocating their proportionate regulation based on sound science) for the following substances: Lead metal, lead monoxide, lead tetroxide.

By far the most commercially relevant use to the Consortium is the use in the production of **lead-based batteries**[314] – the four compounds in the 7th ECHA Annex XIV Recommendation are used in production but are only present in trace amounts in the final, sealed, battery (<0.1% by weight). For the prioritised lead compounds, the most important aspect of the Consortium's advocacy work has been, and continues to be, the call for an **exemption under REACH Article 58(2)** for uses in the manufacture of automotive and industrial lead-based batteries with regard to several pieces of **existing "lead specific" EU legislation** protecting human health and the environment.[315] The Lead REACH Consortium and EUROBAT are also participants of the Cross-Industry Initiative.

For **lead metal**, the follow-up after the 9th ATP on CLP and ECHA's work on lead in ammunition with regard to possible restriction proposals (this activity is understood to not directly affect the defence sector) are being investigated / monitored. Defence industry stakeholders are very concerned about the new harmonised substance classification of lead (massive and as powder) adopted by the 9th ATP on CLP.[316] This classification provides for the rule that metal alloys containing lead in a concentration >0.3 (or >0.03%) will automatically also need to be classified as Repr. 1A. As a result, the use of brass metals (very widely used in defence applications and civil industry, too) might become subject to authorisation if lead was included onto the REACH candidate list and Annex XIV as proposed by Sweden and Denmark in 2014. This would have a major impact on the European defence industry.

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[313] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work.

[314] EUROBAT is the association representing all battery technologies in Europe (lead, lithium, sodium, nickel-cadmium), see www.eurobat.org.

[315] See e.g. http://ila-reach.org/wp-content/uploads/2016/07/Consolidated-paper-Pb-compounds-alliance.pdf.

[316] Commission Regulation (EU) 2016/1179 of 19 July 2016. This Regulation shall apply from 1 March 2018.

See also Annex M of this report for a case study on commercial obsolescence for lead due to RoHS in spite of disapplication for aerospace and defence-related use.

D.10 Hydrazine (CAS 302-01-2)

CRITICALITY FOR DEFENCE

In the defence sector hydrazine is strategic for its use as a propellant fuel in

- fighter Jet Emergency Power Units (e.g. F-16);
- launcher and satellite propulsion (dual use, see case study below);
- submarine propulsion.

It is also used for oxygen scavenging in nuclear power plants.

INFO BOX: Use of hydrazine in fighter Jet Emergency Power Units (F-16)

Defence sector stakeholders have reported that the Emergency Power Units only work with hydrazine; therefore the substance is vital to Fighter Jet missions. Main challenges to ensure continued use under REACH are dependence on upstream suppliers and possible commercial obsolescence. R&D replacement activities for hydrazine specifically in the defence sector are not known. Some MoDs expressed their interest in following the hydrazine issue and assessing the best strategy to deal with it (substitution, authorisation, exemption). Based on a collection of information the use of hydrazine in fighter Jet Emergency Power Units (F-16) was identified as the only use by these MoDs. The further course of action is still to be determined.[317]

RMO STATUS

Hydrazine is included in the candidate list.

With its proposal of 13 May 2016 the European Commission (DG EMPL) has also proposed the introduction of a bOEL for hydrazine (0,013 mg/m^3, 0,01 ppm, skin notation[318]) under the Carcinogens or Mutagens Directive 2004/37/EC.[319] The aerospace and defence sector including the aforementioned uses of hydrazine were not mentioned in the Commission's impact assessment for the proposal of 13 May 2016.[320] For the possible implications of this proposal in case of its adoption reference is made to Annex D.4 above for Cr(VI) compounds.

INDUSTRY INITIATIVE(S) FOR THE SUBSTANCE(S)

A number of industries reaching beyond the defence sector are interested in hydrazine as suppliers / users. The following initiatives in relation to REACH and Annex XIV are known to the Contractor and have been contacted in the frame of the study:

[317] It is an initiative proposed by interested EDA pMS, currently under examination within the EDA framework.

[318] Substantial contribution to the total body burden via dermal exposure possible.

[319] Proposal COM(2016) 248 final for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

[320] See Commission Staff Working Document (SWD(2016) 152 final of 13.5.2016, Table 1, column *"relevant sectors"*, p15: *"chemical blowing agents; agricultural pesticides; water treatment"*.

- *Hydrazine REACH Space Task Force*: An exemption position paper by ASD-Eurospace of 2012 is pending legal clarification by the European Commission (see case study below).
- The *French nuclear sector* has worked together to highlight the strategic importance of hydrazine in nuclear power plants. – *Feedback could not be obtained in the frame of the study.*
- *EPMF (Precious Metals & Rhenium Consortium - PMC)* has been working on the collection of factual data related to the use of hydrazine in the Precious Metals industry (analysis of alternatives, workplace exposure, OEL compliance) to help refine the priority score.
- Hydrazine manufacturers have been working together for joint registration and have contributed additional information to the ECHA prioritisation process in order to help refine the Annex XIV priority score.

CASE STUDY: HYDRAZINE PROPELLANT USE

Hydrazine (EC 206-114-9) has been included in ECHA's candidate list on 20 June 2011 and may be prioritised for inclusion in Annex XIV of REACH at any time. It is not clear whether / when ECHA will take the substance forward in the frame of an Annex XIV recommendation.

In the European **space** industry hydrazine anhydrous is a critical propellant for satellite and launcher programmes. All major European programmes such as Ariane 5, Soyuz, Vega, Galileo,[321] GMES and other satellites produced for public Agencies or for private operators use hydrazine. Due to the candidate list inclusion a task force, open to all users of hydrazine in the European space industry, was set up in October 2011 under co-ordination of the European Space Agency (ESA) with the aim of determining the route to follow: Authorisation or exemption. To this end, and industry survey was conducted to obtain a complete understanding of the different handling steps and conditions of use, and allow an assessment of the applicability of REACH authorisation exemption clauses. As a result of this assessment, an exemption from authorisation was deemed feasible and documented in detail in the **ASD-Eurospace Position Paper of 9 May 2012**[322], which concluded that: *"Based on the assessments carried out, the European space industry is of the opinion that all propellant-related use of hydrazine for space applications is exempted from REACH authorisation subject to the criteria given in this paper."* The main exemption clause applied is REACH Article 56(4)(d) 2nd alt. for *"use as fuels in closed systems"*. Since the exemption clause has not been applied before and the terms are not further defined in REACH, Eurospace has submitted the Position Paper to the European Commission in order to obtain a legal clarification.[323] With the clarification still pending, a parliamentary question was made to the EC on 9 May 2016,[324] asking when the Commission will provide feedback on the Eurospace position paper. On 28 July 2016 the EC replied:[325] *"As long as hydrazine is not included in Annex XIV to the REACH Regulation, the authorisation requirement does not apply to that substance. Therefore, questions about the applicability of specific exemptions to certain space-related uses are of*

[321] Galileo has been mentioned as an example of a space programme that, even though civilian may have military or security-related users; see ESA website, interview with Jean-Jacques Dordain: http://m.esa.int/About_Us/Jean-Jacques_Dordain/The_European_Space_Agency_director_general_in_interview.

[322] ASD-Eurospace, Position Paper Exemption of propellant-related use of hydrazine from REACH authorisation requirement (14 June 2012).

[323] In the meantime ECHA has clarified that the exemption in REACH Article 56 (4)(d) also covers the lifecycle steps preceding the end-use as a fuel, see Q&A ID 1028, available at http://www.echa.europa.eu/web/guest/support/qas-support/qas.

[324] http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+WQ+E-2016-003827+0+DOC+XML+V0//EN .

[325] http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2016-003827&language=EN .

limited practical relevance. The Commission will respond to the issues raised by the European Space Industry, as soon as an agreed interpretation of the relevant provisions of REACH has been reached among the Commission and the Member States."

With regard to the possible REACH impacts the space applications of hydrazine, as well as monomethylhydrazine (MMH) and unsymmetrical dimethylhydrazine (UDMH) are currently addressed jointly by ESA, EC and EDA in the frame of "Critical Space Technologies for European Strategic Non-dependence".[326]

D.11 Lead titanium zirconium oxide (PZT) (CAS 12626-81-2)

CRITICALITY FOR DEFENCE

PZT is used for the manufacture of piezoceramics, which are essential in various defence systems and components, i.e.:

- Aerospace: vibration sensing in aeroplanes, helicopters and spacecraft;
- Naval: underwater acoustics (sonar systems for fishing; hydrophones);
- Electronics: Electro-ceramic components;
- Nuclear systems: Aggressive environments (nuclear facilities & turbines); zirconium oxide in nuclear power plants.

The uses have been reported partly as dual use, and partly as military only use.

RMO STATUS

PZT is included in the candidate list (Score in 2015: 15). According to ECHA potential grouping with some other lead substances (CL) is considered.

The substance has been notified to ECHA under REACH Article 7(2), together with other lead oxides.

For sonar systems in military submarines it has been reported that no substitute seems to be realistic in the next decades, in spite of already ongoing research for substitutes. The REACH defence exemption could provide longer-term solution in such an exceptional case (military use only). Readiness to pay the chemical supplier for continued supply in such case is also necessary.

INDUSTRY INITIATIVE(S) FOR THE SUBSTANCE(S)

Industry initiatives for the substance have not been identified as part of the study.

[326] EC/ESA/EDA, Critical Space Technologies for European Strategic Non-Dependence, Actions for 2015/2017: action U5 – Alternative to Hydrazine in Europe and action N37 – Alternative to MMH and UDMH. See also Section 5.4.

D.12 Cadmium (CAS 7440-43-9)

Cadmium has been targeted by several relevant provisions: the RoHS Directive, REACH Annex XVII entry 23 (see already Section 4.2.4) and lately the REACH candidate list. While both RoHS and REACH Annex XVII entry 23 contain aerospace / defence / safety-specific exemptions / derogations, a blanket REACH authorisation – if realised – could potentially include defence applications as well (just like for Cr(VI) substances), with far reaching impacts for the European defence sector.

CRITICALITY FOR DEFENCE

Cadmium has been in use since more than 50 years. The main use of galvanic cadmium plating is for corrosion protection, surface lubrication and improvement of electric conductivity. Almost all electrical connectors are cadmium plated to ensure the safety critical connections of the avionic system in aircrafts. In addition a huge number of European (and US) Standards request cadmium plating. Cadmium and its salts are very widely used and are therefore considered as very critical by defence stakeholders.

Uses informed include more specifically:

- surface treatment: plating applications (e.g. electrical connector boxes, bolts, structural pieces); cadmium is restricted for those uses (Annex XVII entry 23) with derogations for aeronautics, safety and defence. This also includes e.g. aircraft maintenance.
- soldering and brazing alloys with Ag and Cd; Cd is restricted for those uses (Annex XVII entry 23) with derogations for aeronautics, safety and defence;
- Ni-Cd batteries for airplanes and missiles. Ni-Cd rechargeable batteries are, by far, the largest application across different sectors, tonnage wise (>80%);
- submarine propulsion;
- nuclear systems: neutron detection instrumentation;
- infrared detectors.

Just like Cr(VI), cadmium is not only qualified for use on defence platforms (dual use). Cadmium has been tested over a long period of use and offers certainty of performance, quality and safety. Such attributes are not always offered by alternative substances and processes.

Defence industry stakeholders anticipate that authorisation would move these substances (such as Cr(VI) and nickel) from common use to niche use. Consequently, while critical to the defence industry these substances may become difficult to obtain (obsolescence) and more expensive. As an example, the whole infrared detection supply and integration chain in EU would be severely impacted.

Today there are no real alternatives available to cadmium.

Some defence industry stakeholders consulted reported that R&D to replace cadmium in surface treatment applications has been going on for ca. 20 years. Some defence industry stakeholders have launched projects aiming at replacing not only Cr(VI), but also cadmium in aerospace manufacturing processes with fully company own funding. Promising solutions e.g. with nickel salts have been tested but they do not provide the similar or same physical properties. In addition there is the issue of potential 'regrettable' substitution for nickel salts (see below Annex D.18). In addition, research for new ways of plating continues.

Also several MoDs have been engaging in various activities to eventually substitute or reduce the use of cadmium. The EDA has facilitated a project among interested MoDs to substitute chrome, nickel and cadmium on metal surface (**ECOCOAT**) (see further information on this project in Annex E.1).

RMO STATUS

Cadmium (and several Cd derivatives) is included in the candidate list and also already in Annex XVII (entry 23). Based on the latest ECHA priority score (16 in 2015) it could be recommended for Annex XIV in the near future.

INDUSTRY INITIATIVE(S) FOR THE SUBSTANCE(S)

According to the Cadmium Consortium workplace legislation is the most appropriate risk management option for cadmium used only at the workplace.[327] Contacts with the defence sector do not exist at the moment. The Cadmium Consortium is reaching out as much as possible to downstream users in order to gather socio-economic input in case it the EC would ask for it in the frame of prioritisation for Annex XIV. It was also mentioned that Cadmium is amongst the 510 substances to be prioritised under South-Korean "REACH", which foresees registration by 2018.

CASE STUDY: CADMIUM – ENTRY 23 OF ANNEX XVII

Cadmium has been targeted by several relevant provisions: the RoHS Directive, REACH Annex XVII entry 23 and lately the REACH candidate list. For defence the regulatory impact is both direct and indirect.

- **Direct impact**

Various uses of cadmium are restricted in entry 23 of Annex XVII. *Cadmium plating* is prohibited in certain sectors/applications. However, there is a derogation (par. 7) for articles and components of the articles used in the aeronautical, aerospace, mining, offshore and nuclear sectors *"whose applications require high safety standards"*, as well as for *"electrical contacts in any sector of use, where that is necessary to ensure the reliability required of the apparatus on which they are installed."* The further restriction that cadmium shall not be used in brazing fillers in concentration equal to or greater than 0,01 % by weight (par. 8), does by derogation not apply to *"brazing fillers used in defence and aerospace applications and to brazing fillers used for safety reasons"* (par. 9). Furthermore, cadmium is restricted in EEE above 0,01% by weight in homogeneous materials under RoHS, unless the disapplication for specifically military purposes is used (RoHS Article 2(4)(a)). This could potentially lead to a situation that the use of cadmium in EEE is banned under RoHS in spite of the derogation in REACH Annex XVII, entry 23.[328] Therefore it is important to clarify, whether the disapplication of RoHS Article 2(4)(a) requires the consultation of the national MoD (see Chapter 7).

Defence industry stakeholders for land systems have reported issues with the applicability of entry 23: Cadmium plating (Entry 23, section 6) is restricted for articles falling under tariffs code chapter 87. With regard to products under 87.10 (Armoured Fighting Vehicles and their weapons), this also covers certain defence products.[329][330] The companies concerned need to prepare documentation

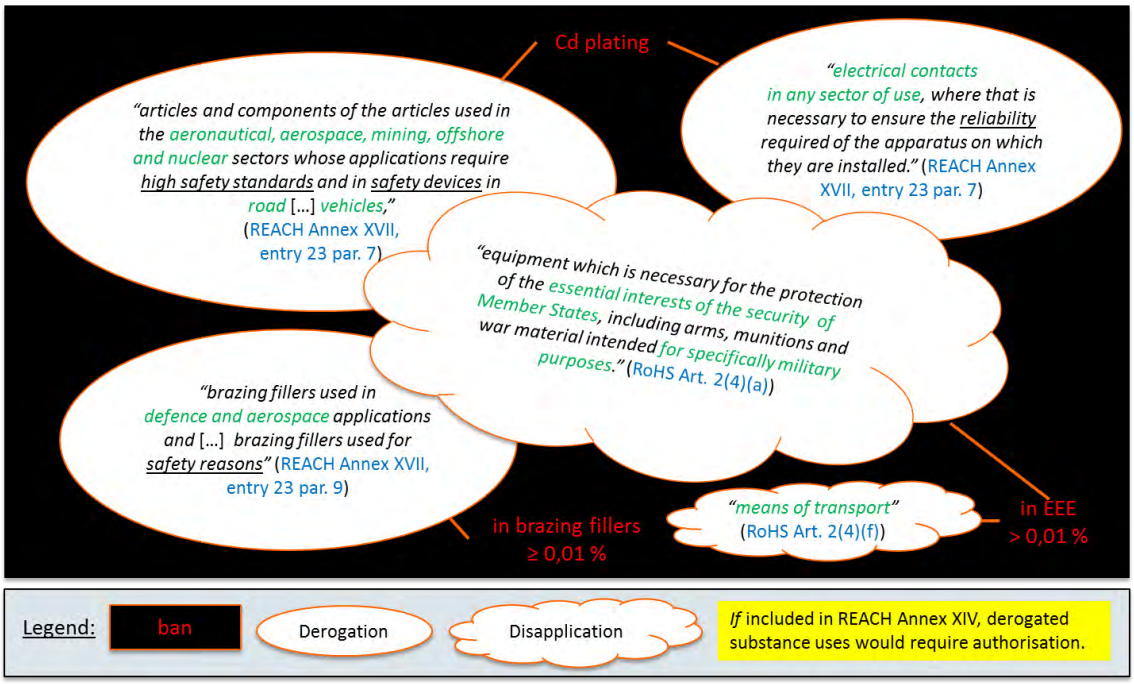
[327] The Cadmium Consortium is also a participant of the Cross-Industry Initiative.

[328] However it should be noted that a number of relevant further exemptions are foreseen in RoHS Article 2 (4), especially for "means of transport for persons or goods" (lit. (f)). This limits the practical relevance of this question.

[329] However, some defence companies are not sure whether the reference in entry 23 to road and agricultural vehicles also extents to tracked or wheeled Armoured Fighting Vehicles in 87.10 of the tariff code. In effect, taking a conservative viewpoint, the consideration was taken that the reference to Chapter 87 included all sub-categories in that chapter.

proving that their use of cadmium is necessary in the interest of safety of the product (exemption in entry 23, section 7 *"in safety devices in road […] vehicles"*).[331] The complex wording of entry 23 (banned, but allowed for A&D / safety) in combination with coverage of cadmium by REACH Article 33 (cadmium is on the candidate list) and RoHS requirements has already led to some confusion in defence supply chains. Figure 22 illustrates the complexity of defence-related exemptions (REACH) / disapplications (RoHS) for cadmium.

Figure 22 Complex defence related derogations / disapplication: Case Cadmium



- **Indirect impact**

Defence industry stakeholders have reported that they have been affected by obsolescence caused by the restriction for the use of **cadmium brazing alloys**. Whilst not being affected legally (derogation for defence and aerospace applications), the supplier withdrew the alloy completely in response to the restriction in 2011. The obsolescence was managed by executing a life time buy of the material in question. The remaining service providers were also increasing the costs related to the supply for military applications.

Cadmium plating was once quite common practice. It is now more of a specialist, niche process and suppliers may decide to cease supplying the required formulations to OEMs. OEMs may then need to support smaller companies in order to maintain the process capability or bring the capability in-house which adds additional cost. As the market shrinks, the continued use of a process could become obsolete. The potential unavailability of cadmium plating is an issue in that it will not be possible to

[330] For example, the restriction applies to weapon systems affixed to an armoured vehicle, but not to the weapon system alone (e.g. a machine gun). This means that the restriction status changes from not restricted to restricted (with exemption possibility), as soon as the weapon system is affixed to the armoured vehicle. This is often difficult to understand for customers and own staff and therefore prone to errors.

[331] For the UK, see above with the requirement of a Technical Dossier.

supply spare parts to the original design to the customers using Armoured Fighting Vehicles' (AFV) incorporation parts which are cadmium plated. Replacement parts are likely to have shorter life because they are more susceptible to wear and corrosion.

The other issue, irrespective of the restriction on cadmium plating, is that the process requires that after plating, the plated surface is passivated by immersion in a solution of hexavalent chrome substances. From September 2017, this will not be possible without authorisation. The commercial availability for non-aerospace military use is likely to become a problem very quickly, according to defence industry stakeholders.

D.13 Ammonium perchlorate (CAS 7790-98-9)

CRITICALITY FOR DEFENCE

The substance is used for propulsion of satellite launchers (dual use).

Some replacement activities are known; it would not be a one-to-one substitution and the whole formulation of the solid propellant would have to be changed; using an alternative oxidizer in a new solid propellant formulation is only at around TRL3 on the NASA TRL scale. For major programmes in development ammonium perchlorate remains the best oxidizer and the least expensive technology.

Ammonium perchlorate also has use in the manufacture of ammunition. Its specific chemistry would make substitution difficult within the weight / volume limitations for ammunition.

RMO STATUS

The substance is not on the candidate list and does not have a harmonised classification for SVHC properties according to CLP Annex VI.

However, it was originally selected for **substance evaluation** on the CoRAP list 2015-2017 in order to clarify concerns about

- Human health: Suspected CMR (carcinogenic) and thyroid toxicity;
- Human health: High potential for worker exposure due to high tonnage (> 1000t) and wide dispersive use;
- Potential endocrine disruptor for the human health and the environment.

In its final evaluation conclusions[332] the BAuA has confirmed that a concern was not substantiated and no further action required with regards to carcinogenicity and endocrine disruption for human health. It also concluded that non-classification for mutagenicity is appropriate and supported the registrants' conclusion that the substance is not toxic to reproduction. However, the endocrine mode of action of the **perchlorate anion** could be demonstrated by the studies relevant for assessing effects in the environment. Therefore the BAuA concluded:

*"Based on the hazardous intrinsic properties of perchlorate, SVHC identification under Article 57 f of REACH seems to be well substantiated based on its endocrine disrupting effects in the environment which has been thoroughly evaluated in this report. Although an inclusion of perchlorates and precursor substances in the **Annex XIV might not be an effective regulatory measure**, to support follow-up EU regulatory actions outside of REACH, SVHC identification might be of high supportive relevance."*

[332] BauA, Substance Evaluation Conclusion document for ammonium perchlorate (10 August 2016).

Subsequently, BAuA has launched an **RMOA** for perchloric acid, its salts and precursors (CAS 7601-90-3, EC 231-512-4), and has already publicly consulted stakeholders.[333] The RMOA is currently under examination; conclusions are expected to be available in the beginning of 2017.

It should also be noted that the EC has recommended the monitoring of the presence of perchlorate in food (Commission Recommendation (EU) 2015/682 of 29 April 2015). Member States should ensure that the analytical results are provided on a regular basis and at the latest by the end of February 2016 to the European Food Safety Authority (EFSA).

INDUSTRY INITIATIVE(S) FOR THE SUBSTANCE(S)

Substance manufacturers have provided input to the BAuA for its assessments. According to one of them it appears that the substance presence in vegetables and water has been identified very far from the manufacturing plants of solid fuel propellants (6 Member States report on that to EFSA[334]) so the case should be compared with the situation in USA where use of natural Chilean fertilizers in the past century is considered to be the main source of perchlorate ion in waters.

A study by the French agency BRGM[335] demonstrates that natural fertilisers used between 1900 and 1950 are an important source of perchlorate ion in water resources in the studied area. This seems to be the first time that a well-documented report brings the evidence of such a contamination in Europe.

Other companies using substances which would generate perchlorate ion in the environment proposed to send additional information to the BAuA.

D.14 Beryllium (CAS 7440-41-7)

CRITICALITY FOR DEFENCE

Beryllium is used in a number of structural components, semiconductors, optics, aircraft inlet probes or nonmagnetic material. Copper beryllium alloys are made into the terminals of electronic and electrical connectors as used in virtually every connector socket used in military vehicles, aircraft, satellites, missiles, ships, and helicopter, and most civil equivalents.

Hence, the use of beryllium is widespread, dual use, critical and without alternative. Relevant R&D activities aiming at their substitution are not known.

As a concrete example, beryllium is used in the manufacture of non-sparking tools for processing and testing of explosive materials. These tools provide a degree of safety when cutting explosives, especially for testing of explosive materials. An alternative material with similar hardness and non-sparking characteristics would need to be identified.

Beryllium is listed by the EC as **Critical Raw Material** (CRM).[336]

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[333] See http://www.reach-clp-biozid-helpdesk.de/en/REACH-en/SVHC-Roadmap-en/DE_RMOA-Liste-en/DE_Stoffliste-en.html.

[334] EFSA, Scientific Opinion on the risks to public health related to the presence of perchlorate in food, in particular fruits and vegetables (October 2014).

[335] BRGM, Recherche des origines de la pollution en perchlorate impactant des captages d'eau potable au sein des AAC de la région de Nemours et Bourron-Marlotte (77) et (45) (November 2015).

[336] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52014DC0297.

INFO BOX: Beryllium as a critical material designated by the U.S. Department of Defense (DoD)

There is no mining and production of beryllium in the EU and the reality is that most beryllium comes from the US where it is classified as the only material both "strategic" and "critical" for defence systems to the US DoD, because of the unique function it performs. The DoD has concluded that its full involvement and support is necessary to sustain and shape the strategic direction of the market such that there must not be a "significant and unacceptable risk of supply disruption".

RMO STATUS

Beryllium is not on the candidate list. The German authority (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, BAUA) is currently finalising an RMOA. On 4 February 2016 the BAuA invited the companies and industry representatives that have been engaged in the RMOA consultations including representatives from the German Federation of Industries (BDI), the German Automotive Association (VDA), aluminium and the aerospace industry. The purpose of the meeting was to review the outcome of their evaluation of Beryllium. The BAuA decided not to put beryllium on the REACH Candidate List or place any restrictions on the uses of beryllium for the time being. The BAuA has stated that *"Because of its unique combination of qualities, beryllium is a strategic and critical material for many industries."*[337] According to BAuA the arguments against authorisation in the present case are lack of alternatives, the high formal burden for industry and that the benefit for worker protection is unclear.

Instead, industry bodies are asked to develop and distribute a voluntary **Product Stewardship Programme** / safe use guidance) to minimize exposure to beryllium at the workplace. Based on its implementation in the enterprises, which will be audited by national enforcement authorities in the frame of a dedicated enforcement activity and evaluated by BAuA, the necessity of further regulatory measures will be assessed.

SCOEL published a draft recommendation for beryllium on 29 August 2016 for public consultation until 30 November 2016. The draft recommendation contains a **very low occupational exposure limit value** (0.02 µg/m^3 - inhalable sampling method). Following due consideration of comments from stakeholders, SCOEL will issue its final recommendation for further evaluation by the Commission. A corresponding EU bOEL could then be proposed for addition to Directive 2004/37/EC (CMD). The Beryllium Science and Technology Association (BeST) believes that such a low value is not justified nor feasible and that the scientific evidence coupled with the socio-economic analysis conducted by the IOM is supportive of an OEL ranging from 1.0 µg/m3 to 0.6 µg/m^3 (inhalable sampling method), in harmony with the recent proposal by US OSHA.

INDUSTRY INITIATIVE(S) FOR THE SUBSTANCE(S)

The Contractor has contacted the Beryllium Science and Technology Association (BeST)[338] in the frame of the study and obtained comprehensive data input. According to BeST beryllium should not be identified as an SVHC and put on the REACH Candidate List. Furthermore it should not be subjected to the authorisation or restriction procedure. BeST participates in the Cross-Industry

[337] Information by Materion on behalf of the Beryllium Science and Technology Association (BeST) dated 22.07.2016.

[338] BeST represents the suppliers of Beryllium in the EU market, as well as traders and industries who rely on the unique properties of beryllium to design for miniaturisation, energy conservation, greater reliability and longer product life. The aim of BeST is to promote sound policies, regulations, science and actions related to the use of beryllium and to serve as an expert resource for the international community on the benefits and criticality of beryllium applications.

Initiative and hence supports the setting of an EU bOEL value based on the most recent and relevant science. BeST further claims:

- EU should support institution of a social dialogue where stakeholders (industry & labour) work toward a common position, similar to that which occurred in the development of the model beryllium standard jointly submitted to US OSHA by labour and industry in 2012.
- The EU should reclassify beryllium metal to differentiate it from soluble beryllium compounds to reflect the most recent science so that workers are informed of the true exposure risks.
- The RMOA must give due consideration to beryllium as a substance critical to the EU. Any initiation of the REACH restrictions and authorisation procedures would be disproportionate.

D.15 Bisphenol A (CAS 80-05-7)

CRITICALITY FOR DEFENCE

Bisphenol A is widely used as an intermediate mainly in the production of polycarbonate and epoxy resins. Epoxy resins uses include adhesives and protective coatings as well as making composites. The use of Bisphenol A is considered critical (no alternative known) for defence applications.

RMO STATUS

The substance has been targeted by several processes and MSCAs:

- **Harmonised classification** initiated by France: A revised harmonised CLP classification as a category 1B substance toxic for reproduction has been adopted by Commission Regulation (EU) 2016/1179 of 19 July 2016. It entered into force 20 days after publication and will become fully applicable on 1 March 2018.[339]
- **Restriction** initiated by France: A French REACH Annex XVII restriction proposal of 2014 for BPA in *thermal paper*[340] is currently pending formal adoption by the EC, following vote of the REACH Committee.[341] The amount of BPA used in thermal paper is minor (about 0.2% of the total volume of BPA in the EU).[342]
- **Substance evaluation** by Germany: The conclusions are still pending (2.9.2016).
- **PACT/RMOA list**: The list shows that an RMOA has been done and the outcome is that it is appropriate to initiate regulatory risk management action, i.e. SVHC. RMOA conclusions/notes are yet to be published.[343]
- **Annex XV SVHC dossier** by France: France has submitted its intention to the ECHA Registry of Intentions in February/March 2016:
    - one on CMR argumentation, published on 9 September 2016;[344]

[339] http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R1179&from=EN

[340] http://echa.europa.eu/view-article/-/journal_content/title/echas-committees-finalise-evaluation-of-bisphenol-a-restriction-proposal

[341] It will apply 36 months after the Regulation comes into force.

[342] http://echa.europa.eu/documents/10162/13580/annex_bpa_pr_15_16.pdf

[343] https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact/-/substance-rev/12938/term.

- one on Endocrine Disruptor (ED) argumentation, to be submitted by February 6, 2017.

INDUSTRY INITIATIVE(S) FOR THE SUBSTANCE(S)

The Contractor has discussed the REACH/CLP status of Bisphenol A with PlasticsEurope, the Association of Plastics Manufacturers.[345] PlasticsEurope has informed that the re-classification was induced by tighter CLP criteria (different CMR categories), not new toxicological findings. The major uses of BPA, which is a high volume chemical, are intermediate uses (polymeric uses, incl. also BPA-based uses of epoxy resins as coatings) and hence not subject to authorisation. BPA manufacturers fear a **stigmatisation effect** from candidate listing, which prevents future innovations using BPA or BPA-based materials. BPA is mainly produced in Germany, the Netherlands, Spain and Belgium. It was expressed that industry has not been approached by the French MSCA for the sake of making a real RMOA. It is not understood why the RMOA has already been concluded and the SVHC proposal is being prepared (by France), while the substance evaluation is still ongoing (by Germany) and the European Food Safety Authority (EFSA) has stated clearly that BPA can be used safely in all current food contact applications.[346] In relation to defence it was expressed that BPA producers are too far away from such end user applications and the volume going into these military uses is very small.

In October 2016 BPA manufacturers have provided comprehensive comments in the public consultation on the French ANNEX XV dossier, in order to oppose against the dossier erroneously describing polycarbonate related uses as being in scope of potential authorisation. BPA manufacturers now wait for the conclusions of Germany on the substance evaluation.

D.16 Diisocyanates

CRITICALITY FOR DEFENCE

Uses of interest for diisocyanates (MDI, TDI, HDI, NDI, IPDI, etc.) in the defence sector include:

- Ammunition: Crosslinkers of polymers such as PBHT, which is essential for formulating composite secondary explosives; the armed forces use these substances in components considered as articles and their quantity is very small, so it is not considered that there is a risk of exposure.
- Polyurethane paints, sealants, glue.

INFO BOX: Polyurethane coatings in the air domain

Together with chromates and cadmium, polyurethane coatings are the backbone of the defence sector's corrosion protection on light alloys. In the light of REACH Regulation, some MoDs are currently trying to identify methods to reduce the use of isocyanates (next to chromates and cadmium).

Polyurethane topcoats containing Methylene Diphenyl Diisocyanate (MDI) are applied on the whole aircraft. Replacement could lead to reduced durability of topcoats, which in turn is likely to shorten re-finish intervals, while the hazardous properties of new materials are not understood.

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344 https://echa.europa.eu/proposals-to-identify-substances-of-very-high-concern-previous-consultations/-/substance-rev/14615/del/50/col/synonymDynamicField_705/type/asc/pre/2/view.

345 www.bisphenol-a-europe.org. A teleconference was held on 31 August 2016.

346 http://www.efsa.europa.eu/en/press/news/150121.

Of course, the use of diisocyanates for polyurethane coatings is not limited to aircraft (although these might be the most impacted systems with many niche uses e.g. anti-collision, antistatic, anti-corrosion). These coatings are also used for land and naval (several different kinds of surfaces) systems. Hence, the whole defence domain is impacted by any relevant regulatory action towards diisocyanates.

INFO BOX: Consequences of an assumed Annex XIV listing of diisocyanates

Many PBX energetic materials are reliant on polyurethane technologies of very specific types. These formulations have required significant development and testing, including system testing within munitions. The development of alternatives would probably have significant costs, and the qualification in existing munition designs could be uneconomic. Inclusion of isocyanates could put 30 years of development effort in PBX technology at risk, with huge costs in qualifying alternatives. Defence industry stakeholders have further reported that there has been no search for alternative technologies yet, as they are effectively still at the early level of technical development with existing formulations.

RMO STATUS

Germany (Federal Institute for Occupational Safety and Health, 'BAuA') has concluded, in an RMOA in 2014 that a restriction under Annex XVII is the most appropriate risk management option because Annex XVII provides a more efficient way of regulating this class of substances due to the complexity of the supply chain and the large number of uses. Additionally, they felt that because of the unique properties of the polyurethane polymer product, large scale substitution was unlikely. Regulation under REACH would establish stricter mandatory handling habits throughout the EU and would guarantee quality management from the top of the supply chain down to the end users.

The proposed Annex XVII restriction[347] serves to restrict the use and placing on the market in substances and mixtures in industrial and professional uses. The proposal limits the use of diisocyanates in industrial and professional applications to those cases where a **combination of technical and organisational measures as well as a minimum standardised training package has been implemented**. Information how to get access to this package is communicated throughout the supply chain. Exemptions are defined for cases where the content of free monomeric diisocyanates in the substance or mixture placed on the market or used is less than 0.1 % by weight, as well as for mixtures containing diisocyanates at higher levels than 0.1 % by weight, which fulfil criteria that show that the potential risks using such products are very low.

The restriction proposal also ensures that MS are free to implement more stringent measures as long as the minimum requirements of training and measures are met. This training shall also be documented by employers to confirm compliance with the requirements. Such proof shall be recognised in all other Member States.

It also calls on manufacturers and importers to develop a set of teaching material in accordance with the provisions of the annex of the entry an official language of the Member State where the substance or mixture is placed on the market. Any training material should be available to the recipients of such substances or mixture, and training should be reviewed and updated after a

[347] Please see BauA, Annex XV Restriction Report – Proposal for a Restriction of Diisocyanates (6 October 2016) for the proposed wording of the Annex XVII entry.

maximum of 8 years, or without delay if new information, which may affect the risk management measures, becomes available and inform the recipients accordingly.

Unprecedented in its mode of operation, the case of diisocyanates serves as a pilot project for REACH restrictions coupled to the substance handling. The date of submission for the German restriction proposal was 7 October 2016.[348]

There are some varying national OELs.

INDUSTRY INITIATIVE(S) FOR THE SUBSTANCE(S)

Industry initiatives for the substance have not been identified as part of the study.

D.17 Gallium Arsenide (CAS 1303-00-0)

CRITICALITY FOR DEFENCE

GaAs is characterised by a complex value chain with wide dispersive use (not limited to military applications, i.e. 'dual use') of very small quantities and low risk, which is adequately controlled. The substance is a critical building block for semiconductors, e.g. in thermal cameras. It is widely used in microelectronics.

In REACH terms the main use of GaAs is the production of wafers, which are considered as articles in terms of REACH Article 3(3).

Gallium is listed by the EC as **Critical Raw Material** (CRM).[349]

RMO STATUS

GaAs is not on the candidate list today. However, it has obtained a harmonised classification as Carc. 1B and Repr. 1B in CLP Annex VI – independent from the physical form[350] - after a lengthy debate in the ECHA Risk Assessment Committee (RAC). A substance evaluation for GaAs, originally scheduled for 2014 in the CoRAP list, was withdrawn.

It is not known at the moment that GaAs is part of the discussions relating to the introduction of EU bOELs.

INDUSTRY INITIATIVE(S) FOR THE SUBSTANCE(S)[351]

There was a discussion in Germany in the last years about introducing a national OEL for arsenic compounds including GaAs. Eventually industry convinced the authorities that the exposure-risk-ratio[352] for the other three arsenic compounds is not valid for GaAs.[353] Therefore it is understood that German authorities do not see a need for further regulation of GaAs at the moment.

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[348] https://echa.europa.eu/registry-of-submitted-restriction-proposal-intentions/-/substance-rev/15016/term.

[349] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52014DC0297.

[350] This is different now for lead metal.

[351] Information from phone interview on 25.07.2016 with Freiberger Compound Materials GmbH, the main producer for GaAs in Europe.

[352] DE: Expositions-Risiko-Beziehung (ERB)

[353] Begründung zu ERB Arsenverbindungen in TRGS 910 (02.02.2015), page 2, see http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/TRGS/Begruendungen-910.html.

Due to its new double harmonised classification there is a latent risk that GaAs will be included in the candidate list at any time. **Candidate listing would mean an immense problem for the EU GaAs industry**, especially because their globally working non-EU customers (mainly from US and Asia) insist on the proof of absence of SVHC in the products supplied, in exceedance of the REACH legal requirements. Against this background a joint initiative of companies from the semiconductor, optoelectronic and end user (incl. defence) industries throughout the whole value added chain, e.g. Airbus Defence and Space and Thales (**IMAT**, Innovative Semiconductor Materials),[354] has prepared a "shadow" Annex XV dossier, which can be used in case an MSCA or the EC/ECHA would propose the substance for the candidate list. This dossier may also provide data input to an industry-RMOA by IMAT, which is currently considered, because GaAs could be selected by an MSCA or EC/ECHA for an RMOA at any time. The aim is to avoid REACH authorisation and restriction for industrial applications.

The IMAT initiative is also followed by the EDA's CapTech Technologies, Components and Modules. According to the EDA a REACH listing could create a problem for legacy radar system upgrades.

The EU industry depending on GaAs is not only impacted with regard to the potential candidate listing for GaAs, but also with regard to essential process chemicals. A process chemical used in the manufacture of GaAs, diboron trioxide (EC 215-125-8),[355] has been prioritised by ECHA for Annex XIV inclusion in 2015. Annex XIV inclusion would have a major impact on the main EU manufacturer of GaAs, because the non-EU supplier does not wish to apply and would stop supply on that case, while the substance is not available from within EU in the quality required for semiconductors.

The IMAT group is part of the Cross-Industry Initiative.

D.18 Nickel salts

CRITICALITY FOR DEFENCE

Nickel salts are critical substances for the defence sector. (Dual) uses are widespread, including:

- surface treatment (including for maintenance activities): corrosion protection such as Zn-Ni, adhesion promotion for metal plating, Ni strike, Ni Plating, Ni-Phos plating, PCB coatings, surface plating (properties other than corrosion protection), processing of high temperature Nickel alloys
- Ni-Cd batteries for airplanes and missiles

INFO BOX: Nickel uses in plating processes on electrical connectors

Nickel salts are used on all plating as "under-layer" of the definitive plating (e.g. under gold for contacts, under cadmium or ZnNi for connectors). There is no other kind of under-plating that could be used today for this task.

Nickel salts are also used in Ni plating, one of finishing that are qualified for connectors plating.

Moreover, nickel salts are used in ZnNi plating that are under study to replace cadmium for connectors plating.

[354] Industry initiative „IMAT", Innovative substances in the spotlight of chemicals legislation REACH.
[355] See the case study for diboron trioxide above in Annex D.8.

There is no solution at this time to replace this substance. Some connector manufacturers consulted during this study have stated that manufacture would move out of Europe to already existing manufacturing centres, if the substances would be subject to Annex XIV.

RMO STATUS

Nickel salts are not on the candidate list today. The French authority (Anses) has completed an in-depth RMOA for nickel sulphate (CAS 7786-81-4) in April 2014,[356] following consultation of both other Member States and the general public. It has recognized that nickel plating is also used in electrical connectors for critical applications such as aerospace and defence, and that Ni-based batteries are used in military aviation.

The Anses opinion has been followed by an interministerial consultation. The official communication of the decision by the French Prime Minister is expected shortly.

As zinc/nickel is considered as an acceptable substitute for some Cr(VI) and cadmium applications (where less performance is considered acceptable), the issue of "regrettable substitution" arises, if nickel salts were included in candidate list and Annex XIV in the future.

Today the national OELs for insoluble nickel compounds are very different. It is understood that nickel compounds are on the working list of the EC (DG EMPL) for the introduction of an EU bOEL, scheduled to be proposed by the end of 2016 ('2nd list').

INDUSTRY INITIATIVE(S) FOR THE SUBSTANCE(S)

According to the Nickel Institute (phone interview on 27 July 2016) workplace legislation is the most appropriate risk management option for (inorganic) nickel salts used only at the workplace such as nickel sulphate.[357] Concerns identified by authorities can be fully addressed by workplace legislation (including by an EU-wide OEL). Generally for metals the supply chain is typically very complex. As authorisation is about substitution, and it is not possible to invent new metals, authorisation would lead to severe restrictions in the future with respect to metals choice for downstream users.

D.19 Petroleum substances

CRITICALITY FOR DEFENCE

Most defence sector stakeholders consulted have expressed interest in petroleum substances, e.g. in NATO fuel. It is evident that this group of substances is important for the sector.

RMO STATUS

The EC's SVHC Roadmap states in relation to CMRs that *"there is a need to develop an approach to assess the petroleum streams (approach 2013-2015, **systematic assessment from 2016**)."*[358] Hence, petroleum and coal stream substances ('PetCo') which have CMR or PBT properties are part of ECHA's SVHC Roadmap Implementation plan. So far they have been left out from screening exercises with regard to their complex nature as UVCBs, particularly variable and complex.[359]

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[356] https://www.nickelinstitute.org/~/media/Files/Sustainability/RMOAsSection/RMOA_NiSO4_PUBLIC.ashx?la=en

[357] The Nickel Institute is also a participant of the Cross-Industry Initiative.

[358] EC, Roadmap on Substances of Very High Concern (5 February 2013), page 14.

[359] UVCB: Substance of Unknown or Variable Composition or from Biological origin.

According to ECHA's most recent analysis of the SVHC Roadmap *"there are over 300 registered substances with a harmonised classification as CMR 1A or 1B and of those over 100 have already been placed on the Candidate List.* ***About one-third of the remaining substances are petroleum and coal derivatives".***[360]

In the frame of the SVHC Roadmap implementation plan a **'PetCo'** Working Group of ECHA, MSCAs, the EC and accredited stakeholder organisations (such as Concawe) was created, in order to address petroleum and coal derivatives systematically under REACH, starting with collaborative work on shortcomings in the registration dossiers.[361]

A large amount of the uses of petroleum substances, such as intermediates[362] and fuels[363], are exempted from authorisation, which reduces their assessment priority. In March 2016 the PetCo group identified 20[364] high priority substances having widespread uses, defined as professional and consumer uses with high volumes, on an *"SVHC screening list"* for further actions to better understand their hazards. In the coming period, Concawe will focus on the completeness of the available data for these 20 petroleum substances, with the purpose of demonstrating that these are used with adequate risk management measures that can ensure safe use. It is envisaged that the PetCo WG is concluding its work by the end of 2016, and Member States will start evaluating shortlisted petroleum substances and their group members from 2017, with a view to identify relevant SVHC amongst them for potential inclusion in the candidate list by 2019.[365]

INDUSTRY INITIATIVE(S) FOR THE SUBSTANCE(S)

The Contractor has contacted FuelsEurope[366] and Concawe, representing the European petroleum refining industry. According to FuelsEurope[367] the refining industry recommends taking an integrated approach which includes the following, in relation to Annex XIV:

- To keep the addition of petroleum substances to the candidate list to a minimum by applying criteria that consider uses and hazard better.
- The evaluation of petroleum substances should be prioritised in a way that allows industry and authorities sufficient time to improve data and carry out testing in an efficient way; consideration of alternatives for putting a substance on the SVHC list, such as restrictions or measures under the Chemical Agents Directive.

[360] See ECHA, Report on the Operation of REACH and CLP 2016, page 85.

[361] See ECHA, Report on the Operation of REACH and CLP 2016, page 40, 85; ECHA, Roadmap for SVHC identification and implementation of REACH risk management measures, Annual Report of 4 April 2016, page 17 et seq..

[362] REACH Article 2(8)(b).

[363] REACH Article 56(4)(c) [*use as motor fuels covered by Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels*] and (d) [*uses as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems*] .

[364] Out of 207.

[365] Information by Concawe, phone call on 4.8.2016.

[366] See e.g. FuelsEurope, REACH position paper – Annex I: SVHC Roadmap (July 2015).

[367] FuelsEurope position paper on REACH and the Refining industry.

E. JOINT R&T ACTIVITIES ON REACH RELATED SUBSTITUTION AT EDA AND NATO AVT RTG

Substitution-related R&T work for common military applications of SVHCs is being addressed collaboratively at EU and international level, as shown below by a number of examples of projects coordinated by the EDA and NATO AVT RTG.

E.1 EDA CapTechs projects

***"Antifouling Coatings for War Ships (ACWS)"* (EDA, 2008-2011)**

The three-year Antifouling Coatings for War Ships (ACWS) project started in 2008 with two member countries: United Kingdom, represented by the Defence Science and Technology Laboratory (Dstl), and France, represented by Direction Générale de l'Armement (DGA). Through an Information Exchange, the Netherlands joined the project in November 2009. Seven partners formed the industrial consortium to share the work split between five Work Packages and thus to share the costs. The University of Southampton and Dstl were the British entities, while the French partners comprised DGA Ingénierie de Projets, DGA Naval Systems, Directions des Constructions Navales Services and the MAtériaux Polymères-Interfaces-Environnement Marin (MAPIEM) laboratory. The latter also acted as Contractor in this project, leading and managing the Industrial Consortium. The Dutch industrial entity was Toegepast Natuurwetanschappelijk Onderzoek (TNO) and joined the project at a later stage, called Antifouling Coatings for War Ships Information Exchange (ACWS IEX) project.

This EDA project was targeted at requirements for antifouling systems for naval applications and extension of effective lifetime of existing or newly emerging paint systems under operational conditions of naval ships. The project had two major objectives:

1) Identify products that could show enhanced performance during increased docking intervals from 6-10 years;
2) Develop methodology that helps to establish antifouling performance of ship hull coatings in periods less than one year.

In detail, this project was targeted at evaluating high performance antifouling (AF) coatings to meet British, French and Dutch naval requirements, with a special focus on Self-Polishing copolymers (SPC) coatings and Controlled Depletion Polymer (CDP) coatings. The objectives were to comply with present and future environmental legislations, health and safety regulations (REACH, European Biocidal Products Directive 98/8/EC ...) and to potentially increase dry-docking intervals beyond 5 years. One of the evaluation approaches has been to develop accelerated ageing methodologies to assess long-term AF efficiency in less than one year.

More specifically, the naval requirements, predominant fouling organisms and AF products (binders, biocides and formulations or commercial coatings) were identified. This work was followed by an evaluation and testing of emerging technologies that could offer improved AF performance, such as screening novel binders, natural product biocides and paint formulations, with the ultimate aim of developing a novel SPC antifouling system (not in the project scope). Different solutions were studied and tested. Then, an accelerated ageing protocol for SPC and CDP coatings characterisation and two protocols for a short term determination of the residual AF efficiency were developed. Finally field experiments took place.

***"Environmentally Compliant Coatings in Aeronautic (ECOCOAT)"* (EDA, - 2013)**

The EDA-coordinated project *"Environmentally Compliant Coatings In Aeronautic (ECOCOAT)"*, with France, Finland, Germany and Italy as participating countries, was carried out by a consortium of leading European industrial partners from Eurocopter, Safran, Dassault Aviation, MBDA, DGA AS (France), CSM (Italy), VTT (Finland), EADS, Cassidian, Wiweb (Germany). The project aimed at developing alternatives for priority hazardous substances to be banned in surface treatments, while nowadays most of corrosion protections for metallic parts are based on chromium and cadmium substances. Certain protections (e.g. cadmium plating and its chromic passivation for protection of steels for mechanical parts and fasteners) were selected for the R&T of alternatives. As a result some promising solutions were identified after the analysis of tests on samples and demonstrators. Nevertheless, the TRL of these solutions should be upgraded to become industrial alternatives to the chromium or cadmium in all configurations and all environments. The ECOCOAT project was concluded in 2013.

***"Corrosion Control on Navy Ships (CCNS)"* (EDA, 2013 -)**

The EDA-coordinated CCNS project *"Corrosion Control on Navy Ships (CCNS)"*, was initiated in 2013 for a duration of 36 months with the participation of France (leader), Germany, Italy, UK. The project is being carried out in partnership with Institut de la Corrosion (IC) (France), DGA (France), DCNS (France), WIWEB (Germany), WTD71 (Germany), BAE Systems (UK), Aish Technologies (UK), University of Southampton (UK), DE&S (UK) and Centro Sviluppo Materiali (Italy). The CCNS project aims at increasing the operational availability of naval ships and counteracting cost increases for corrosion control and surface treatment. These aims are to be achieved by extension of dry-docking maintenance intervals (6-10) years while taking into consideration ship security and compliance with environmental regulations (**REACH, BPR, VOC**). The major risks involved are unsuitability or clampdown on existing solutions due to ever stricter environmental controls. To counter these risks the target is to define new adapted alternatives and in particular adaptations in the maintenance base conditions. To achieve this, investigations have to be well-thought-out in the most critical areas of the Corrosion Control Technology. The technical scope of the project covers corrosion and fouling in seawater piping systems (Cu alloys, Stainless steel, Ni base alloys, Ti), Cathodic Protection optimization, improving performance of Protective Coatings and producing a guideline for paint selection, cathodic protection, antifouling strategy and maintenance base conditions.

E.2 NATO AVT RTG projects

BACKGROUND

NATO has a Science and Technology (S&T) Programme which is focussed through broad area Panels reflecting S&T priorities for the alliance. One of these broad areas is Applied Vehicle Technology (AVT). These Panels have several ways of operating, but mainly use Research Technology Groups (RTGs) who are tasked with a specific programme of collaborative work. They consist of 4 or more alliance members and possibly partners and can include government, industry, and academia. Each partner brings work and information which is synthesised and developed collaboratively to provide NATO with data and capability to meet present and future needs.

The two activities described below are complementary, but separate AVT RTGs.[368]

***"Environmentally Compliant Materials & Processes for Military Vehicles"* (AVT-247/RTG-084, 2016-2018)**

In January 2016 NATO has launched an activity "Environmentally Compliant Materials & Processes for Military Vehicles" (ref. AVT-247/RTG-084). REACH and RoHS are amongst the key drivers mentioned. The objective of this three-year activity is to review materials and processes utilised in repair and maintenance (R&M) of military assets in all three domains of land, marine and air, determine areas of concern that need to be addressed and provide guidelines on environmentally compliant solutions. While a previous activity (AVT-114, 2003-2006) focused around hexavalent chromium and cadmium alternatives, additional controlled substances such as beryllium, nickel and lead are being looked at now as well. Particular attention is paid to legacy systems. It is proposed that an up-to-date resource available to all NATO nations and partners is developed, contributing to interoperability and standardisation within NATO.

As a possible approach to the review exercise one of the participating nations has defined key priority areas and developed a risk profile for each of them for procurement, in-service and disposal phases, covering environmental, operational, PR and economic aspects. The key priority areas include:

- Petrols/Oils/Lubricants;
- Lead;
- Corrosion Prevention;
- Cadmium;
- Legacy Disposal;
- Adhesive and Sealants;
- Flame Retardants.

The activity will run until December 2018.

The Terms of Reference further note: *"The problem of identifying and adopting environmentally friendly materials and technologies is common to all military platforms and should be addressed globally. In addition, development of a common approach in replacing hazardous materials in military vehicles will contribute to interoperability and standardisation of manufacturing, repair and maintenance processes among NATO forces."*

[368] See https://www.sto.nato.int.

***"Effect of Environmental Regulation on Energetic Systems and the Management of Critical Munitions Materials and Capability"* (AVT-293/RTG-103, 2017-2019)**

In January 2017, NATO will launch a dedicated activity to assess the impact of environmental regulations (including REACH) on energetic systems across NATO and its partners. Justification for the study is because REACH will affect the availability of energetic components/substances for munitions and this requires that data are generated to manage use. Furthermore, REACH may also affect the choice of new materials for future applications. The study is, consequently, needed to ensure that NATO has the equipment to meet its future needs.

Some of the objectives of the study will be to review to examine R&D developments with industry, academia, institutes and regulatory bodies and also to identify short term critical materials for immediate action, assess existing research activities for regulatory compliance, assess modelling to predict potential health and environmental effects and propose research activities to cover any gaps that are identified. The study is expected to run for 3 years.

F. NATIONAL REACH DEFENCE EXEMPTION PROCESSES: ADDITIONAL INFORMATION

This Annex contains additional information that was collected by the Contractor during the defence stakeholder consultation.

F.1 National defence exemption procedures and EDA Code of Conduct (CoC) 2015

Since the entry into force of REACH the EU Member States have used the defence exemption possibility to a varying extent. In almost all Member States consulted, internal processes have been established to assess and decide on exemption requests. In many cases it has been necessary to enact national legislation and administrative rules to define the defence exemption process.

The national Ministries of Defence (or their subordinate offices/agencies) play a central role in the process, as the authority to confirm the "interests of defence" lies in all cases with them. In most Member States consulted other governmental agencies[369] are also involved in the processing and decision on exemption requests, in particular the chemical safety assessment, and sometimes as granting authority or co-decision makers.

Member States have spent resources to different extents for the set-up and implementation of national defence exemption processes. Where exemption requests are to be processed, the impact in terms of financial and human resources and potential liability risks is naturally higher. The financial impact for the MoDs is not only determined by the resources required in establishing and managing the exemption process, but also by the fact, that the exemption-related costs for the applicant are ultimately borne by the MoD (and, hence, the tax payer).

Some Member States have a very conservative approach towards the use of defence exemptions. There is a prevalent view among MoDs that the defence exemption shifts the responsibility for the safe use of the substance and the liability for through life risks back to the authorities granting the defence exemption (MoD). They are of the opinion that the defence exemption should be limited and is useful only in very specific cases, e.g. where there is a defence-only use (no dual use).[370]

TREND

From the consultation with MoDs it appears that the level of exemption activity has increased after the first sunset dates in 2015 (here: phthalates, lead chromate, 2,4-dinitrotoluene). This suggests that the activity will further increase as more sunset dates pass (in particular for chromium trioxide etc. in September 2017) and could have resource implications for the MoDs.

EUROPEAN HARMONISATION OF REACH DEFENCE EXEMPTION CRITERIA

In order to reduce the mentioned differences and to harmonise the use and assessment criteria for the granting of national defence exemptions in the interest of contributing to a level playing field, as well as minimising related costs, for the EU defence industry, the participating Member States have elaborated and subscribed to the **EDA Code of Conduct on REACH Defence Exemptions (EDA CoC) in 2015.**

[369] Such as defence materiel organisations, Ministries of Environment, Member State REACH Competent Authorities.

[370] The case of lead titanium zirconium oxide used for sonar systems in military submarines was mentioned as a possible example by one MoD, see Annex D.11. However, no defence exemption has been granted for this use to date.

INFO BOX: The EDA Code of Conduct on REACH Defence Exemptions (March 2015)

In 2015 an EDA Code of Conduct on REACH defence exemptions (EDA CoC 2015)[371] was agreed by the subscribing Member States,[372] with the aim to **harmonise** the handling of national defence exemptions in the area of REACH at the European level. The EDA CoC stipulates a **last-resort approach** for REACH defence exemptions in that it foresees that the granting of the defence exemptions should be considered only after the alternative methods of (1) complying with REACH and (2) substitution with more benign alternatives have been examined. Furthermore, exemption procedures and requirements should preferably **mirror REACH** safety standards to minimize the risk to human health and the environment.

To this end a common ***"Framework for Applying for a Defence Exemption from a Requirement of REACH"***[373] was adopted as Annex to the EDA CoC. Drawing heavily on the REACH requirements, it contains an agreed set of minimum standards for a defence exemption application dossier, including for

(1) **Basic application information**, e.g. REACH Article for which exemption is sought;

(2) **Defence Exemption justification**, referring to four "business cases" for defence interest: national security, information disclosure limitations, protection of a critical capability, urgent operational requirements; for *"high-risk"* substances (Annex XIV/XVII) an **analysis of alternatives** and explanation of **time constraints/substitution plan** for alternatives is also required.

(3) **Health and environmental risk assessment** for *"high-risk"* substances. This includes a **chemical safety assessment** (limited to the relevant uses and exposure routes in the military use), as well as an **analysis of risks** associated with **alternatives**.

The EDA CoC is regarded as a **major step** towards European harmonisation of defence exemptions. Further work is needed to ensure its adaptation, coherent application and further improvement. Eventually **reciprocal acknowledgment** of defence exemption decisions should be achieved.

Most MoDs consulted have reported that their national processes were already in line with the EDA CoC by now. A few Member States[374] are still pursuing further alignment measures, e.g. to include the requirement of a chemical safety assessment for Annex XIV substances (EL) or build up the process for the first time (PT), or pursue further alignment in cases that the procedure is already mostly aligned with the EDA CoC (SE). Only for these Member States additional human and financial resources to handle exemption requests based on the new/aligned procedure may be necessary.

Overall, the *Ministries of Defence* consulted agree that the EDA CoC provides a workable solution towards harmonisation of national defence exemption assessments to achieve a more level playing field for the EU defence industry. Nevertheless, MoDs see the need for further harmonisation, in a first step to consider the other EU Member States' defence needs and then with regard to the reciprocal acknowledgment of foreign defence exemptions.

[371] EDA Code of Conduct on REACH Defence Exemptions (March 2015).

[372] Currently all EDA participating Member States as well as Norway, but with the exception of Poland (analysis ongoing) have subscribed to and are participating in the implementation of the EDA CoC.

[373] EDA Annex to CoC – Framework for applying for a defence exemption from a requirement of REACH (March 2015).

[374] EL, PT, SE.

Table 22 below provides a comparative overview of key aspects of national REACH defence exemption systems in those EDA participating Member States whose MoDs participated in the study consultation. For further information on national REACH defence exemption systems, including for other Member States (AT, CY, PL, RO, SK), please see the available information on the EDA REACH Portal: https://reach.eda.europa.eu.

Table 22 Key aspects of national REACH defence exemption systems

Member State	Applicant for exemption	Granting authority	Scope and validity of exemption	Description of national procedure (and link to exemption information on EDA portal)	Conditions/Procedures for Acknowledgment/Recognition of Foreign Defence Exemptions	REACH defence exemptions granted (-11/16)
Belgium	Private companies or MOD itself	The Federal public service Health, Food chain safety and Environment and the Belgium MOD are the Belgian authorities mandated to grant an exemption.	n/a	The defence interest will be assessed by the MOD and the Federal public service Health, Food chain safety and Environment will contribute to the health and environmental risks assessment. The final decision will be taken by both the Minister of Defence and the Minister of the Environment. (https://reach.eda.europa.eu/belgium)	Belgium's legislation does not recognize foreign defence exemptions.	**0** - Procedure exists but has not been tested yet
Finland	Defence Forces Logistics Command has authority to make official exemption applications to Defence Command	Defence Command is the registration and authorisation authority concerning defence exemptions.	For REACH authorisation: in accordance with the principles defined in article 60 (Par. 9(e) time-limited review period)	https://reach.eda.europa.eu/finland	Finland's chemical legislation does not recognize foreign defence exemptions.	3 (based on CLP and Reach Regulation)
France	Private companies or public entities (MOD itself)	Co-decision of the MoD and the MoEnv	Exemption can apply to a substance, a mixture or an article. The applicant should indicate start date and desired duration of defence exemption. The validity of exemption can be extended.	1. MoD (inter-service Commission): defence interest assessment. 2. MoEnv: chemical safety assessment (https://reach.eda.europa.eu/france)	Process for own exemptions is applied	**0**

Member State	Applicant for exemption	Granting authority	Scope and validity of exemption	Description of national procedure (and link to exemption information on EDA portal)	Conditions/Procedures for Acknowledgment/Recognition of Foreign Defence Exemptions	REACH defence exemptions granted (-11/16)
Germany	Contractor of the Bundeswehr	Federal Ministry of Defence (BMVg)	Time-limited (until authorisation or substitution is achieved). Product-based: The defence exemption covers the use of a certain amount of the Annex XIV substance by a specific company for the production of one particular kind of product for one specific contract and customer.	https://reach.eda.europa.eu/germany	Foreign defence exemptions are taken into consideration during the national procedure; however the exemption decision will be based on a separate national assessment.	**15** since 2015, all from authorisation
Greece	Request of the Hellenic Ministry of National Defence (HMoD) or of a defence industry	Hellenic REACH Competent Authority (General Chemical State Laboratory): www.gcsl.gr	Not limited	Not required so far to submit dossier-level information to EL Competent Authority; https://reach.eda.europa.eu/greece	The current Legal Act doesn't include a respective clause. Amendment is under discussion to incorporate the EDA CoC	**63**: 14 for the MoD (Hellenic Air Force), 49 for the "Hellenic Defence Systems S.A" - in the biministerial decision
Italy	Supplier, i.e. companies interested in REACH defence exemption must be directly linked (by supply contracts) with the Italian MoD	MoD (Secretariat General of Defence and National Armaments Directorate)	The dossier is evaluated, at least every two years, to consider the opportunity to maintain the exemption granted.	https://reach.eda.europa.eu/italy	MoD takes into consideration exemptions granted from other Member States, but the decision on REACH exemption will be based on the national security interests.	**0**

Member State	Applicant for exemption	Granting authority	Scope and validity of exemption	Description of national procedure (and link to exemption information on EDA portal)	Conditions/Procedures for Acknowledgment/Recognition of Foreign Defence Exemptions	REACH defence exemptions granted (-11/16)
Netherlands	Only the Minister of Defence may apply. Third parties must produce an exemption dossier.	REACH and BPR: national REACH competent authority (by Royal Decree): Ministry of Environment & Infrastructure. CLP: Ministry of Health Welfare & Sports	National security and/or security of friendly nation. Depending on the requirements, the duration of the Defence exemption may be limited in time or be permanent.	The MOD will introduce safeguards, that are at the same level as required by REACH; https://reach.eda.europa.eu/netherlands	Will be done on case by case basis. In case, more than one Member State is in need of Defence exemption, NLD MOD prefers them to work together in order to establish safe use.	**0**
Norway	Exemption can be owned by supplier, industry or MoD	Environmental Agency (EA), only following recommendation of the MoD on the application. Cooperation between MoD and EA. Applications shall be forwarded to The Norwegian Defence Materiel Agency.	National security and/or security of friendly nation. A defence exemption will be limited in time.	National procedures are still under discussion.	Not yet decided.	**3** (based on CLP and Reach Regulation)
Portugal	Private companies and MoD (Armed Forces, mostly)	The Directorate-General for Nacional Defence Resources will be a significant “player” in the decision of granting an exemption	The exemptions will be limited in time.	The national procedure is still in development. https://reach.eda.europa.eu/portugal	n/a	**0** - No defence exemption has been asked for or granted.

Member State	Applicant for exemption	Granting authority	Scope and validity of exemption	Description of national procedure (and link to exemption information on EDA portal)	Conditions/Procedures for Acknowledgment/Recognition of Foreign Defence Exemptions	REACH defence exemptions granted (-11/16)
Spain	Supplier, manufacturer or importer	MoD: National Armament Directorate (**DGAM**) with the support of Subdirectorate of Inspection, Regulation and Industrial Strategy of Defence (**SDGINREID**) of the DGAM. The MoD is the body which grants the defence exemptions, in connection with Health and Environmental Ministries (a technical report is requested). This Sub directorate created a **special Unit of REACH exemption (UER)** that has the responsibility to work and coordinate the REACH exemption applications, EDA REACH Spanish MoD representation and any REACH related issues.	The exemption certificate is valid for a period of **three years**, after which the supplier should apply for renewal if considered.	See EDA REACH Portal. A multidisciplinary group of experts belonging to the MoD is in charge of carrying out the dossiers assessment as support to DGAM before granting an exemption. Procurement representatives are part of this group of experts as well as armed forces representatives, toxicological lab, environmental, prevention of occupational hazards, R & D and other related organizations. (https://reach.eda.europa.eu/spain)	Will be considered, however, the exemption decision will be based on the assessment according to national procedure	**0** granted/ 0 rejected / 1 application withdrawn

Member State	Applicant for exemption	Granting authority	Scope and validity of exemption	Description of national procedure (and link to exemption information on EDA portal)	Conditions/Procedures for Acknowledgment/Recognition of Foreign Defence Exemptions	REACH defence exemptions granted (-11/16)
Sweden	Only certain authorities connected to the MoD may apply for defence exemptions, chiefly the Swedish Defence Materiel Administration (FMV). Should industry wish to apply for a defence exemption, they need to go through one of the appointed authorities under the MoD. The defence authority in question is responsible for the application as the applicant.	Surgeon General (the regulatory authority for the Swedish Armed Forces (SAF)), after consultation with the Swedish Chemicals Agency (KemI)	A time limit is imposed on the Surgeon General's decision and applies only to the substance, mixture or goods being applied for. Exemptions will be reviewed after a pre-determined period of time.	https://reach.eda.europa.eu/sweden	None	**0**

Member State	Applicant for exemption	Granting authority	Scope and validity of exemption	Description of national procedure (and link to exemption information on EDA portal)	Conditions/Procedures for Acknowledgment/Recognition of Foreign Defence Exemptions	REACH defence exemptions granted (-11/16)
UK	The MoD (Project Team for substances that they manufacture or import) or Defence Industry Partner.	Secretary of State (SofS). These exemptions will be conferred by written certificates, the content of which will conform to UK legislative requirements.	An exemption certificate is the internal MoD equivalent of a REACH Registration number. It is time-limited, depending on the substance and/or use, and reviewed regularly. Minimum expiry date of 2 years, and will be reviewed annually and at the end of each validity period. The MoD REACH process mirrors the REACH Actor obligations, but within the limited environment of MoD use.	This system is administered on behalf of the MoD by a Defence Equipment and Support (DE&S) policy team. Initial screening by Project Team. Scrutiny by a senior board within DE&S that will make recommendations to the SofS for the granting of an exemption certificate on a case-by-case basis. The exemption process will be subject to scrutiny from the HSE as the REACH CA in the UK. An annual report of exemptions in place will be submitted to the UK Competent Authority (CA) for REACH and SofS. (https://reach.eda.europa.eu/united-kingdom)	The REACH Enforcement Regulations 2008 foresees its Article 7 (1) obligation by an automatic recognition of foreign defence exemption decisions	**10** exemption certificates covering 10 substances have been issued.

F.2 Industry experience

Industry experience with defence exemption requests has been fairly limited to date. Some level of exemption-related activity is mainly reported from France, Germany and the UK.

EXPERIENCE IN THE MS OF ESTABLISHMENT

The consultation of defence industry stakeholders has confirmed that REACH defence exemptions have been **used only in exceptional cases** to date. One example is the case of an Annex XIV substance for which no authorisation has been applied for and the sunset date has passed. Hence, defence exemptions were granted to mitigate the resultant obsolescence risk in the interests of defence.

Views of defence industry stakeholders about the national exemption processes vary depending on the MS. In some countries the exemption process is considered to work well, whereas in others the reluctance of the national MoDs to grant exemptions is criticised. In some cases the scope of a granted defence exemption is considered as too narrow (e.g. if product-based instead of substance-/use-based), thus necessitating multiple exemption requests for the same substance and use.

Defence industry stakeholders have also reported that the **information collection** for a successful exemption request (e.g. description of substitution efforts and why they were not successful) may be very challenging, where the eligible applicant for the exemption and the substance user are not the same companies (e.g. in Germany the exemption request has to be made by the Contractor of the MoD, the substance user may be further up in the complex supply chain).

From the MoD side it was highlighted that in comparison with REACH submissions to ECHA national defence exemption applications go through a slimmer process (limited to the military use), which reduces the relative cost impact for the applicant.

EXPERIENCE FOR OTHER MS

Defence industry stakeholders further report that the biggest problem is the lack of reciprocal acknowledgment given transnational supply chains. Also, little is known about the defence exemption processes in other EU Member States than the own MS, in spite of the information being publicly available on the EDA REACH portal.[375] Defence exemption application forms are only available in the native language of the issuing MoD. This makes it very difficult for non-national industry to understand what is needed in order to apply.

PRECEDENCE OF STANDARD REACH PROCESSES

Defence industry stakeholders highlight the fact[376] that the defence exemption process should not be used as an alternative to the normal authorisation process unless this is necessary in the interests of defence. Thus, in most cases, defence applications need to be covered by the normal authorisation process just as civil applications. It is reported that many stakeholders in the REACH process, e.g. ECHA and its committees seemed initially to be unaware of this limitation. As a result, comments by defence companies (e.g. during public consultation) were disregarded by the stakeholders because of the assumption that military uses were already covered by defence exemptions (although this is not the case). This created the hampering situation that defence companies were told to “use the normal

[375] https://reach.eda.europa.eu.
[376] Which is also mirrored in the EDA CoC 2015.

authorisation process first" by MoDs when asking for defence exemptions, and to "ask for defence exemptions" when asking that defence applications are sufficiently taken into account during decisions on authorisation applications and exemptions from restrictions. However, this might also be attributed to the fact that the EDA CoC was adopted only recently (in March 2015) thus not allowing enough time for stakeholders to familiarise with its rationale and principles. Following the EDA's clear communication to ECHA of 9 July 2015 in the case of decaBDE and the subsequent inclusion of military aircraft in the derogation for the draft Annex XVII entry[377] it can be assumed that the principles of the EDA CoC on REACH defence exemptions, adopted by Member States, are now clear and future misunderstandings will be avoided.

IMPACT OF THE EDA CoC

77% of the defence industry stakeholders consulted didn't know whether the EDA CoC is actually improving the situation of reducing the national differences regarding defence exemptions (see question 1.18. in Annex C). As stated in Annex F.1, the national exemption processes are already considered by MoDs consulted to be in line with the EDA CoC in the majority of cases. A main issue remains its workability in EU transnational supply chains.

CONCLUSIONS ON INDUSTRY EXPERIENCE

Overall it can be said that – as the defence exemption processes have been MS-specific, the same applies to the industry stakeholder experience. It varies from one MS to the other, and often the industry experience with the REACH defence exemption is limited. The exemption possibility is considered useful more as an exceptional tool as foreseen in REACH Art. 2(3) when there is a defence-specific reason for not sharing information with ECHA, in order to maintain a military capability, e.g. while testing alternatives for defence only use (i.e. after sunset date), whereas normally standard REACH processes are followed to ensure operations in the transnational supply chains.

Some industry stakeholders are of the opinion, that the transparency of national exemption requirements and procedures should be further improved, also by means of provision of the application information and forms in other than the national language. These forms could then be collected for example on the EDA website.

F.3 Shortfalls

The continued need for the REACH defence exemption as an instrument to secure military capabilities in exceptional cases is undisputed. However, three major challenges associated with the use of the defence exemption have been identified. They concern:

- **national differences** with regard to defence exemptions (discussed in the previous two sections);
- the common **dual use** of substances for civil and military applications;
- **cross-border operations** in today's typical transnational supply chains.

[377] See info box on the case of decaBDE below in Annex F.3.

DUAL USE OF SUBSTANCES

Defence stakeholders consulted agree that the REACH defence exemption cannot be used to support the continued use of a substance outside the defence domain, chiefly for civil applications. Most substances used for the production of defence equipment have also – and primarily – been used for the same technologies in the civil domain ("dual use") including sectors with lower performance requirements. Therefore, if a substance is withdrawn from the civil market due to REACH constraints (registration, authorisation, etc.), it becomes unavailable also for military customers. Thus, the defence exemption alone cannot mitigate such **commercial obsolescence risks**.

INFO BOX: Omission of military aircraft in the restriction exemption proposal for decaBDE

The ECHA restriction proposal for the substance bis(pentabromophenyl) ether (decabromodiphenyl ether) (**decaBDE, EC 214-604-9**) contained an exemption provision only for civil aircraft.[378] Based on the response by ECHA to the comments/proposals from defence industry in the public consultation on the restriction proposals, there seemed to be a misconception on defence exemptions, which are seen as the only means to deal with REACH issues related to defence, thus leading ECHA, when examining issues/substances that have an impact to both civil and defence applications/uses (as was the case in the specific consultation), to exempt the military uses from the overall discussion and propose these to be dealt with under REACH Article 2(3), i.e. through granting defence exemptions. On **9 July 2015 EDA** clarified in writing the main principles of the EDA CoC to ECHA competent bodies (RAC, SEAC, Secretariat), in particular the view shared by the Member States and defence industry, that the defence exemption can only be a **last resort**, and **not a panacea**. As a result, the restriction derogation has been extended to military aircraft.[379][380]

NATIONAL SECURITY

The differences between defence and security are increasingly blurred in the light of today's security threats. In his State of the Union 2016 speech,[381] the President of the European Commission Jean-Claude Juncker has said:

"A Europe that protects is a Europe that defends – at home and abroad.

We must defend ourselves against terrorism."

"That is why my Commission has prioritised security from day one…

But there is more to be done."

As shown in the impact analysis (Section 3.3.2), there is uncertainty whether the REACH defence exemption can be applied to uses in the interest to **national security** (example of sniffer dogs). The Framework to the EDA CoC 2015[382] lists *"national security"*[383] as a business case for justifying a

[378] All related documents regarding the ECHA restriction process for decaBDE can be found at http://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/1897/term.

[379] ECHA (RAC & SEAC), Opinion on an Annex XV dossier proposing restriction on Bis(pentabromophenyl) ether (DecaBDE), 2 June / 10 September 2015, page 20.

[380] The draft EC Annex XVII amendment as notified to the WTO is available at https://members.wto.org/crnattachments/2016/TBT/EEC/16_1812_01_e.pdf.

[381] Jean-Claude JUNCKER, President of the European Commission, State of the Union 2016.

[382] See EDA Annex to CoC – Framework for applying for a defence exemption from a requirement of REACH (March 2015), page 5. The UK also seems to follow this approach, see https://reach.eda.europa.eu/united-kingdom: *"[…] AND it is in the interest of Defence (or National Security) […]"*).

REACH defence exemption. It was also noted during the study consultation, that REACH should take better account of crisis situations.

One MoD has informed: *"The REACH exemption refers to in the interest of defence. Defence is defined as the action of defending from or resisting attack. However* ***identifying the difference between security and defence is complex and various documents and government articles tend to speak of them together, e.g. security includes defence****. In a French white paper[384] it states: The major innovation compared to the previous White paper is that the security interests are appraised globally without restricting the analysis to defence issues. A national security strategy is defined in order to provide responses to "all the risks and threats which could endanger the life of the Nation." The scope of national security includes the defence policy, but is not limited to it. In order to better ensure the defence of the interests of France and the mission of protecting its population, the national security strategy calls upon the interior security policy, for anything which is not directly related to individual security of persons and property or law and order, as well as the civil security policy. Other policies such as foreign policy and economic policy also contribute directly to national security."*

CROSS-BORDER OPERATION

Intensifying international defence cooperation is a development that highlights the need for solutions with regard to national REACH defence exemption and cross-border operations.

INFO BOX: International defence cooperation

The defence sector has been implementing initiatives to enhance more cooperation between all stakeholders by mutual development, production, operation and maintenance of defence platforms.

OCCAR (Organisation Conjointe de Coopération en matière d'ARmement) is an international organisation whose core-business is the through life management of cooperative defence equipment programmes.[385]

Some further examples of international defence cooperation, with associated REACH impacts for owner and user, include:

- The *European Air Transport Command (EATC)*: The EATC is the command centre that exercises the operational control of the majority of the aerial refuelling capabilities and military transport fleets of a consortium of seven Western European countries. The Netherlands and Luxembourg cooperate in the purchase, maintenance and operation of the Airbus A330 Multi role tanker transporter.

- *16 German Leopard 2A6* tanks leased by the Netherlands that will be operating in an integrated GE-NL Army unit.

[383] But only meaning that "*providing information on defence substance uses would result in breach of security*".

[384] Présidence de la République, The French White Paper on defence and national security (2013).

[385] http://www.occar.int/news

F.4 Exclusion of the defence sector from REACH

In the survey the following question was asked to MoDs and defence industry stakeholders:

Question: *Beyond the current defence exemption which has to be granted for each substance and REACH process, do you consider that a* ***specific exemption or disapplication*** *for defence related applications (such as under RoHS) covering all substances would help mitigate the REACH impact?*

A clear majority of MoDs (73%) and defence industry stakeholders (90%) responding would be in favour of an exclusion solution for defence. The overall message received from the defence industry is that an exclusion of defence from the REACH scope (fully or partly), whatever its form, is very desirable since it will give more time to perform substitution adequately.

Below is an overview of answers from MoDs and defence industry stakeholders that were clearly in favour of such an exclusion possibility:

[MoD] *"Yes, it would mitigate the REACH impact. Yes, we would support it."*

[MoD] *"A general provision for defence uses (as the RoHS) might indeed prove to be helpful. If proposed/ discussed, we would be positive and open to further discussion."*

[MoD] *"It would* [be] *certainly easier to handle. It would require fewer resources which are huge part of the impacts of REACH and REACH exemptions."*

[MoD] *"Yes a clause like Art.2.4 on RoHS directive could be the better solution.*

Even will be wider " … for security purposes"

[MoD] *"Yes this would be helpful to mitigate REACH impact since most supply chains and military equipment are indeed international and the defence exemptions are national. They way defence exemptions are handled today will become problematic in the long run since each member state only can grant exemptions in their own jurisdiction. If for example a substance is manufactured in one member state and then used in defence materiel in other countries, then the question is if this substance really is of interest of defence in the manufacturing member state if they themselves do not use the substance? Furthermore, many military operations are international and defence exemptions will make joint operations more difficult."*

[Defence industry] *"Yes of course, in specific cases, even if the exemption is granted for a limited period. It permits to better plan the substitution. … These costs could be used more effectively to substitute."*

[Defence industry] "*Most definitely – an automatic mutually recognized pan-European defence exemption would be useful due to the safety criticality & reliability of the nature of the product & its lifespan within the field of operations but there is still the limitation mentioned above concerning no guarantee that the substance will be supported."*

[Defence industry] *"Of course. This approach would be a great step forward."*

[Defence industry] *"Yes. We believe that it would be more appropriate for REACH to contain a derogation, similar to the derogation in RoHS:*[386] *"This regulation does not apply to substances where their use is necessary for the protection of the essential interests of the security of Member States, including*

[386] One MoD highlighted that a common issue is that the supplier believes that they can use the RoHS exemption without any consultation with the MoD. Frequently the delivered product comes as "compliant" with exemption but is effectively a non-compliant product.

development, operation and maintenance of arms, munitions and war materiel intended for specific military purposes". However the long term benefit may be limited, due to the time that has already elapsed since the Regulation was enacted, and the number of substances already substituted or withdrawn from the market.

Alternatively a REACH restriction could be applied, for example to hexavalent chrome, which restricts use for any purpose other than defence."

[Defence industry] *"Exemptions for defence products, as under RoHS (there are further product categories excluded like aircraft as means of transport and equipment going to space) would remove most of our products from the scope of REACH. This would significantly mitigate impacts to the company. For all dual use – like for RoHS – REACH would still be applicable."*

[Defence industry] *"Yes, this would be a cost avoidance and eliminates duplication of effort for both us and our customers with a standardized exemption or disapplication."*

[Defence industry] *"Yes, it would remove the uncertainties in the current exemption processes and enhance information security related to defence products."*

[Defence industry] *"Yes and it will give the same chances of competition to the European manufacturers – or non EEA in the call for tenders. At the least, it will be necessary to recognize the same rights for all European members."*

However, there are also more differentiated views:

[MoD] *"MOD policy is to comply with legislation and where there are exemptions instigate departmental arrangement that achieve the same outcomes. MOD policy also requires avoidance of the use of hazardous substances in new equipment and removal from legacy where possible. Where there are permissive exemptions we use them only when necessary to maintain a military capability.*

This applies to RoHS where we expect compliance and only use mercury, cadmium, lead solder etc. when it is necessary e.g. as a safety device, electrical contacts, airworthiness etc."

[MoD] *"Hard to say since RoHS, covering only a few substances, didn't prevent a massive industry shift to lead free soldering, to which the defence industry must adapt, although it makes its life easier for the few applications which need to remain lead based.*
Maybe either REACH could offer disapplication for substances which are essential and will need to be used in the defence sector for the next 40 years (which means MODs and defence industry will be ready to finance this), or authorisation application rules should be extremely simplified for small quantities, which should be our case most of the time for substances uses which will remain defence specific in the long run."

[Defence industry] *"Within some industries where the products have high safety requirements and are subject to qualification, the potential for a general exemption from REACH for Annex XIV substances would be beneficial for the defence industry. However, the use of those substances in non-defence use could be difficult to assess and police."*

[Defence industry] *"YES disapplication is a much more valuable system. However this would not cover the dual use."*

[Defence industry] "*Yes, a general exemption from REACH duties would be very helpful since this would reduce bureaucracy & management costs for REACH and provide transparency and long-term reliability for the entire supply chain (which is not given by singular defence exemptions). For example: while the amount of the substance used is still quite low (and therefore the risk would still be there that the supplier stops producing*

the substance for economic reasons because his margin is too low with such low volumes), it is still much more likely that the supplier of an Annex XIV substances will continue to produce this substance if all defence uses were clearly exempted from REACH than if there was need to apply for a large number of single defence exemptions.

The most important benefits would apply with regard to spare parts: due to the longevity of most defence equipment (several decades), defence products need spare parts for a long time after the original production. Thus, today, a variety of SVHC substances are needed for maintaining existing defence items. Equally high benefits are seen for electronic components for defence products.

However, it is [NDIA]*'s opinion that the introduction of such a general exemption for defence applications would be difficult to implement in REACH without opening the REACH legal text, which the* [NDIA] *members are not in favour of."*

[Defence industry] *"A defence exemption or disapplication to specific applications would facilitate the continuing end-use of chemicals but not necessarily upstream supply or formulation. Such an approach may therefore create a blind-spot for defence industry in the need to assure the continued supply of substances and mixtures, still requiring much of the data engagement and supply chain engagement activity. It is also unclear whether defence customers would be satisfied by a greater degree of laissez-faire with respect to risk to workers, environment and users."*

Only a small minority is clearly **against** a change of the current situation and believes that the national granting of a defence exemption on a case-by-case basis is most appropriate. Arguments brought forward against an exclusion from the REACH scope (fully or partly) for defence include:

- Consideration of defence interest as a national matter;
- Current defence exemption procedures ensure proper risk assessment;
- There is not enough experience with the implementation of the EDA CoC 2015;
- Not clear how to cover the frequent dual use;
- Change of the legal text is not desired.

G. AUTHORISATION APPLICATIONS FOR DEFENCE: ADDITIONAL INFORMATION

G.1 Overview of main REACH applications for authorisation relevant for defence

Note: This overview shows the applications analysed for the study. It may not be exhaustive in terms of defence-relevant authorisation applications. Those applications highlighted in green were used to calculate the cost/benefit ratio average.

Company	Substance	Use	Dossier Number	Domain	Military/Dual Use	AfA type	Requested review period	Approved review period‡	Application tonnage
Rolls-Royce	DEHP	The processing of a stop-off formulation containing DEHP during the diffusion bonding and manufacture of aero engine fan blades.	0001-01	Aerospace	Dual	Downstream	5-10 years	7 years	1t/y
Deza	DBP	Use of DBP in propellants Formulation: Industrial use of DBP as a burning rate surface moderant, plasticiser and/or coolant in the formulation of nitrocellulose-based propellant grains. Use at industrial site: Industrial use of DBP-containing propellant grains in manufacture of ammunition for military and civilian uses, and pyrocartridges for aircraft ejection seat safety systems [includes propellants for police force ammunition and excludes propellants intended for manual, private reloading of ammunition cartridges by civilian users, i.e., licensed individual sports shooters and hunters. No direct consumer use of DBP or its mixtures is covered by this Use.]	0005-02	Munitions	Dual	Downstream	12 years	12 years	100t/y
Roxel -Rocket Motors	DEHP	Industrial use of DEHP in manufacture of solid propellants and motor charges for rockets and tactical missiles	0007-01	Munitions	Military	Downstream	4 years	4 years	300kg/y
Roxel -Rocket Motors	DBP	Industrial use of DBP in manufacture of solid propellants and motor charges for rockets and tactical missiles	0007-02	Munitions	Military	Downstream	4	4 years	10kg/y

Company	Substance	Use	Dossier Number	Domain	Military/Dual Use	AfA type	Requested review period	Approved review period‡	Application tonnage
DCC Maastricht B.V. OR	Lead sulfochromate yellow (C.I. Pigment Yellow 34)	Distribution and mixing pigment powder in an industrial environment into solvent-based paints for non-consumer use	0012-01	All	Dual	Upstream	-	7 years	2100t/y
DCC Maastricht B.V. OR	Lead sulfochromate yellow (C.I. Pigment Yellow 34)	Industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating etc.)	0012-03	All	Dual	Upstream	12 Years	7 years	840t/y
DCC Maastricht B.V. OR	Lead sulfochromate yellow (C.I. Pigment Yellow 34)	Professional, non-consumer application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture etc.) or as road marking	0012-05	All	Dual	Upstream	12 years	7 years	1260t/y
DCC Maastricht B.V. OR	Lead sulfochromate yellow (C.I. Pigment Yellow 34)	Distribution and mixing pigment powder in an industrial environment into liquid or solid premix to colour plastic/plasticised articles for non consumer use	0012-07	All	Dual	Upstream	12 years	7 years	2100t/y
Etienne LACROIX	Lead Chromate	Industrial use of lead chromate in manufacture of pyrotechnical delay devices contained into ammunition for naval self-protection	0028-01	Munitions	Military	Downstream	15 years	- (RAC/SEAC opinion: 7 years)	12kg/y
CTACSub	Chromium trioxide	Formulation of mixtures	0032-01	Aerospace and Land	Dual	Upstream	12 years	- (RAC/SEAC opinion: 7 years)	9,000t/y
CTACSub	Chromium trioxide	Surface treatment for applications in the aeronautics and aerospace industries, unrelated to Functional chrome plating or Functional chrome plating with decorative character	0032-04	Aerospace	Dual	Upstream	12 years	- (RAC/SEAC opinion: 7 years)	1,000t/y

Company	Substance	Use	Dossier Number	Domain	Military/Dual Use	AfA type	Requested review period	Approved review period‡	Application tonnage
CTACSub	Chromium trioxide	Surface treatment (except passivation of tin-plated steel (ETP)) for applications in various industry sectors namely architectural, automotive, metal manufacturing and finishing, and general engineering (unrelated to Functional chrome plating or Functional chrome plating with decorative character)	0032-05	Land, naval	Dual	Upstream	7 years	- (RAC/SEAC opinion: 4 years)	1,000t/y
Akzo Nobel Pulp and Performance Chemicals	Sodium dichromate	Use of Sodium dichromate as an additive for suppressing parasitic reactions and oxygen evolution, pH buffering and cathode corrosion protection in the electrolytic manufacture of sodium chlorate with or without subsequent production of chlorine dioxide.	0041-01	All	Dual	Upstream	12 years	-	0-10 tonnes combined
Akzo Nobel Pulp and Performance Chemicals	Sodium dichromate	Use of Sodium dichromate as an additive for suppressing parasitic reactions and oxygen evolution, pH buffering and cathode corrosion protection in the electrolytic manufacture of potassium chlorate.	0041-02	All	Dual	Upstream	12 years	-	
Brenntag UK Ltd, Henkel AG & Co. KGaA, AD International BV	Sodium dichromate	Use of Sodium dichromate for surface treatment of metals such as aluminium, steel, zinc, magnesium, titanium, alloys, composites and sealings of anodic films	0043-02	Aerospace	Dual	Upstream	12 years	-	1300 t/y
Brenntag UK Ltd, Henkel AG & Co. KGaA, AD International BV	Sodium dichromate	Use of Sodium dichromate for the electrolytic passivation of tin plated steel for the packaging industry	0043-03	Aerospace	Dual	Upstream	4 years	-	1300 t/y
CCST	Strontium chromate	Formulation of mixtures	0046-01	Aerospace	Dual	Upstream	12 years	-	200t/y
CCST	Strontium chromate	Application of paints, primers and specialty coatings containing Strontium Chromate in the construction of aerospace and aeronautical parts, including aeroplanes / helicopters, spacecraft, satellites, launchers, engines, and for the maintenance of such constructions.	0046-02	Aerospace	Dual	Upstream	12 years	-	200t/y

Company	Substance	Use	Dossier Number	Domain	Military/Dual Use	AfA type	Requested review period	Approved review period‡	Application tonnage
SOFRADIR	Potassium Dichromate	Industrial use of potassium dichromate-based mixtures during the steps of initial and final etching of CZT layers during the production of opto-electronic components gathering a readout and an infrared detecting circuit with the MCT technology	0048-01	All	Dual	Downstream	7 years	-	250kg/y
SOFRADIR	Potassium Dichromate	Industrial use of potassium dichromate based mixture during the etching of both InSb substrate sides during the production of optoelectronic components gathering a readout and an infrared detecting circuit with the InSb technology	0048-02	All	Dual	Downstream	4 years	-	50kg/y
NEXTER	Chromium Trioxide	Industrial use, of a qualified mixture of chromium trioxide by spraying or immersion, and of a qualified mixture of dichromium tris(chromate) by pen application, for the chromate conversion coating of welded mechanical structures of armoured vehicles and associated parts made of high mechanical properties aluminium alloys for military use, and requiring a maintained electrical conductivity after severe climatic environments, atmospheric corrosion resistance and paint adhesion.	0057-04	Land	Military	Downstream	7 years	-	600kg/y
NEXTER	Dichromium tris(chromate)	Industrial use, of a qualified mixture of chromium trioxide by spraying or immersion, and of a qualified mixture of dichromium tris(chromate) by pen application, for the chromate conversion coating of welded mechanical structures of armoured vehicles and associated parts made of high mechanical properties aluminium alloys for military use, and requiring a maintained electrical conductivity after severe climatic environments, atmospheric corrosion resistance and paint adhesion.	0057-05	Land	Military	Downstream	7 years	-	10kg/y
Circuit Foils	Chromium trioxide	Industrial use of chromium trioxide for the treatment of copper foil used in the manufacture of Printed Circuit Board	0058-01	All	Dual	Downstream	12 years	-	15.8t/y

Company	Substance	Use	Dossier Number	Domain	Military/Dual Use	AfA type	Requested review period	Approved review period‡	Application tonnage
Circuit Foils	Arsenic acid	Industrial use of arsenic acid for the treatment of copper foil used in the manufacture of Printed Circuit Board	0059-01	All	Dual	Downstream	12 years	-	3.25t/y
Gentrochema BV	Sodium dichromate	Formulation of mixtures of sodium dichromate for surface treatment of metals such as aluminium, steel, zinc, magnesium, titanium, alloys, composites, sealings of anodic films; and the electrolytic passivation of tin plated steel for the packaging industry.	0063-01	Aerospace	Dual	Upstream	12 years	-	1300t/y
Gentrochema BV	Sodium dichromate	Use of Sodium dichromate for the electrolytic passivation of tin plated steel for the packaging industry.	0063-03	Aerospace	Dual	Upstream	4 years	-	1300 t/y
MTU Aero Engines AG	Chromium Trioxide	Functional chrome plating for aerospace applications for civil and military uses, comprising coating of new components for aircraft engines as well as maintenance, repair and overhaul work on aircraft engine components	0066-01	Aerospace	Dual	Downstream	15 years	-	350kg/y
MTU Aero Engines AG	Chromium Trioxide	Surface treatment for aerospace applications for civil and military uses, comprising treatment of new components for aircraft engines as well as maintenance, repair and overhaul work on aircraft engine components, unrelated to functional chrome plating	0066-02	Aerospace	Dual	Downstream	15 years	-	40kg/y
Herstal	Chromium Trioxide	Industrial use of chromium trioxide in the hard chromium coating of military small- and medium-caliber firearms barrel bores and auxiliary parts subject to thermal, mechanical and chemical stresses, in order to provide hardness, heat resistance and thermal barrier properties, as well as corrosion resistance, adhesion and low friction properties	0070-01	Munitions	Military	Downstream	12 years	-	5t/y

Company	Substance	Use	Dossier Number	Domain	Military/Dual Use	AfA type	Requested review period	Approved review period‡	Application tonnage
Souriau sas Amphenol Limited AMPHENOL SOCAPEX ITT Cannon GmbH Connecteurs Electriques Deutsch TE UK Ltd	Chromium trioxide	Industrial use of a mixture containing hexavalent chromium compounds for the conversion of cadmium coated circular and rectangular connectors in order to achieve a higher level of performances than the requirements of international standards as well as to withstand harsh environments and high safety applications (such as in the military, aeronautic, aerospace, mining, offshore and nuclear industries or for the application in safety devices for road vehicles, rolling stock and vessels).	0072-01	All	Dual	Downstream	12 years	-	4.76t/y
Souriau sas Amphenol Limited AMPHENOL SOCAPEX ITT Cannon GmbH TE UK Ltd	Chromium trioxide	Industrial use of a mixture containing hexavalent chromium compounds in conversion coating and passivation of circular and rectangular connectors in order to meet the requirements of international standards and special requirements of industries subject to harsh environments.	0072-02	All	Dual	Downstream	7 years	-	5.86t/y
Souriau sas	Chromium trioxide	Industrial use of a mixture containing chromium trioxide for the etching of composite connectors used by industries subject to harsh environments, to mainly ensure adhesive deposit to meet the requirements of international standards.	0072-03	All	Dual	Downstream	4 years	-	3.7t/y
Connecteurs Electriques Deutsch	Potassium Dichromate	Industrial use of a mixture containing hexavalent chromium compounds for the conversion of cadmium coated circular and rectangular connectors in order to achieve a higher level of performances than the requirements of international standards as well as to withstand harsh environments and high safety applications (such as in the military, aeronautic, aerospace, mining, offshore and nuclear industries or for the application in safety devices for road vehicles, rolling stock and vessels).	0072-04	All	Dual	Downstream	12 years	-	4.76t/y

Company	Substance	Use	Dossier Number	Domain	Military/Dual Use	AfA type	Requested review period	Approved review period‡	Application tonnage
Connecteurs Electriques Deutsch	Potassium Dichromate	Industrial use of a mixture containing hexavalent chromium compounds in conversion coating and passivation of circular and rectangular connectors in order to meet the requirements of international standards and special requirements of industries subject to harsh environments.	0072-05	All	Dual	Downstream	7 years	-	5.86t/y
Souriau sas; TE UK Ltd	Sodium dichromate	Industrial use of a mixture containing hexavalent chromium compounds for the conversion of cadmium coated circular and rectangular connectors in order to achieve a higher level of performances than the requirements of international standards as well as to withstand harsh environments and high safety applications (such as in the military, aeronautic, aerospace, mining, offshore and nuclear industries or for the application in safety devices for road vehicles, rolling stock and vessels).	0072-06	All	Dual	Downstream	12 years	-	4.76t/y
Souriau sas Amphenol Limited AMPHENOL SOCAPEX	Sodium dichromate	Industrial use of a mixture containing hexavalent chromium compounds in conversion coating and passivation of circular and rectangular connectors in order to meet the requirements of international standards and special requirements of industries subject to harsh environments.	0072-07	All	Dual	Downstream	7 years	-	5.86t/y

‡ A dash (-) indicates that the opinion from the ECHA committees (RAC and SEAC) are still under development.

G.2 Review of submitted authorisation applications covering military uses

From the questionnaire responses, the large majority of defence companies that responded indicated that they themselves, or members of their supply chain, had been **impacted by the authorisation process**.

As shown in Figure 23, more than 75% of companies from the defence industry described **Cr(VI) as being critical** to their defence operations. This is reinforced by the number of authorisation applications covering defence inclusive uses for this group of substances with over 85% being for hexavalent chromium compounds. In total, thus far, almost 89% of applications involving a military use have been for *inorganic* substances. This demonstrates the importance of some inorganic substances to the defence sector. Furthermore, inorganic substances gain their properties from the presence of metal atoms, in particular oxidation states and reactivities. Like for like substitution with different metals of the periodic table is difficult in some cases, while it is impossible in most. As a result, this reliance on current, SVHC containing technologies is understandable and necessary to meet the stringent demands of military standards.

Figure 23 Applications for authorisation covering defence by Substance and Substance Type

TONNAGES

The uses in the submitted applications for authorisation cover applications in land, sea, air and space systems as well as munitions and are applications from both upstream, e.g. from formulators, and downstream, e.g. from prime contractors. From the downstream applications, 56% are for tonnages of 1 tonne or lower of a substance; **the use with the smallest quantity is 10 kg/year**, and the **median tonnage** covering all the applications with a military use is **3.25 t/year**.

COSTS

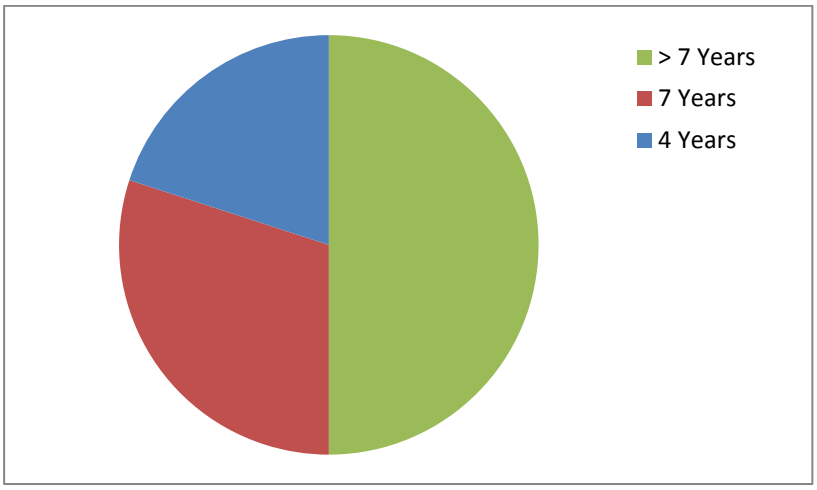
Direct costs of applying for authorisation are discussed in Section 4.1.2.3 and Annex H.7, here the focus is placed in the cost of **non-use scenarios**. For all authorisation applications covering defence applications and included in Annex G.1, it is possible to assess the potential overall monetary impact of all non-use scenarios added together. This comes up to an estimated cumulative non-use cost of € 53.2bn for all the substances, according to the applicants. In particular, the largest economic impact to a single downstream user applicant with military uses would be € 1.3bn for its uses of a chromate in the surface treatment of aircraft engine components.

The **total simple average cost to benefit ratio** of all applications with military uses is approximately **1.77 million : 1** (see Section 4.2.3.1).

REVIEW PERIODS

Analysis of the applications covering military uses, either exclusively or in a dual use, shows that half of the applicants (50%) have requested a review period **longer than the "normal"** review period of 7 years. About 30% of applicants have requested a 7 year review period for their use, and only 20% have requested "bridging" or 4 year review periods (Figure 24).

Figure 24 Review periods requested in the authorisation applications analysed



This is confirmed by the study survey results. When consulted, industry respondents considered that the review periods contemplated today by ECHA are **too short (even 12 years)** for defence equipment, which can have production, utilisation and maintenance lifecycles of up to 80 years. This most likely means that defence companies will be required to **re-apply for authorisation** on most SVHC substances used **several times** over the expected lifecycle of their equipment.

G.3 Streamlining and simplification of authorisation applications

Many respondents to the questionnaire highlighted the need to streamline and simplify the Authorisation process for defence equipment given their critical need to continue using certain Annex XIV substances to fulfil functional requirements over a the long periods of time required to find a suitable replacement. This may imply applications for several renewals of authorisations

INFO BOX: Ongoing EC initiative for low volumes and legacy spare parts

In 2015 the EC launched a consultation on the simplification of the authorisation process for low volumes and legacy spare parts.[387] The objective of this consultation was for stakeholders to provide comments on the proposed scope, conditions and review period for the specific case of authorisation applications for "low volumes" (< 100 kg) including the level of detail on the information required in the applications and also to comment on the definition and scope of "legacy spare parts" and indicate which substances listed in Annex XIV of REACH are used in the production of legacy spare parts as well as the normal length of time the legacy spare parts are expected to be supplied in order to preserve the functionality of the articles for which they are intended.

A simplification process for the use of Annex XIV substances in low volumes was thought necessary because the potential benefits for the human health and the environment in terms of reduced risks related to their substitution versus the costs of an authorisation application are disproportionate.[388]

The EC has now proposed for the first time **extended use-specific sunset dates** under REACH Article 58(1)(c)(i) for the use of certain substances *"in the production of **spare parts** for the repair of articles the production of which ceased or will cease before the sunset date applicable to that substance, where that substance was used in the production of those articles and the latter cannot function as intended without those spare parts, and for the use of the substance (on its own or in a mixture) for the repair of such articles, where that substance was used in the production of those articles."* - in order to **avoid the premature obsolescence** of articles. However, the transitional arrangement is proposed only to allow for the adoption of implementing measures for simplified applications for authorisation, which are envisaged for these cases. *[389]*

Of particular interest in the discussions on this topic was the potential **volume threshold** for low volume use, which was highlighted by many stakeholders. ASD in its position paper points out that while supportive of the moves to introduce a simplified process for low volumes, the use should not be limited to downstream application nor should it be limited to 100 kg covering all the (different) uses of the same substance. They argue that such moves are necessary to reach the goal of simplification.

Additionally, **spare parts** that are intended for articles produced and placed on the market before the sunset date are also being considered for simplified authorisation process. Provision of these parts is in limited numbers and decreases as the articles for which they are intended reach their end of life. The costs associated with authorisation for these parts are thought to be disproportionate because research on alternatives for such naturally obsoleting uses is technically and economically difficult, similarly to requalification of legacy designed defence equipment.

Furthermore, defence products are produced in very limited numbers and small lines, which may have since ceased operation. As a result some of the know-how or design requirements are no

[387] http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8081: Accessed 11.12.2016.
[388] EC, "Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs" (December 2015).
[389] See http://ec.europa.eu/growth/tools-databases/tbt/nview.cfm?p=EU_407_EN.

longer available to allow for changing of MRO operations which, in any event, would require military qualification which is a time consuming and very costly in the defence sector.

Spare parts manufactures mostly lack the capability to assess or qualify alternatives, being independent of the OEM. This is also a significant argument as to why the simplification needs to be extended to repair use of substances/mixtures, and that the repair use of substances/mixtures should not be limited to only legacy defence equipment and should include equipment both in production and use as inclusion of maintenance will avoid premature obsolescence and disposal of the equipment and extend their useful life. This position is similar to that adopted by ASD.[390]

G.4 General exemptions from REACH authorisation: Intermediates and Scientific R&D

Further to the exemption clauses discussed in Section 4.2.3.5 defence industry stakeholders also reported issues with other general REACH exemption clauses from authorisation:

USE AS INTERMEDIATES (REACH ARTICLE 2(8)(b))

Intermediates are exempted from REACH authorisation (REACH Article 2(8)(b)). Some defence industry stakeholders have reported continued issues with the application of the REACH intermediate definition, including persisting differences in authority interpretations. The decision of the ECHA Board of Appeal of 25 May 2016 in case A-010-2014 (Nordenhamer Zinkhütte GmbH, diarsenic trioxide) demonstrates, how persisting uncertainties around REACH legal definitions and interpretation differences – here: intermediate definition - can drive up industry's cost to ensure business continuity under REACH Annex XIV.[391] Whereas such uses are mostly limited to manufacturers in the chemicals industry, a wrong course of action by those actors may also lead to unforeseen supply chain disruptions affecting the defence industry.

USE IN SCIENTIFIC R&D (REACH ARTICLE 56(3) WITH ARTICLE 3(23))

Uses of Annex XIV substances in scientific research and development are exempted from authorisation according to REACH Article 56(3) with Article 3(23). Some defence industry stakeholders have reported that the interpretation of *"scientific research and development"* (SRD) is still not clear at all. Indeed the two key elements of the definition in REACH Article 3(23) *"any scientific experimentation, analysis or chemical research"* and *"carried out under controlled* conditions *in a volume less than one tonne per year"* are not further defined by REACH. However, a number of clarifications for industry have already been made by ECHA, e.g. in its responses to public consultations on its draft Annex XIV recommendations, its *Guidance on Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD)*[392] and Questions and Answers.[393]

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[390] JOINT ASD/AEA POSITION PAPER "REACH AUTHORISATION CONSULTATION ON APPLICATIONS FOR LOW VOLUMES AND AN EXTENSION OF TRANSITIONAL ARRANGEMENTS FOR USES IN LEGACY SPARE PARTS" (17 April 2015).

[391] See the discussion of this decision in Annex J.

[392] Latest version 2.0 of November 2014, see http://echa.europa.eu/documents/10162/13632/ppord_en.pdf.

[393] E.g. regarding use for monitoring and quality control (ECHA REACH Q&A 0585 and 0844) and lifecycle steps (such as formulation preceding the end-use in SRD (ECHA REACH Q&A 1030), available at http://echa.europa.eu.

H. REACH IMPACTS ON THE EU DEFENCE SECTOR: ADDITIONAL INFORMATION

H.1 List of REACH benefits according to defence sector stakeholders

MoD respondents that indicated that they had made, or will soon implement, improvements to their RMMs due to REACH, the **main areas of improvement** were cited as being:

- Improvements of **internal directives and training** regarding implementation of REACH;
- REACH implementation **audits** during the production process;
- Improvement in the **quality of EHS data** on substances, including labelling, packaging, and compatibility rules for storage of chemicals, though it was noted that it was sometimes difficult to get all the necessary information, for example because of intellectual property issues:
  - One way this data is reaching MoDs is through **SDSs**;
  - Harmonisation of layout and information in SDSs has introduced a level of transparency into the supply and use of substances and mixtures throughout the EU.
- **Increased ease in documenting some uses** of particular substances and mixtures which allows a better understanding of any potential regulatory impacts and the type of systems involved
  - The knowledge disseminated due to Article 33 was highlight by one MoD as enabling users to improve safety measures during e.g. maintenance.
- REACH has eased the process of assessing relevant information needed to conduct risk analysis.

Of the 41% of **defence industry** respondents that indicated that they **had made improvements** to their RMMs due to REACH (see question 1.13 in Annex C), the main areas of improvement were cited as being:

- **Implementation of new methods to identify SVHCs** in new and legacy products within the supply chain to allow:
  - Communication of SVHC contents to customers to ensure safe use;
  - Monitoring of the presence of SVHC and other substances to avoid potential obsolescence problems of substances/mixtures used in production that may enter in Annex XIV.
- Chemical risk reduction by **replacement of SVHC** substances, where possible:
  - In some instances, this entailed new risk assessments on health and safety at work as a consequence of using a replacement substance/mixture.
- As end users defence companies have limited visibility of all substances and mixtures used in the materials and products. They are, consequently, reliant on SDS data to ensure that the hazards of the substances and mixtures are known such that the risks can be mitigated. **Improvements in the information contained in SDS** has:
  - Made it easier to better understand the risks involved with using particular substances so the risk management planning can be improved;

- Allowed easier monitoring of chemicals imported and substances used in manufacturing processes;
- Improved the knowledge and the control of the chemicals used by the staff that are incorporated to the products and provided better awareness of EHS aspects relying with chemicals.

The reasons for the implementation of these improvements were varied and included recommendations from the RAC in the frame of applications for authorisation. **Authorisation driven improvements** were identified by those companies that were involved the process as being:

- Improved equipment of workstations to reduce the workers' exposure as proposed by the RAC as a condition of authorisation;
- Independent review of risks as part of the authorisation application process. Any areas for improvement were identified and corrected;
- Review of the effectiveness of exposure controls e.g. LEV effectiveness for Cr(VI).

Of those that have implemented the improvements, only a minority believed that these measures delivered an actual benefit to worker health and the environment, while the remainder pointed to existing (national) regulations that already covered safe use and suggested that there had been no significant change in benefit due to REACH.

Nevertheless, it was noted by several respondents that REACH and CLP processes have, to an extent, **supplemented** national laws on some topics, for example substance and mixture hazards which are communicated through SDSs. This, in turn, has added to the knowledge base for health, safety and environment planning, though the length and complexity of eSDSs, as well as the inclusion of information not relevant for military uses, were highlighted as factors which negatively affect the ease of obtaining the desired information.

Furthermore, 39% of the defence industry stakeholders consulted see **direct benefits from REACH other than related to health, safety and the environment** (see question 1.17. in Annex C). The following examples have been provided by some defence industry stakeholders:

- Activities in the company triggered by REACH have created a review of data sets (e.g. SDS, supplier database) that lead to **better data quality**.
- REACH helps **improve knowledge** on the substances' properties (toxicological, ecological), and the hazards of using these substances and mixtures. Valuable hazard information on substances is now accessible on the ECHA website.
- The exchange of information within the **supply chain** (upstream & downstream) has improved and stronger relationships have been established within the aerospace industry. They have for example confirmed the effectiveness of hexavalent chromium throughout the industry.
- REACH has further facilitated the **investigation of safer alternatives** in manufacturing processes & products.
- There is generally **greater awareness of global regulatory activity** by enterprise and business management.
- As an EU Regulation REACH contributes to a **level playing field** within the EU/EEA.

REACH compliance confers an **added value to products**. Many respondents noted that REACH compliance is one of a selection of criteria used when selecting suppliers. EU based suppliers are viewed favourably due to the perception that they already have knowledge of and are compliant with REACH (see Annex H.4).

H.2 List of significant explanations on competitiveness by defence industry

Reasons given for Loss of competitiveness:

[National Defence Industry Association] *"Within our supply chain. Some of our subcontractors/suppliers have been obliged to invest in new process and installations (case of surface processing)."*

[National Association] *"Even if the current contracts are inside EU, potentially the MoD and/or Prime Contractors could utilize components/systems from non-EEA countries and then, free from REACH issue."*

[Ammunition] *"Mainly when your customers are out of EEA, because they are less understanding with this regulation which doesn't apply in their country. They are not ready to pay more to substitute a substance which represents no danger for them, mostly in a military application."*

[Aerospace] *"More administrative tasks and diversion of R&D budget"*

[Electronics] *"Potentially could outsource defence manufacturing to non-EU countries if such platforms are affected by (predominantly) authorisation issues/costs"*

[Ammunition] *"REACH led to higher costs for the products (due to REACH implementation) while technological performance was reduced (or maintained at best) due to substitution"*

[Ammunition] *"not competitive in a call for tender in front of a non EEA country which doesn't have to comply with all the regulation"*

[Ammunition] *"R&D spent for substitution efforts were not available to further improve our products (with regard to functionalities / performance). If a product contains a SVHC (candidate), customers are more reluctant to buy (although this use is still allowed). Customers not satisfied with performance of new products with substitutes"*

[Ammunition] *"But in some cases the technological performance is reduced to fulfil the REACH requirements. This situation lowers our global competitiveness because we are not able to score with low prices."*

[Components] *"We had to decrease our budget for product performance related R&D to pay for the development of a replacement solution (with no performance improvement). This weakens our competitiveness compared to suppliers not submitted to REACH regulation."*

Reasons given for Gain of competitiveness:

[National Association] *"the well proved REACH/Obsolescence management could reassure the Customer that impose specific clause in current (or potential) contracts"*

[Aerospace] *"Compliance is a significant strength point for EEA market customers."*

H.3 List of key REACH-induced uncertainties for defence industry in EU

Table 23 List of key REACH-induced uncertainties for defence companies operating in EU

REACH process uncertainties	Business and supply chain uncertainties
Authorisation Will the substance be included in the candidate list and Annex XIV? Probability and when? (roadmap missing) How is the RMOA for substances of interest to a certain industry conducted in the various Member States? Which issues are considered? Will the specific industry be involved? Non-binding nature of the conclusions… What are the timelines for Annex XIV inclusion, authorisation decision and review? Use conditions, review periods, use coverage associated with an EC authorisation decision? (example of chromium trioxide) When will the simplified EC rules for low volumes and legacy spare parts come into force? Content of those rules? To which substances will they apply? **Legal interpretation uncertainties:** May one rely on or claim an exemption (e.g. intermediate use, Article 58(2), fuels, etc.)? Does the restriction apply? (example of cadmium) Does a particular ammunition type (there are many different types) qualify as an article only, or in combination with a substance/mixture? Different opinions of MoDs, suppliers, customers? Impact on SDS, labelling, registration and authorisation duties. Uncertainty what the exact interpretation of the ECJ Judgment on Article 33 will be (whether it will be necessary to report the component, too). How are the national enforcement authorities assessing REACH compliance? Different standards? Does the SME definition apply to a certain company? **Defence Exemption** Defence exemption policy implementation between EU Member States is uncertain, especially for cross-border operations	**Authorisation:** Who should apply for authorisation? Should a consortium be formed? How to organize? Will supply continue after the Annex XIV sunset date? Uncertainty on substitution of SVHCs (e.g. chromates): how to value other possibilities (like authorisation, defence exemption, offshoring) in comparison to substitution, especially since qualification is needed after substitution? Which option is best for a company? Will a proposed alternative be itself identified as SVHC for authorisation or restricted in the foreseeable future? Is it worth the investment? By when will the alternative be fully qualified and implemented? Once implemented, is it going to work reliably for the next years and decades as the solution we had to phase out? How will industry respond to the authorisation decision (e.g. when setting a short review period)? **REACH Article 33 and 7(2), C&L notification:** What SVHCs/hazardous components are included in imported mixtures and (complex) articles or used in their manufacture (i.e. process chemicals)? Uncertainty of how to compile Article 33 data most efficiently, and who to provide to within downstream user (DU) / end customer – military users are typically large, diverse organisations. **REACH Registration 2018:** Will all the substances in my products be registered by 2018? By whom? Which substances are affected? Will supply continue after 31.5.2018? **Other** Uncertainty about role of UK with regard to REACH due to decision to leave the EU (“Brexit”, see Annex H.9)

H.4 Adaptation of procurement strategies due to REACH

The adaptation of the procurement strategy is a key tool to mitigate REACH-related obsolescence and ensure continued security of supply.

56% of defence industry stakeholders consulted stated that REACH had an impact on the selection of their suppliers (e.g. EU vs. non-EU) and on procurement strategy in general.[394] This was often linked to the purchase of chemical products to avoid **registration** duties.

Many respondents noted that REACH is one of a selection of arguments to preferably use **EU suppliers**, as they would be REACH compliant and so reduce impact of costs and administrative burden in future. Some respondents stated that it is clear procurement strategy to avoid working with suppliers outside of the EU due to REACH. Another argument to purchase European is that supplier selection includes assessment of REACH knowledge and control and so to get reliable information and documentation.

Respondents noted that due to the fact that **authorisation** is budget and knowledge intensive they consider switching supply, as some companies (mainly SMEs) would not be able to cope with necessary investments. Another strategy considered is to purchase articles from outside the EU to avoid authorisation.

In general it can be said that the impact of REACH is that companies preferably purchase European until the point that a certain substance is on candidate list or falls under authorisation and if the EU manufacturer ceases the production of substances included in Annex XIV. In this case there is no other choice than to import this substance from outside the EU. Another strategy mentioned is to import substances and mixtures only in low amounts (lower than 1t per substance per year).

Main drivers and defence company responses are summarised in Table 24 below:

Table 24 REACH impact on procurement strategy of EU defence companies

REACH drivers	Industry responses
Registration burden	Switch to reliable REACH-registered (EU) sources (Note: not possible for non-EU formulations) Lower the imported volume per substance below the registration threshold of 1 t/y
Authorisation burden (e.g. for SMEs)	Switch to reliable REACH-authorised (EU) sources
Cease of EU manufacture of Annex XIV substance	Switch to non-EU import out of necessity

[394] See question 1.9. in Annex C.

H.5 Supply chain communication and (extended) Safety Data Sheets

The complexity of the defence supply chains and number of supply chain actors is one of the key factors that influences decisions related to different REACH processes, e.g. upstream authorisation applications.

The major issues related to communication are:

- Length of the chain and the number of actors;
- Transparency, including intellectual property issues;
- Quality of SDSs.

LENGTH OF THE SUPPLY CHAIN AND THE NUMBER OF ACTORS

Defence companies are **often 6-8 tiers away** from the substance manufacturers and importers, with these companies located internationally and spanning many different countries, both inside and outside of the EU. The supply chain complexity, therefore, complicates the implementation of REACH.

There is often **no direct relationship** between the defence company and the suppliers of most of the substances/mixtures used by them or in course of manufacturing components for their complex articles. This is further complicated by the involvement of many SMEs where, it has been stated, communication is often ineffective.[395]

The **numbers of suppliers involved at each level** may number in the thousands which includes multiple levels within component suppliers, multiple levels of formulators, for example paints are often mixtures of mixtures. Since products such as space vehicles, armoured vehicles or aeroplanes may contain **hundreds of thousands to millions of parts**, the number of companies involved is huge, with some supply chains having up to 30,000 suppliers, many of them SMEs.

TRANSPARENCY, INCLUDING INTELLECTUAL PROPERTY ISSUES

In addition to the difficulties of communication due to the number of participants, supply chain **transparency is limited in order to protect confidential business information in relation to chemical products and upstream suppliers used**. As a result, direct contact between downstream defence companies and suppliers far up the supply chain is very rare. As an example, one company noted that of their REACH budget over the past 5 years, about 70% was estimated to have been spent on supply chain communication. This involved the internal resources of the company required to try to engage upstream and also the IT systems that were put in place to facilitate it.

[395] JOINT ASD/AEA POSITION PAPER "REACH AUTHORISATION CONSULTATION ON APPLICATIONS FOR LOW VOLUMES AND AN EXTENSION OF TRANSITIONAL ARRANGEMENTS FOR USES IN LEGACY SPARE PARTS" (17 April 2015).

CASE STUDY: IMPORTED "BLACK BOX" EQUIPMENT AND LEGACY SYSTEMS

An example of an EU company that develops and produces components of a missile for a US company was given. In this project the US customer defines parts and materials irrespective of the REACH Regulation. Also, equipment is provided from the US company to be incorporated into the missile system by the EU company, the make-up of which is a complete unknown black box.

The same EU company is also involved with another US developed missile defence system. The EU company provides after-sales-services like technical service and maintenance of military systems that were developed and produced outside not only their company but also the EU. Some of these systems were developed 30 or more years ago and as a result, the information on constituent materials and substances is very limited and the maintenance and technical services are set for many years before the implementation of REACH. Quite often there is not even a drawing set available any more. A redesign is not feasible or economically viable for such legacy systems, and exchange of parts or substances sometimes can be physically impossible. Any modifications would affect the performance but cannot be verified against quality requirements of the systems. In any case, influencing design may not be an option for EU based importers.

Whilst some parts are designed in detail by prime contractors, many parts are manufactured in accordance with functional specifications, for which the **part supplier holds the design and the intellectual property on the manufacture and substances/mixtures used**. Downstream customers for these parts will not have sufficient knowledge of the materials and chemicals used to be able to track and manage the authorisation process. This makes it very difficult to identify potential problem areas and address substitution in a timely manner. Complex supply chains aggravate this issue because even if information is passed down the supply chain, it frequently doesn't reach the end user who is the only part of the supply chain that can approve a change.

It was stated that defence companies, generally, do not know which substances/mixtures they rely on as these are provided within the supply chain, and further they did not know which of the registration deadlines, if any, these substances were due to be registered. This lack of transparency has, consequently, increased uncertainty in relation to how much of an impact the 2018 registration deadline will have in relation to obsolescence.

As a result of the inability to obtain information from the supply chain,[396] challenges exist with getting enough information from suppliers/manufactures so that defence companies can fulfil REACH and CLP obligations. Most of these companies noted some difficulty in obtaining any information upstream. This is particularly prevalent where mixtures are being imported from outside of the EU from e.g. the USA and suppliers claim intellectual property on the constituents of the substances within a mixture or are bound by existing limiting regulations such as ITAR.

Nevertheless, it was highlighted that, where communication along the supply chain had occurred, it **increased the knowledge and understanding of substances at risk** of potential regulatory action e.g. authorisation, and allows industry to plan to lessen the risks to its processes.

[396] Some work is ongoing e.g. IPC 1754.

QUALITY AND COMPLETENESS OF SDSs

The quality, conformity and completeness of Safety Data Sheets (SDSs)[397] provided has also been identified as an issue by some companies and MoDs.

The use of the **SDS is a main tool for defence companies to identify substances for their manufacturing and maintenance processes**. As SDSs do not require total disclosure of all the substances present in e.g. a mixture, and it is expected that many substances requiring REACH registration by 2018 would not be disclosed in an SDS, industry does not have full visibility to its overall exposure.

It was also noted by some companies that they **had not obtained extended Safety Data Sheets (eSDSs)** from their supply chain and of those that had, some needed to proactively ensure that their use specific exposure scenarios were included. This situation was also replicated for MoDs where few eSDSs had been received.

From the end-user/maintenance perspective of the MoDs it was stated that there was a **discrepancy between the eSDS requirements and some actual user needs**. The information contained in the eSDSs received had not been targeted to the specific use of the MoDs and required a lot of time to analyse and find use relevant information. It was pointed out that the **length of some eSDSs** is up to 200 pages meaning it was difficult to identify the critical information and increased the probability that this information would be overlooked.

It was reported that some MoDs were required to produce their own SDSs for maintenance-related substances and mixtures based on limited information provided by a US based company for military equipment which was purchased in a state-to-state transaction. Trade secrets are a common reason for not disclosing compositional information in imported mixtures (see info box).

INFO BOX: Trade secrets in safety data sheets – Example of the US

EU REACH requirements for mixture SDSs do not foresee nondisclosure of compositional information with reference to trade secrets. Although GHS has been adopted in US (Hazard Communication Standard 29 CFR 1910.1200(g)), there are certain differences from CLP and REACH. US safety data sheets (according to Standard 1910.1200 App D) do not display hazard classification of hazardous components in section 3.2., which is a European requirement according to REACH Annex II. US manufacturers themselves may assess and decide if a component must be regarded as a trade secret. In such cases, the correct name, identification number and the actual concentration of the component will not be displayed – just a statement telling that this information has been withheld as a trade secret. In practise, components are frequently designated trade secrets in SDSs.

However, it has been acknowledged by industry and MoDs that the provision of the (e)SDSs has **increased knowledge**, in general, of the substances of concern within mixtures, etc. and they have also contributed positively to knowledge of the hazards associated with particular substances and

[397] Safety Data Sheets are the key tool under REACH for transmitting appropriate safety information on substances and mixtures down the supply chain (see REACH Article 31 and Annex II). REACH registrants or any actor in the supply chain who is required to prepare a CSR need to place the relevant exposure scenarios in an annex to the SDS (so-called "extended" safety data sheet). Exposure scenarios provide further safe use guidance for the downstream user. SDSs do not have to be provided for articles.

mixtures, though many companies and MoDs maintain that this information has not meant that they needed to introduce additional RMMs as those that were in place were already sufficient.

CONCLUSIONS

Given the supply chain complexities and various practical and legal limitations of information provision (e.g. due to intellectual property claims, non-EU restrictive legislation (e.g. ITAR) requirements, legacy systems) supply chain communication under REACH is a difficult and costly process. The provision of information is not always complete, even when communication has been established.

The length, number of actors and internationalised nature of defence supply chains make the implementation of REACH a difficult and costly process, with some stakeholders noting that dedicated software is essential to cope with the complexity.

Safety Data Sheets are generally accepted as a useful tool to transmit safe use information for substances and mixtures, but in practice they do not always answer actual user needs.

H.6 List of significant comments by MoDs relating to Security of Supply (SoS)

"Reformulations with a loss of performance or reliability are not acceptable in the defence sector. The defence exemption would be "used" in that case."
"Substances are used for their properties. That's why it is difficult to replace a substance and have the same reliability. In this light there is a risk of reduce performance and reliability."
"Due to REACH requirements, Industry is working hard in accomplishing regulation, this includes in some specific cases, substitutions of substances and/or changes in sub supplier that require new homologation tests for product dossiers. The timeframe in these cases is a hard issue to maintain and this is going to impact de SoS.(Security of Supply)."
"A change may be necessary in the acquisition strategy because in order to maintain defence capabilities, promoting the import of systems (items) directly from outside the EU may be necessary, which will impact negatively on the EU industry."
"There is the risk that upon expiry of a sunset date certain substances are not purchasable at the European Single Market and substitute products do not satisfy the military requirements respective reliability, safety, and performance."
"The cost intensive registration and authorisation of these substances is disproportionate to the amounts needed in defence products. Therefore the security of supply might not be ensured with the result that certain systems might not be as procurable anymore as today."
"The application of REACH is described within the specifications and the tender of the equipment to be procured. Therefore if a supplier cannot comply with these requirements (specifications etc.) will not be selected and therefore the contract will not be awarded. This situation may jeopardize SoS if the procurement is realised through single source."
"REACH imposes a risk of obsolescence for chemicals listed in Annex XIV. If chemicals become obsolete, it may result in a negative impact on defence capability. Specifically this may become a problem in the supply of maintenance chemicals."
"Some equipment and commodity suppliers are procuring substances and articles from outside the EU. Supply chains outside the EU are more difficult to manage and monitor. There is an increase in counterfeit materials in the EU."
"The main challenge for SoS comes from obsolescence triggered by the REACH processes: Authorisation, restriction and registration."

H.7 REACH related additional costs for actors in the European defence sector

As mentioned in Section 4.1.2.3, the reporting of REACH related additional costs by defence industry stakeholders consulted was not homogeneous. Hence, figures given are possibly not representative. The same applies also to MoD responses. The time to provide stakeholder input was also very limited due to the timeline constraints of the project.

ILLUSTRATIVE EXAMPLES ("SNAPSHOTS") OF REACH RELATED ADDITIONAL COSTS

Table 25 below attempts to provide a more structured overview of REACH related additional costs (direct + indirect, **excluding R&D/Substitution**) reported by individual companies operating in EU defence supply chains, depending on the domain they belong to, their company size (small, medium, large) and whether an annual cost or total cost up to now was reported. For further conclusions from the data collected reference is made to Section 4.1.2.3.

Table 25 Sampled REACH related additional costs (direct + indirect, excluding R&D/Substitution).

Domain	Example Costs Per Year (To Date)	Example Total Costs (To Date)
Aerospace	n/a	620 K€
	1,000 K€	n/a
	7,000 K€	n/a
	n/a	9,000 K€, 70% of it related to Article 33 compliance
	n/a	Millions of €
Ammunition	300 K€	n/a
	n/a	250 K€
	50 K€	200 K€
	n/a	655 K€
	n/a	500 K€
	n/a	1,500 K€
Component and Subsystem Suppliers	n/a	600 K€
	200 K€	200 K€
	n/a	300 K€
	235 K€	n/a
	n/a	15,000 K€

Legend: Company size

Small	Medium	Large

QUANTIFICATION CHALLENGES FOR REACH RELATED COSTS DURING THE STUDY & IN GENERAL

The significant cost impact of chemicals legislation such as REACH on the EU industry cannot be ignored. A recent study for the European Commission[398] confirmed that

- The estimated average annual **total direct cost** for all legislation relevant to *chemical companies* surveyed during the period 2004-2014 approaches €9.5 billion, representing around 2% of their turnover and **12% of the value added**.
- The pieces of legislation generating the highest monetary obligations are **REACH**, plant protection products and biocides.
- The major milestones of the evolution of cost include the introduction of **REACH** and **CLP**.

For the European defence sector in particular, a number of uncertainties relate to the further development of the cost impact:

- The impact of the **registration deadline in 2018** on procurement costs is still to be seen.
- The same applies to the **further evolution of Annex XIV**. The substitution requirement associated with it creates significant costs, which go **far beyond the direct costs** to obtain and maintain a REACH authorisation.
- The specific requirements to communicate information on **substance in articles (REACH Article 33)** are still unclear today.

In particular with respect to the two latter points (authorisation-related costs and Article 33) the conclusion in the aforementioned study for the EC that "*[i]t is expected that CLP and REACH costs will decrease after 2017 and 2018 respectively […]*"[399] is **unlikely to be applicable to the defence industry** and also contrary to the expectations of MoDs and defence industry consulted based on the experience so far.

Overall, it is acknowledged that the **assessment of REACH related costs**, beyond more obvious direct costs related to REACH registration, **has only started**, using a clear methodology to make it meaningful.[400]

It should be acknowledged that there are most likely **limitations to the quantitative assessment** of indirect costs, for example the costs related to developing (R&D) and implementing substitutes to substances to be phased out, as well as the costs of managing the consequences of substitution (such as the cost of more frequent maintenance phases, the precise impact of reduced performance, unavailability of systems, delocalisation, etc.).[401] It will also be difficult, if not impossible, to quantify the REACH-related cost included in the price for defence products procured (transfer of such cost via the product price can normally be assumed, according to MoDs and defence industry consulted).

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[398] technopolis group, Cumulative Cost Assessment for the EU Chemical Industry (April 2016), page 8, 10, 11.

[399] technopolis group, Cumulative Cost Assessment for the EU Chemical Industry (April 2016), page 142.

[400] EC, "Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs" (December 2015), formulates as a key recommendation *"to carry out a study to determine the full **costs of the REACH Regulation** […]. It is only once such a study has been carried out that it will be possible to assess the efficiency of the REACH Regulation, in terms of its environmental, health and safety benefits, as well as those pertaining to competitiveness and innovation"* (page vi).

[401] As an example, even the recent cost-specific study for the European Commission by technopolis group, Cumulative Cost Assessment for the EU Chemical Industry (April 2016), was not able to come up with robust assumptions for estimating the relevant costs based on the provided qualitative information (page 8).

H.8 Complexities and joint activities to determine the REACH status of ammunition

The European defence industry produces several tens of different types of ammunition. It has been difficult for defence companies and MoDs to determine which types are considered in REACH terms as articles only, and which ones are **combinations of an article (functioning as a container) and a substance/mixture**. The determination is very important for REACH and CLP purposes, as a different set of duties is connected to manufacture, import and use of substances on their own and as part of mixtures[402] on the one hand and articles[403] on the other hand.[404]

As a current example (September 2016), it has been reported from one MS that the local enforcement authority is asking the company producing "powders"[405] for ammunition to provide information it doesn't have because this authority considers them as substances/mixtures and the company considers them as an article according to available defence sector guides.[406] The case highlights the persisting confusion in the area.

The ECHA Guidance on articles[407] has been the main guideline for decision-making, but the indicative questions 4a-4c and 5a – 5c do not always lead to unambiguous conclusions.

ECHA has clarified that *ammunition cartridges that are designed to launch a projectile (e.g. a bullet)* are considered to be articles with an integral substance/mixture (the propellant).[408] However, as also expressed by ECHA, this does not necessarily apply to ammunition where the function of the object is the deliberate release of a mixture (i.e. flares, gas grenades, etc.). Therefore, a number of cases are still under discussion today. They concern the qualification of **colorant mixture, or CS gas mixture, or "smoke composition" included in some specific ammunition types**.

MoDs have been working together in the EDA REACH Task Force to reach a potential common position on the REACH status of certain ammunition types.[409] Industry (ASD and GICAT) work to provide EDA/REACH Task Force with detailed information on what they consider as consequences of this status classification.

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[402] E.g. registration, authorisation, SDS, labelling of hazardous substances/mixtures, C&L notification.

[403] E.g. REACH Articles 7(2)/33, restrictions, CLP labelling of explosive articles.

[404] Defence stakeholders consulted have expressed that - when dealing with borderline cases of explosives and ammunition that may be classified either as articles or combination of an article and a substance/mixture - then REACH SDSs and CLP labels most likely do not add any extra value (see Section 4.2.5), as opposed to the case of explosive substances and mixtures.

[405] Denomination by tradition of the technical domain but in fact are hard objects machined in a sophisticated way to have a precise shape, a specific number of holes of a given size etc. in order to fulfil their function.

[406] Current guides include: GICAT, Application of the REACH Regulation to Ammunition, 28 August 2014; BDSV, Discussion REACH - Classification of ammunition as articles with an integral substance / mixture, September 2014.

[407] ECHA, Guidance on requirements for substances in articles, December 2015.

[408] See ECHA Q&As, question ID 1059, modified date 04/08/2016, available at https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/reach/Requirements+for+substances+in+articles (last seen 28.8.2016)

[409] One MoD pointed out that the manufacturer/importer has the obligation hence the MoDs should not influence the decision. This is particularly an issue where the balance of design/shape of the object versus chemical constituents can only be assessed by the manufacturer. Any fallout (breaches etc.) from this decision would be their risk. The EDA "classification table" may include a case-by-case exemption for some cases.

H.9 "Brexit" and its possible impacts on REACH regulatory compliance

On 23 June 2016 the UK voted in a referendum to leave the EU. The referendum result was based on popular concerns over immigration, budget contributions and overregulation in the EU. However, the legal process of withdrawing from the EU has not started yet under Article 50 of the Lisbon Treaty, though the process is expected to start by the end of March 2017 resulting in withdrawal from the EU by end of March 2019. The due process of withdrawal is currently subject to constitutional judicial review in the UK Supreme Court as the British Parliament and the devolved administrations of the UK, particularly the Scottish Parliament, are expecting to have their say in the Article 50 process.

The UK's post-EU arrangements are still subject to negotiation upon the triggering of Article 50. The two main alternative scenarios debated are called "soft" and "hard" Brexit. A **soft Brexit** would preserve the UK's access to the EU single market and seek continuity also in other arrangements in the EU keeping the UK within the European Economic Area (EEA) or with similar arrangements. This continuity would probably require continued adherence from the UK to the EU's four freedoms for free movement of goods, capital, services and people with further requirements on the continued application of EU law in the UK and some form of financial contribution to the EU's activities. On the other hand, a **hard Brexit** would entail the UK leaving the single market to gain a higher level of control over its borders, making new trade agreements and not being subject to EU laws. So far the UK's Prime Minister May has stated that *"We are not leaving the European Union only to give up control of immigration again. And we are not leaving only to return to the jurisdiction of the European Court of Justice."*

The **defence sector** in the EU-28 does not operate in a bubble, with no exposure to external influences. Brexit is a serious issue, not just to multinational platform integrators and other large downstream users, but also to the wider manufacturing and distribution sector with complex supply chains spanning across the EU and beyond. Hard Brexit would clearly seem to be detrimental for the defence sector. There would be disruption of the well-established supply chains resulting from the two systems emerging where there earlier was just one. Upon the UK leaving the single market and establishing a separate parallel national regulatory regime referring only to UK national courts that UK national regime would start to diverge from the EU's acquis communautaire, the body of common rights and obligations that is binding on all the EU MS as it would no longer refer back to EU institutions such as the Court of Justice of the European Union (CJEU). The setting up of two parallel systems to replace one common system would seem to lead to duplication of compliance work and increase inertia in the supply chain.

Looking at REACH in particular there is no clarity yet whether REACH will remain intact, be revised, replaced, or removed entirely from its current direct application in the UK. REACH will remain in force up to the point of the UK's withdrawal from the EU and the UK industry is being advised to continue with their work towards the 2018 registration deadline. But to prepare for Brexit the UK government is looking to introduce a Great Repeal Bill to end direct application of EU law in the UK but to transpose parts on EU law into UK domestic law, wherever practical, on exit day. If REACH was to be made part of UK domestic law the references to EU institutions such as ECHA and the EC granting registrations and authorisations subject to appeal at the CJEU would need to be replaced by references to authoritative UK domestic institutions such as the Health and Safety Executive (HSE) subject to appeal in the UK national courts. It is highly uncertain and unprecedented that third country national authorities would be capable of being mutually recognised as equivalent to EU institutions as empowered in the REACH Regulation and if existing REACH rights could then be

somehow grandfathered and new rights granted under the UK parallel system that could then in turn be mutually recognised in the EU.

As the REACH compliance process will be far advanced also in the UK at the point of exit in 2019, it would clearly be in the interests of the UK chemical industry for the negotiating parties to find a solution that would preserve the value contained in the REACH compliance work completed so far. However, it remains equally possible that at the point of hard Brexit and in the absence of a negotiated settlement the REACH rights of UK companies could no longer be maintained and they would no longer exist outside the jurisdiction of ECHA, the EC and the CJEU in a third country.

H.10 Stakeholder calls for more EDA REACH/CLP Support

Among **defence sector stakeholders**, several MoDs and defence industry stakeholders have called for more EDA support on REACH/CLP or referred to the benefit of EDA's prior engagement, as illustrated by the following list of comments from the study consultation.

Defence stakeholder calls for more EDA support on REACH/CLP / references to EDA's engagement
[MoD] *"We believe that EDA has a significant role to play in this field, to promote EU MS collaborative efforts towards substitution of SVHC. Relevant actions are of course under way and may need to be stimulated."*
[MoD] *"Also, the significant work of EDA REACH Task Force on preparing the "Table of the Classification of Ammunition" concerning the requirements of REACH, could be expanded (as a separate task) to incorporate CLP and other requirements, to describe various aspects of applicable legislation and to highlight potential improvement ideas."*
[MoD] *"Note recent EDA/ECHA communication has ensured restriction tolerating use by civil aircraft has now been extended to military aircraft."* [see also Annex F.3 info box "Omission of military aircraft in the restriction exemption proposal for decaBDE"]
[MoD] *"We finance industry R&D work for new designs or new maintenance solutions for our workshops, after analysis of the proposals value, favouring joint R&D, possibly under the EDA umbrella, according to the amount of our R&D budget we can dedicate to this issue."*
[Defence industry association] *"EASA have agreed to be an independent check for any claims made by industry should the ECHA committees require this. It was suggested it would be reasonable for EDA to play a similar role."* [see also Annex N.4]
[Defence industry association] *"EDA has done a good job in trying to standardize the defence exemption process. The biggest problem is mutual recognition given trans-national supply chains."*
[Defence industry association] *"EDA could help by actively spreading (more) information on the limitations of use of defence exemptions to REACH stakeholders like ECHA, SEAC & RAC members, national competent authorities, REACH committee representatives..."*
[Defence industry association] *"Such cut-off criteria are not yet specified by REACH stakeholders. We would therefore welcome if EDA joined the discussions on the information duties of Art. 33 and, e.g., provide examples on how a reasonable level of reporting might look like for very complex defence products."*
[Defence industry association] *"would welcome if EDA could disseminate this knowledge also amongst MoDs, because several MoDs still ask the defence industry to "use Article 58 (2) REACH" or to justify why they did not do so…"*
[Defence industry association] *"would welcome if EDA provides a framework for discussions amongst EU MoDs on CLP issues, e.g. to discuss whether to exempt military ammunition from the need to be labelled according to CLP provisions or to reach an agreement on how CLP labelling of*

military ammunition should be done in a uniform way. ”

[Defence company] *”We need from EDA to hear us and to help us to find shared solutions with the other European countries, also to be the spokesman of European companies to the European Commission or ECHA.”*

[Defence company] *Do you consider that more funding for R&D for alternatives to SVHC substances like the ones on the REACH candidate list for authorisation should be made available by the EU? If yes, possibly under which scheme/programme? ”Coordinated by EDA”*

Consultations with **non-defence industry stakeholders** also underlined the benefit of further clarifying the EDA's possible role with regard to REACH/CLP support in relation to the defence industry. Furthermore, interviews with industry representatives of upstream suppliers belonging to the chemicals industry confirmed that the awareness of defence uses and concerns is generally limited or these are of little interest due to the small market share represented by defence. At the same time, the consultation of these stakeholders has shown a high level of interest in enhanced information exchange and other collaboration with defence sector stakeholders, for example with regard to gathering required socio-economic inputs for Risk Management Option Analyses and/or (other) sector-level contributions to public consultations under REACH or related pieces of EU legislation (such as OSH).

Improvement proposals to address the stakeholder calls for a stronger EDA role for REACH/CLP support are addressed in Section 9.1.2 and 9.3.7.

I. VIEWS CONCERNING MOD REACH ”ROLE(S)”: ADDITIONAL INFORMATION

A list of explanations given by the **MoDs** who consider that they may have direct obligations as addressee of REACH according to the definitions of Article 3 REACH, can be found hereafter:

“The MoD is considered one legal entity under REACH. The MoD do directly import substances and articles. The MoD act as manufacturer and downstream user in development and delivery of military products. At disposal the [Authority] *manage disposal of military materiel (reseller role).”*

”[Entity under the MoD] *as a free standing authority is responsible for delivering defence logistics to the* [national] *Armed Forces.* [Entity under the MoD] *would be considered mainly as an importer. We do not consider* [entity under the MoD] *as being a re-seller when delivering defence equipment to the Armed Forces.”*

”YES, however the issue has not arisen to date. The MoD does not currently act as a REACH importer of substances or mixtures to the EEA. We only buy finished articles. The main maintenance activities are outsourced to private companies.”

”In this case (USA substances) we are considered as an importer by REACH definition (supplier as well). An import shall be deemed to be placing on the market even if we don't supply the substance or make it available for a third party. No registration obligation due to low amount.”

”YES: MoD imports munitions and industrial chemicals from outside EU. Assesses the need for a Defence exemption. Responsible for safe use of the exempted substance, mixture and or article”

"YES: Everybody is involved in the chain production/acquisition process and has to be defined the direct obligations."

"Mostly REACH importer and end-user (as opposed to downstream user). Importing REACH products from non-EEA countries obligates either to registration or authorisation."

"YES: Because the state is also a "legal person", the MoD is an actor in the REACH process and should comply with it as importer/DU/supplier."

"In some MoDs, the procurement agency officially delivers the articles to the armed forces, with all needed information, according to a number of regulations (e.g. radionuclides): So there is a need for consistency. Also, at one point [some] *MoDs considered to make their procurement agencies public companies, without changing anything to their role. In that case, they would have put the equipment on the market but not in the current situation? It would be important to find other examples where the state and private sector have different legal obligations for the same activities."*

REACH MSCAs of the six LoI countries and Greece were also consulted on the question of REACH status of national MoDs/Armed Forces. Their answers are given in anonymised form below:

"We don't have an official position. The issue has only been discussed internally."

"REACH defines as «importer, downstream user, distributor and manufacturer» any natural or legal person. We believe that it has to be clarified with ECHA and on an EC level, whether the meaning of legal person in REACH includes governmental bodies and entities of public sector."

"In [Member State] *the implementing authority for Article 3 of REACH is the Ministry of Defence. Industries that will not request the MoD for exemption shall comply with duties and obligations under REACH. CLP Regulation shall be applied in any case."*

"We have no answer."

"A definitive view cannot be provided without previous consultation to our legal services."

"We believe that REACH applies irrespective of how certain activities are qualified and that the REACH text do not provide for special exemptions for "governmental bodies". The sole exemption is the afore-mentioned provision in Art. 2(3) REACH."

"Our intention in completing only part of the questionnaire was not to provoke an alternative dialogue on the remaining questions. As we have no further specific information at this stage to share in relation to REACH/CLP and the defence sector, I do hope that you will accept my apologies in declining a follow-up of this nature by phone."

J. RELEVANT CJEU JUDGMENTS AND ECHA BOA DECISION

The CJEU has made a number of judgments that are relevant for the present study. The ECHA Board of Appeal (BoA) has also recently made an interesting decision, which is relevant for the exemption from authorisation for intermediate uses (see below). The judgments/decisions (and their context, as appropriate) are summarized in the present Annex.

CJEU JUDGMENT OF 10 SEPTEMBER 2015 IN CASE C-106/14

In its judgment of 10 September 2015 the CJEU has ruled that[410]

"Article 33 […] must be interpreted as meaning that, for the purposes of application of that provision, it is for the supplier of a ***product*** **[with]** ***one or more constituent articles*** *[of] which contain(s) a* [candidate list] *substance […] in a concentration above 0.1% weight by weight* ***of that article****, to inform the recipient and, on request, the consumer, of the presence of that substance by providing them, as a minimum, with the name of the substance in question."*

With this the CJEU has clarified that the **calculation** of the 0.1% threshold in complex articles for the application of REACH Article 33 should be done **based on each single constituent article (component article)** instead of the complex article as a whole.

The judgment is in line with the prior dissenting minority view of six Member States,[411] who represent the ***"Once an article – Always an article"*** (O5A) doctrine, and therefore did not support the previous version of the ECHA Guidance on requirements for substances in articles of April 2011 that relate to the majority interpretation[412] of the limit. A unique cover-page *"Note to the Reader"* by the ECHA Executive Director pointed to this lack of support and warned that ***"Consequently, companies may face diverging enforcement practices as to some of its aspects."***

Furthermore, the CJEU has not unambiguously stated whether SVHCs also need to be **declared** on a component article level, i.e. whether **localisation information** should be given by default. However, some of the deliberations of the CJEU seem to point into that direction:

"The duty to provide information is aimed indirectly at allowing those operators and consumers ***to make a supply choice in full knowledge*** *of their properties of the products,* ***including those of articles forming part of their composition****.* […] *The duty to provide information imposed on successive operators all along the supply chain is therefore intended to* ***follow the article to which it relates*** *through to the final consumer.* […] *It would be incompatible with such a duty to take the position that the inclusion of an article as input in a complex product can interrupt the transmission of that duty to provide information to each of the operators along the supply chain, given that* ***that duty relates directly to the presence of a substance of very high concern in that article****."*[413]

At the same time, the CJEU has made rather clear that *"…in the absence of any specific provision* [governing specifically the situation of a complex product containing more than one article]*, there is no need to draw a distinction not provided for by the REACH Regulation between the situation of*

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410 http://curia.europa.eu/juris/document/document.jsf;jsessionid=9ea7d2dc30d5d17a25a482df4777be19b722670fc3ea.e34KaxiLc3qMb40Rch0SaxuTa3f0?text=&docid=167286&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=1125929

411 Austria, Belgium, Denmark, France, Germany and Sweden.

412 The majority was represented by the other Member States, the EC and ECHA.

413 See number 78 – 80 of the Judgment.

articles incorporated as a component of a complex product and that of articles present in an isolated manner."[414]

The CJEU has also made clear that difficulties for importers to obtain the required information from their suppliers in non-EU countries do not affect the interpretation (here: of REACH Article 7(2)).[415]

CJEU JUDGMENT OF 25 SEPTEMBER 2015 IN CASE T-360/13

The applicant VECCO[416] claimed that the Court should partially annul the [Annex XIV inclusion for chromium trioxide] in so far as it does not contain in its annex […] under the title 'Exempted categories of use', the following exemption: *'use of chromium trioxide for production purposes in aqueous solution, thereby complying with an exposure value of maximum 5 µg/m³ (or 0.005 mg/m³)' or similar language aimed at exempting the 'use of chromium trioxide in electroplating, etching processes, electropolishing and other surface treatment processes and technologies as well as mixing', or words to that effect, from the scope of the contested measure'*.

The Court has dismissed VECCO's action, providing the following main findings on the scope of REACH Article 58(2) in particular:[417][418]

Par. 33 […] 'Community legislation' within the meaning of Article 58(2) of [REACH] is a rule of law adopted by a European Union entity intended to produce binding effects. […]

Par. 40 […] in so far as Directive 98/24[419] *does not refer to a particular substance, as is the case of the substances mentioned included in Annex I to that directive,*[420] *it cannot be considered specific, […] The Commission […] was, by contrast, fully entitled to take the view that,* ***in the absence of limit values****, the directive at issue did not constitute 'existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance' within the meaning of Article 58(2) of Regulation No 1907/2006.*

Par. 41 […] Article 58(2) […] constitutes a strict exception to the principle confirmed by Article 57 of that regulation, in conjunction with recital 69 in the preamble thereto, according to which substances of very high concern must, as a rule, be included in Annex XIV to Regulation No 1907/2006 and be subject to the authorisation procedure laid down in Article 60 of that regulation. It follows that the approach advocated by the applicants would be liable seriously to jeopardise the purpose and functioning established by that regulation and cannot therefore be accepted.

Par. 44 […] In so far as [Directive 2004/37[421]] *does not refer to any substance other than benzene, vinyl chloride monomer or hardwood dusts, for which it lays down maximum values for*

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[414] See number 50 (and 49) of the Judgment.

[415] See number 68 of the Judgment.

[416] Verein zur Wahrung von Einsatz und Nutzung von Chromtrioxid und anderen Chrom-VI-verbindungen in der Oberflächentechnik eV, established in Memmingen (Germany). A group of 185 individual applicants was also part of the action.

[417] http://curia.europa.eu/juris/document/document.jsf?text=&docid=168623&pageIndex=0&doclang=en&mode=req&dir=&occ=first&part=1&cid=771177

[418] The case is currently under appeal.

[419] Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, so-called Chemical Agents Directive (CAD).

[420] Annex I to CAD at present includes only *inorganic lead and its compounds*.

[421] Carcinogens or Mutagens Directive (CMD).

occupational exposure, it cannot be considered either 'specific' or to impose minimum requirements. […]The reasoning set out in paragraph 41 above is also applicable to Directive 2004/37.

Par. 45 It must therefore be concluded that, as regards chromium trioxide, neither Directive 98/24 nor Directive 2004/37 constitutes 'existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance' within the meaning of Article 58(2) of Regulation No 1907/2006.

ECHA BoA DECISION OF 25 MAY 2016 IN CASE A-010-2014

The appellant Nordenhamer Zinkhütte GmbH (Germany) is a registrant of diarsenic trioxide as a transported isolated intermediate. The German MSCA agreed originally with the interpretation as intermediate. However, ECHA found in its compliance check decision that diarsenic trioxide, as used in the appellant's plant, does not qualify as an intermediate under REACH Article 3(15). Since diarsenic trioxide was included in Annex XIV in 2012, with sunset date on 21 April 2015, and '*by way of precaution in order to avoid any legal downside'* with regard to the ECHA opinion (not an intermediate use), Nordenhamer Zinkhütte GmbH submitted an application for authorisation of the *'industrial use of diarsenic trioxide to produce a copper concentrate in the purification of the leaching solution in a zinc electro winning process'*. On 4 September 2015 the EC granted the authorisation with a review period of 12 years. On 25 May 2016 the ECHA Board of Appeal annulled ECHA's compliance check decision and remitted the case back to ECHA for re-evaluation, finding that *"the Agency misinterpreted Article 3(15) in the present case and erred in law in deciding that diarsenic trioxide is not an intermediate on the premise that the production of copper residue and subsequently copper concentrate does not constitute the 'main aim' of the production process in the Appellant's plant."*.[422]

[422] See http://echa.europa.eu/documents/10162/3ddab5ca-db7a-4e85-8bfe-65e6bc2c8cf4, par. 65.

K. CLP LABELLING OF AMMUNITION: ADDITIONAL INFORMATION

K.1 Overview of key CLP provisions for the labelling of explosives

Article 4

8. For the purposes of this Regulation, the articles referred to in section 2.1 of Annex I shall be classified, labelled and packaged in accordance with the rules for substances and mixtures before being placed on the market.

Annex I

1.3.5. ***Explosives placed on the market with a view to obtaining an explosive or pyrotechnic effect***

Explosives, as referred to in section 2.1, placed on the market with a view to obtaining an explosive or pyrotechnic effect shall be labelled and packaged in accordance with the requirements for explosives only.

[…]

2.1. Explosives

2.1.1. Definitions

2.1.1.1. The class of explosives comprises

(a) explosive substances and mixtures;

(b) explosive articles, except devices containing explosive substances or mixtures in such quantity or of such a character that their inadvertent or accidental ignition or initiation shall not cause any effect external to the device either by projection, fire, smoke, heat or loud noise; and

(c) substances, mixtures and articles not mentioned in points (a) and (b) which are manufactured with a view to producing a practical, explosive or pyrotechnic effect.

For more detailed special labelling rules relevant for military ammunition reference is made to Annex 1 (small packaging exemptions, outer packaging) and Annex 2 (labelling elements for explosives) of the ASD paper *"Concerns, observations and suggestions for the EDA to consider on the application of CLP regulation to ammunition (as „explosive articles")"* of 9 May 2016.

K.2 Available authority views concerning CLP labelling of ammunition

During the study consultation it was expressed that some MSCAs do not seem to realise that the requirement to label explosives might also apply to ammunition. On the other hand, a number of authorities responding to the study survey have shared their views on how to apply CLP to ammunition qualifying as "explosive articles":

- EC

  "COM believes that ammunition/military explosives ***have to be labelled*** *under the CLP Regulation but in accordance with section 1.3.5 of Annex I, such articles should be labelled*

*in accordance with the **requirements for explosives only**.[423] However, in accordance with article 1.4, MS may allow for an **exemption** from labelling of ammunition/military explosives where necessary in the interest of defence.*

- UK MSCA (HSE):[424]

  *"A practical issue has arisen in the UK around CLP in the context of labelling for military explosives/ammunition, in particular, whether the definition of munitions under CLP requires them to have labels affixed immediately to their surface. In discussion with Ministry of Defence contacts and having reviewed CLP requirements on explosive articles, the UK Competent Authority for CLP believes a reasonable interpretation of CLP labelling requirements for explosive articles is that they **apply to the packaging** containing the article and not to the article itself. By way of example, a shell classified as an explosive article does not require a CLP label to be affixed directly – the label must instead be affixed to the surface of the packaging containing it. This interpretation is based on a close reading of CLP Article 4.8 which mandates that an explosive article be labelled and packaged "in accordance with the rules for substances and mixtures".*

  We understand that this issue around the application of CLP labelling rules to military explosives/ammunition may have arisen in other EU Member States and we would like to present this as a sensible interpretation of CLP that could be adopted at EU level."

- DE MoD:

  The DE MoD further added in relation to the **labelling for transportation** and **CLP Article 33**: *"To meet the requirements for transportation, the UN RTDG[425] rules for hazard classification, labelling and packaging must additionally be taken into account. As the CLP and UN RTDG-based hazard classification for explosives and explosive articles follows the same procedures, there is no contradiction in the classification itself. But the labelling according to UN RTDG is more detailed. That is why CLP-based labelling on the outer package can be omitted. The inner and intermediate package must be labelled according to CLP."*

Based on the opinions currently available **labelling of ammunition/military explosives is considered as necessary**, but a pragmatic approach is suggested to its implementation. In the Contractor's understanding **all opinions expressed and detailed above are consistent.** However it was felt that a solution still needs to be found for complex cases, namely when there are several levels of intermediate packaging or none at all.

[423] The same position was expressed by the DE MoD, which concluded: *"Therefore explosive substances and mixtures as well as explosive articles (including ammunition) are to be labelled only with the Globally Harmonised System (GHS) pictogram "exploding bomb".*

[424] Same proposal from DE MoD and FR MoD. Similarly, the Swedish MoD (FMV) is of the opinion that ammunition labelling according to CLP should be made down to the smallest reasonable transportation package (not labelling of individual ammunition objects).

[425] UN Recommendations on the Transport of Dangerous Goods.

L. COMPARATIVE REGULATORY BURDEN

The vast majority of defence industry stakeholders responding agree that REACH causes a significantly higher burden for their business than its non-EU equivalents (e.g. TSCA).

Here is a snapshot of responses from major defence companies:

"REACH causes a significantly higher burden than for any other regulation (product declaration plus substitution plus authorisation plus notifications to ECHA plus risk management measures plus monitoring. USA applies a more pragmatic approach that prohibition of some hazardous substances is only applicable for new programmes and not for the legacy programmes."

"The REACH regulatory burden currently far exceeds that of non-EEA chemicals regulations."

"We have not been requested to provide hazardous material data on articles to Non-EU customers on anything like the scale required under Article 33 of REACH."

"TSCA is truly an EHS requirement that does not affect articles. It is a chemical manufacturing and factory regulation. REACH imposes burden and risks far and beyond what TSCA or any other regulation."

"REACH clearly provides for high regulatory burdens when compared to other chemical legislation. Because in some countries weapons and ammunition is totally exempted from chemical legislation."

Some EU industry stakeholders point out that the burden and associated workload under other chemical regulations such as in US (+ some dedicated state regulations such as California), Canada, China, Japan, Korea, India is much lower, mainly because

- the burden of proof in relation to chemical safety is less with industry;
- the approach, including substances addressed, is more targeted;
- the requirements do not encompasses various actors through the complex supply chain and articles, such as REACH;
- hazardous substance reporting can be required but the substitution is not mandatory;
- the ban of some hazardous substances can only be on new programmes (and not for the legacy programmes). This may offer a competitive advantage to non-EU competitors.

At the same time, the vast majority of defence industry stakeholders able to respond expect that the regulatory burden and the number of hazardous substances targeted under these non-EU chemical regulations is going to increase in the foreseeable future (see question no. 1.27. in Annex C).

Indeed, chemical regulations in several non-EU countries have been developing in the wake of the EU's lead on REACH in the recent years, but the extent is expected to remain appreciably behind the REACH demands in the foreseeable future.[426]

[426] In June 2016 the TSCA reform was agreed in the US after long negotiations. The new China 'RoHS2' could also have some impact on electronic equipment sold to China, according to defence industry stakeholders.

According to defence industry stakeholders, difficulties may arise where there are major inconsistencies between EU and non-EU regulations. In this context, it is interesting to note that all of the non-EU defence companies consulted, but only a minority of EU defence companies (17%), consider that they may **re-use REACH information for compliance with similar chemical regulations outside EU**.[427] Possible examples mentioned include:

- Some REACH elements like the tracing of hazardous substances in articles can be partly used to demonstrate compliance with regulations outside EU or to support customer specific requests on material declarations.
- Possible TSCA (United States Toxic Substances Control Act) implications, but data would be in a different format;
- Compliance with US legislation on Conflict Minerals.

INFO BOX: Non-EU rules on the use or avoidance of hazardous substances

Defence companies are also required to be compliant with non-EU rules on the use of hazardous substances, e.g. the US Aerospace Industries Association National Aerospace Standard NAS 411-1 (Hazardous Materials Target List) for aerospace, the Maritime Green Passport for vessels, Conflict Minerals legislation (US) etc. Increasingly, along the international supply chains, many industrial actors are also specifying lists of substances which should not be used in components of any new product designs.

The responses reflect the role of defence companies as article producers and exporters. Therefore, chemical regulations outside EU mostly do not apply to their products / activities.

M. IMPACTS OF OTHER EU CHEMICALS REGULATIONS: ADDITIONAL INFORMATION

This Annex provides additional information with view to Chapter 7 of the Study Report.

BPR: DURABLE PAINTS AND COATINGS: CONFLICT OF VOC AND BPR

The use of durable paints and coatings are essential for the long term maintenance of defence capabilities against wear and tear and the elements. However, up to 85% of the total market of paints is now **water based** in the interest of limiting the emissions of **volatile organic compounds (VOCs)** due to the former wide use of organic solvents in certain paints, varnishes and vehicle refinishing products. This **replacement process under the VOC Directive 2004/42/EC** has significantly reduced the emissions of VOCs in the atmosphere. According to paint manufacturing sources, in the area of liquid detergents there is no other replacement option for VOC emitting solvent based paints than water based products (except niche products).

Water based products require protection against the development of micro-organisms in the can and also on the dry film. Without protection, the water based paint products would deteriorate and become waste within a few days before even being used. The damage caused by micro-organisms on paints vary from change of viscosity, change of pH, generation of bad smell, change of colour, destruction of product ingredients with associated loss of product function and efficiency, generation of gas, visible surface growth and biofilm formation and human health risk (infection, allergies, etc.). This makes it necessary to use biocidal control of micro-organisms,

[427] See question no. 1.16. in Annex C.

which have the capacity to grow fast in the presence of water and organic matter at ambient temperature.

The most widely used in-can biocidal products are 5 isothiazolinone and 13 formaldehyde releaser in-can preservatives. These two families are often used in combination as some products only offer fungicidal activity and other products are good bactericides but present some weaknesses on other microorganisms. These biocidal product types are now under review under the BPR. If the formaldehyde releasers became classified as Carc. 1B on the basis of the pure formaldehyde classification this would lead to their exclusion as active substances under the BPR Article 5 exclusion criteria. On the other hand, the istohiazolinones are all skin sensitisers of different potencies, some with existing specific concentration limits.

Without effective in-can preservatives the paint industry would either need to stop producing water based products or the entire supply chain until the end user would need to keep the products in sufficiently cold conditions to limit the development of micro-organisms as there is no know chemical alternative. The first option would be clearly against the VOC Directive leading to increased concentrations of VOCs in indoor air. The second option would require all players to acquire cooling equipment including end users, which is unrealistic and energy intensive.

The progressive replacement of VOC emissions by formaldehyde and isothiazolinone releasers is not ideal but effective use of paint in the future would require a **holistic perspective** where the regulation of VOCs and BPRs are looked at by the regulators together rather than separately. Under the current legal framework for example the experts concerned with risk assessment are not able to consider such combined socio-economic effects from progressively increased regulation of both VOCs and BPRs. This can be compared and contrasted with REACH within which also socio-economic effects can be taken into consideration as a part of its regulatory process for SVHCs.

ROHS: COMMERCIAL OBSOLESCENCE FOR LEAD IN SPITE OF DISAPPLICATION FOR AEROSPACE AND DEFENCE

RoHS, at first a purely European directive, was quickly adopted in various forms by other countries, leaders in Electronics production, resulting in a massive, global transition to lead-free electronics. The Aerospace & Defence sector, while exempted/out-of-scope from RoHS, faced a disruption of their supply chains when their electronics suppliers abandoned lead. This was a problem because, due to the specificities of the sector concerning safety, reparability and heritage requirements, many were prompted to switch to lead-free without the fitting R&D and Industrialisation activities. Major concerns for the sector are the long term reliability of the new, lead-free solders (not much of an issue for consumer electronics) and the growth of tin whiskers which are an unacceptable risk for satellites where no repair is possible and where they can lead to total satellite failure.

N. IMPROVEMENT PROPOSALS: ADDITIONAL INFORMATION

This Annex provides additional information with view to Chapter 9 of the Study Report.

N.1 Illustrative recent examples of "phased" approaches instead of straight authorisation

During the first years of REACH implementation authorisation was seen as the "default" process to achieve substitution of SVHC; and indeed the REACH text makes it fairly straightforward for ECHA and MSCAs to include substances in the candidate list and promote them further to Annex XIV. Recently,[428] however, the complexities and possible negative impacts of authorisation on innovation and competitiveness have become more apparent.

A **change of regulatory mindset** with regard to the means to achieve substitution has started with the **EC's SVHC Roadmap to 2020**. It has defined for the first time other than purely hazard-based criteria to identify candidate list substances, via substance screening and RMOA assessment. RMOs suggested by ECHA and MSCAs have become increasingly differentiated, reaching beyond SVHC identification / Annex XIV to different forms of restrictions and voluntary programmes, e.g.

- **Exposure-based restrictions** under Annex XVII, e.g. for NMP (NL MSCA);
- **Handling-based restrictions** under Annex XVII, e.g. for diisocyanates (DE MSCA, pilot case);
- **Targeted restrictions** under Annex XVII, e.g. for octamethylcyclotetrasiloxane (UK MSCA);
- **bOELs under EU OSH legislation**, e.g. for nickel sulphate (FR Anses);
- **Voluntary product stewardship**, e.g. for beryllium (DE MSCA);
- **Voluntary substitution**, e.g. for 1,2-dibromoethane (ECHA, on request from the EC).

While all of these RMOs do not exclude a later addition of the authorisation process in order to ensure substitution, they show that a more **"phased" approach** is already taken. In case of voluntary programmes (example of) substitution is encouraged prior to regulatory action.

The above listed example of ECHA's RMOA for **1,2-dibromoethane**[429] illustrates this phased approach well. The substance is used as anti-knock additive in leaded aviation gasoline (Avgas) used by piston engines which represent around 50 000 aircraft. This use falls under the scope of authorisation. ECHA considered **all SVHC Roadmap 2020 criteria to include it in the candidate list as fulfilled**. However, the EC intervened as follows:

*"To address the health and environmental concerns in Europe from the use of leaded aviation gasoline **a support for transition to unleaded gasoline should be considered in the European regulatory framework**. […]*
*Taking regulatory measures (e.g. under the fuel quality directive or under a separate new directive) at this stage would result in preventing certain general aviation (GA) operations in Europe since there would be **no feasible alternative** to the current fuel that can be used.*
***Before imposing a transition to unleaded aviation gasoline**, there is **first** the need to **develop** a high octane with low aromatic content unleaded **substitute** to the existing leaded gasoline for aviation, **then** propose the development of a **new international fuel standard** for this unleaded gasoline, **get the fuel approved** by the engine and aircraft manufacturers, **ensure availability** of the unleaded fuels at the airports and airfields in Europe **and finally consider the best regulatory option to transition to unleaded aviation gasoline in Europe.**"*

[428] As mainly illustrated by the example of chromates.
[429] ECHA, Analysis of the most appropriate risk management option (RMOA) for 1,2-dibromoethane (16 July 2015).

ECHA did refrain from further action at that stage, highlighting that the substance will be revisited in the relevant re-screening activity to consider any new information on the progress of substitution etc. mentioned above. A timeframe of five years was mentioned to allow a reassessment.

Hence, an approach of encouraging substitution before regulating it is taken – **"innovate first, regulate later".** Further significant statements in the REACH regulatory arena confirm that this idea has been gaining momentum (highlightings by the author):

- ***"Ideally, we should decide today if we want to ban something in 15 years, because then it will stimulate the markets."***[430] (Bjørn Hansen, Head of Unit of Sustainable Chemicals in DG Environment);
- *"**Government can play an important role in supporting innovation**. Time is needed for innovation development, adoption, and diffusion to support transition to safer chemicals. It is important that **early signals** be provided to the marketplace on substances of potential concern to initiate innovation activities. **The Candidate List – and even earlier warnings on substances of potential concern** – provides a prioritisation signal to target R&D on the development of safer alternative chemicals and technologies for SVHCs. […] ECHA can use its regulatory powers to strengthen implementation of the REACH goal of substitution of SVHCs. It can also use its discretionary powers to facilitate and encourage early marketplace actions to identify, develop, and adopt safer substitutes (**even before regulation**)."*[431]

N.2 Additional information on Risk Management Option Analysis (RMOA)

RATIONALE

Following the EC's SVHC Roadmap to 2020[432] Risk Management Option Analysis (RMOA) has become the usual standard approach for MSCAs and ECHA to determine the most appropriate Risk Management Option (RMO)[433] for substances *"that matter most"* (as identified in the screening process as the first step). The RMOA approach as such is commonly accepted and applied today by ECHA and MSCAs, who exchange information and best practices on their RMOA work in the frame of Risk Management Expert (RIME) meetings. ECHA's PACT/RMOA list[434] shows to the public, for which substances an RMOA is underway or what is the conclusion. Sometimes the full RMOA is also published on the ECHA website.

The development of a set of EU-level common rules for RMOA in the near future is seen as an important evolution of REACH helping to achieve all of its goals, for a number of reasons:

- Principle of proportionality
- EU level playing field for industry

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430 https://newsletter.echa.europa.eu/home/-/newsletter/entry/chemicals-are-at-the-core-of-the-circular-economy-and-europe-s-future.

431 Joel TICKNER and Molly JACOBS, University of Massachusetts Lowell, Lowell Center for Sustainable Production, Improving the Identification, Evaluation, Adoption and Development of Safer Alternatives: Needs and Opportunities to Enhance Substitution Efforts within the Context of REACH (August 2016), page 22 and 34.

432 EC, Roadmap on Substances of Very High Concern (5 February 2013).

433 No further action is also a possible outcome of the RMOA.

434 http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact.

- Predictability and ability to contribute for industry
- Consistency with non-REACH laws and policies
- The complexity of RMOA being a new tool
- Active MSCAs have accumulated experience on RMOA
- Non-active MSCAs will be enabled to prepare RMOAs
- Efficiency

Principle of proportionality

Evidently, the principle of proportionality applies to REACH. Recital (130) of REACH clarifies that *"In accordance with the principle of proportionality, as set out in Article 5 of the Treaty, this Regulation does not go beyond what is necessary in order to achieve those objectives."*

Especially with regard to regulatory risk management under REACH, the CJEU has also clarified:[435]

> *"According to settled case-law, the principle of proportionality, which is one of the general principles of European Union law, requires that measures adopted by European Union institutions do not exceed the limits of what is appropriate and necessary in order to attain the objectives legitimately pursued by the legislation in question;* ***when there is a choice between several appropriate measures recourse must be had to the least onerous****, and the disadvantages caused must not be disproportionate to the aims pursued […]."*

Therefore, the RMOA - though often referred to as *"voluntary"* in the absence of an explicit REACH provision[436] - mandates a diligent choice of the appropriate RMO. This applies even more, if the chosen route is inclusion in the candidate list, given its legal and often also commercial implications ("stigmatisation effect").

EU level playing field for industry

Since there are no EU-level guidelines for RMOA, the level playing field envisaged by REACH as a Regulation could be at risk. **There are no agreed criteria on when to choose authorisation or restriction or when OSH legislation could be regarded as sufficient.** The EC has pointed out during the study consultation, that the main challenge still lies in the different approach of Member States to the choice of the best RMO. From the industry side it was expressed that the difference in criteria applied by MSCAs during the RMOA (e.g. national OELs) may yield different RMOA outcomes depending on the Member State, including for substances of the same group.

Predictability and ability to contribute for industry

While the PACT list offers visibility of the substances under scrutiny and the concern considered, the predictability of the authority's conclusion is limited. Of course, to the extent that a proper RMOA is by its nature open-ended, a certain level of uncertainty needs to be accepted. However, more detailed EU-wide RMOA evaluation criteria than set out in the EC's SVHC Roadmap to 2020

[435] Judgment of the General Court of 7 March 2013 in case T-93/10.

[436] Recital (21) of REACH insinuates the idea of using different risk management options based on information generated by REACH: *"Although the information yielded on substances through evaluation should be used in the first place by manufacturers and importers to manage the risks related to their substances, it may also be used to initiate the authorisation or restrictions procedures under this Regulation or risk management procedures under other Community legislation. […]*

are possible and could greatly improve predictability for industry, its own regulatory risk assessment as well as pre-emptive preparations.

This links to the other current shortfall: the absence of a systematic **stakeholder consultation** during RMOA. Most RMOAs rely on information that cannot be retrieved from ECHA's registration and other databases (e.g. data on sector-specific applications, alternatives and socio-economic consequences of regulatory action, the characteristics of the supply chain(s)). It may not even be known, at the beginning of an RMOA, which information may become relevant. Therefore, it appears useful to have a default channel for the collection of third party input, beyond authority contact details on the PACT list. Today, only the DE[437] and FR MSCAs are known to have conducted such public stakeholder consultations, some others have it as part of their process.

A common framework for RMOA would also help industry prepare proactively for the process, in order to have the right information available. During the study consultation it was noted that different Member States ask different questions, even when cases are directly comparable. This, according to industry, renders the proactive preparation for RMOAs more difficult and extends the time needed for gathering information during the RMOA.

Consistency with non-REACH laws and policies

Risk management conclusions in the RMOA framework should take into account and thus be consistent with other relevant EU legislation and policies, such as the **EU OSH legislation, CRM policy and Circular Economy**. The interface between REACH and these aspects is not very clear today and would benefit from further clarification by the EC to avoid possible conflicts (see Section 9.2.3).

Risk management approaches concluded in an RMOA should be aligned and fit in the global picture of these and other EU activities. RMOA under REACH could be an appropriate vehicle for REACH competent authorities to tie in the objectives of related policies, and ensure that REACH effectively manages risks - as intended – instead of creating new ones.

The complexity of RMOA being a new tool

RMOA - if done properly - is not a simple tool. The draft RMOA by the FR Anses for nickel sulphate is an often quoted example; it has more than 200 pages.[438] It was good to have such an RMOA in the beginning. With RMOA guidance for both MSCAs and for proactively contributing industry, an appropriate level of complexity can be achieved in a shorter and focused RMOA. RMOAs typically require data input beyond registration data and multi-disciplinary expertise in regulatory, chemical and workplace safety, economic, technical etc. matters.

Some main challenges for doing RMOA were given by MSCAs or ECHA in their survey responses:

- The quality of the information being provided by companies in their registration dossiers;[439]
- The complex scientific issues related to the identification of substances with PBT, vPvB and ED properties or other substances with equivalent level of concern;

[437] The German MSCA has implemented a specific consultation procedure at the beginning of each RMOA process, see http://www.reach-clp-biozid-helpdesk.de/en/REACH-en/SVHC-Roadmap-en/DE_RMOA-Liste-en/DE_Stoffliste-en.html.

[438] Anses, Draft Analysis of the most appropriate Risk Management Option for Nickel Sulphate (April 2014).

[439] See ECHA, Report on the Operation of REACH and CLP 2016 (May 2016).

- The lack of information which is not required in registration dossiers that could help to better assess the different risk management options, e.g. socio-economic consequences of regulatory action on the substance of concern, the potential for substitution by alternative substances in its uses, the characteristics of the supply chain(s);
- The lack of information about downstream uses and the precise exposure situations in those downstream uses;
- To decide how much and what kind of information is needed for concluding on the best RMO.

Active MSCAs have accumulated experience on RMOA

Further to ECHA, the few active MSCAs on RMOA have accumulated useful experience, expertise and own national guidelines over the past years. RMOs suggested have become increasingly differentiated, reaching beyond SVHC identification and Annex XIV (see list given in Annex N.1).

Yet, all of these RMOs do not exclude a later addition of the authorisation process in order to ensure substitution. Such a "phased" approach is certainly in the interest of proportionality and should be promoted, leading to the use of authorisation as a last resort rather than a default tool.

Relevant experience is also accumulating within industry, as illustrated by the RMOA guidelines of Eurometaux.[440]

This experience could be a very useful input for a stocktaking exercise and structured reflection in the frame of EU-wide RMOA guidelines.

Non-active MSCAs will be enabled to prepare RMOAs

A number of MSCAs consulted, including those with no or less RMOA activity to date, but also some of those with experience of RMOA have confirmed that more harmonised criteria across EU to conduct RMOAs would help. Their comments during the consultation are given below:

Question asked: *"Do you believe that it would be helpful to have more harmonised criteria across EU to conduct RMOAs? If yes, in what respect would you like to see guidance?"*
"Yes we believe that more harmonised criteria to conduct RMOAs would be very helpful in order to facilitate the work."
"Yes, the more harmonised the better would be, also guidance."
"A harmonised approach would help in a form of a stepwise question approach."
"Yes, we would appreciate more harmonised criteria with regard to exposure of workers and ED properties."
"It would be helpful to have some more convergence in preference for certain regulatory measures, in particular authorisation. This is, however, difficult to achieve because Member States have different political preferences in the balance between the need for a precautionary approach on the one hand and administrative costs on the other."
"Harmonised criteria in conducting RMOA are considered helpful even if there is a consolidated experience in EU. Guidance are helpful and should focus on the structure of the RMOA and information sources"

[440] Eurometaux, Guidelines for an Industry Risk Management Options Analysis (RMOA) (January 2016); the document is currently being updated.

This shows that more harmonised criteria across EU to conduct RMOA would help promote the RMOA assessment across the EU.

Efficiency

Since 2014, the EC - with the support of ECHA – has conducted a parallel call for information on the socio-economic consequences of Annex XIV inclusion for substances recommended for it by ECHA, as input for its related decision-making. While this is a welcome step for industry, it comes much too late in the process. At this point of time, financial and human resources for taking the substance through the Annex XIV pipeline have been spent by the SVHC dossier submitter, ECHA and the Member States,[441] while the EC may finally decide not to include the recommended SVHC. In its latest draft Commission Regulation for amending Annex XIV of REACH of September 2016,[442] the EC has decided to postpone the decision on Annex XIV inclusion for

- **N,N-Dimethylformamide (DMF)** - to ensure a consistent regulatory approach;
- **Refractory ceramic fibres**[443] **–** to decide on the most relevant regulatory approach;
- **ADCA**[444] and **borates**[445] **–** with regard to the broad range of uses and industries concerned.

All of these aspects could have been taken into account already at the RMOA stage, without an unreasonable effort on the side of ECHA and MSCAs.

EU-harmonised RMOA guidelines would be suitable to overcome the difference - built into REACH - of authorities proposing substances for the candidate list (MSCAs), recommending them for Annex XIV (ECHA) and deciding on their inclusion (EC in collaboration with the Member States and the European Parliament) and help ensure the best use of public resources.

For all these reasons the upcoming REACH review is a suitable point of entry to take the still new, but central RMOA tool to the next level in the interest of proportionality, predictability, consistency, efficiency and contributing to an EU level playing field for industry.

IMPLEMENTATION

Harmonised RMOA guidelines should address the **purpose and scope, process and validity of RMOA**:

Purpose and scope of RMOA

An RMOA should aim to determine the most relevant, proportionate and consistent regulatory approach to manage a given risk, i.e. an identified concern. It does not necessitate an exhaustive assessment of uses, alternatives and socio-economic impacts of different regulatory options, but still it needs to consider the relevant data on a summary level for the authority to reach a well-informed policy decision. The key **issues to be addressed** in an RMOA are given in Section 9.2.1.

In particular, when considering inclusion in the candidate list for authorisation:

- Information on uses, supply chains, industry sectors and final customers affected (i.e. socio-economic consequences), substitutability issues (incl. R&D efforts) and possible

[441] Member State Committee at ECHA.
[442] Available at http://ec.europa.eu/growth/tools-databases/tbt/nview.cfm?p=EU_407_EN; last accessed: 11.12.2016.
[443] See also Annex D.7.
[444] See also Annex D.6.
[445] See also Annex D.8.

market responses of an assumed candidate list inclusion (e.g. "stigmatisation effect") should be broadly known to the authority and taken into account for its RMO impact analysis.

- The purpose of the recommended candidate list inclusion should be clarified in the interest of predictability by ECHA/MSCA in the RMOA conclusions, if different from eventual authorisation.[446]

INFO BOX: REACH restrictions as an alternative RMO to authorisation

Today there are no agreed criteria on when to choose authorisation or restriction (case-by-case assessment). A restriction requires the confirmation of an *"unacceptable risk to human health or the environment* […] *which needs to be addressed on a Union-wide basis"* (REACH Article 68(1)). A main benefit of restriction as an RMO is its flexible scope. For example, a restriction may contain derogations for essential uses (e.g. for certain defence applications, see e.g. for cadmium and decaBDE) which could not be exempted in Annex XIV based on REACH Article 58(2), thereby reducing the need for authorisation. But their introduction requires detailed information on uses and alternatives available to the authorities. Overall, the restriction process has been very burdensome for the authorities. The issue has been tackled within ECHA's Restriction Efficiency Task Force (RETF).[447] For the European defence sector, restrictions (incl. pre-REACH ones) have had fairly limited impact (see Section 4.2.4).

Process of RMOA: Web-based stakeholder consultation

A complex tool requires a structured process and information collection. Since key sets of the information are not available in ECHA's databases and have to come mainly from industry:

- **Web-based EU-wide stakeholder consultation (including in English)**, as already practiced by some MSCAs, should be introduced as a standard.
- The information about upcoming/ongoing consultations should also be **published on the ECHA website**, in order to optimize the reach to all interested stakeholders.

The **consultation forms** should be drafted in a way that limits the amount of information input to the relevant aspects not covered in the ECHA databases, and avoid an information overload. Industry sector-level input should be promoted.

To further support a harmonised RMOA process that can be applied by all MSCAs, the following is proposed as part of EU-level RMOA guidelines:

- A **generic RMOA workflow** establishing a step-by-step approach to conduct RMOA;
- A **corresponding template to document RMOA assessment and conclusions**;
- **Publication of the RMOA document and conclusions** on the ECHA website.

[446] Otherwise it is assumed that eventual inclusion in the authorisation procedure is envisaged, as foreseen in the Regulation, see REACH Article 59(1): *"*[…] *establishing a candidate list for eventual inclusion in Annex XIV".*
[447] ECHA, Report of the Task Force on Restriction Efficiency (21 October 2014).

Validity

It is not the objective to make the RMOA conclusions legally binding. However, the **indication of follow-up and review timelines** is proposed to be foreseen (as already practised today in some cases).

N.3 REACH links with EU OSH legislation, CRM policy and Circular Economy

This Annex provides a more detailed discussion of the interface and potential conflicts of REACH with the EU OSH legislation, CRM policy and circular economy, with a specific focus on defence sector issues.

EU OSH LEGISLATION

The aim of REACH is to protect human health and the environment in the production, placing on the market and use of substances. The health & safety of employees is also taken into account, as evident from a number of its provisions, e.g. recital (7), Article 35 (Access to information for workers), Article 110 *(… establish rules of procedure concerning worker protection issues."*), Annex I Section 1.4.1 (identification of DNEL(s) for workers) and Section 7 (Chemical Safety Report Format) and various Annex XVII entries.

At the same time, REACH recital (12), Articles 2(4)(a) and 14(1) make clear that EU worker protection legislation in place is **not affected by REACH** and continues to apply, i.e. in particular

- **Council Directive 89/391/EEC** of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work;[448]
- **Council Directive 98/24/EC** of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (Chemical Agents Directive (CAD));
- **Directive 2004/37/EC** of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Carcinogens or Mutagens Directive (CMD)).

Under these Directives employers are (already) required to eliminate dangerous substances, wherever technically possible, or to substitute dangerous substances with less dangerous substances.[449]

EU workplace legislation is also taken into account by REACH, as shown by several provisions such as Articles 9(4) and 37(4)(f), Annex II (Requirements for the compilation of safety data sheets) Part A Sections 0.2.2., 8.2.1. The reference to the requirements of legislation for the protection of workers and the environment may serve to justify derogations from REACH in order to avoid

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[448] Note: According to its Article 2(2) *"This Directive shall not be applicable where characteristics peculiar to certain specific public service activities, such as the armed forces or the police, or to certain specific activities in the civil protection services inevitably conflict with it."*; see http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:31989L0391.

[449] In its final report of 12 March 2012 for DG ENV "Technical assistance related to the scope of REACH and other relevant EU legislation to assess overlaps" (page 272) the consultancy Milieu Ltd., concludes: *"If the substance has not been substituted under CMD, it could be subject to the REACH authorisation requirement. Thus though the substitution requirements of the CMD and REACH might overlap, in effect there is practically no double regulation."*

duplications with OSH legislation, e.g. derogation with respect to registration obligations (Article 9(4)) and the preparation of a chemical safety report (Article 37(4)(f)).

However, a number of questions regarding the interface between REACH and OSH legislation are not addressed explicitly and are thus still unclear today, importantly

- how EU workplace legislation (CAD, CMD) and **Occupational Exposure Limits (OELs)** as "risk management options" set under these may impact the promotion (or not) of SVHCs to Annex XIV and the introduction of occupational exposure-based restrictions in Annex XVII;[450]
- whether OELs according to CAD and CMD may be seen as *"existing specific Community legislation imposing minimum requirements relating to the protection of human health…"* in the sense of **REACH Article 58(2)**, qualifying for a workplace-specific exempted use in Annex XIV.

The OEL issue has gained momentum in the recent past as shown by the broadly supported ***Cross-Industry Initiative for better chemicals regulation (CII),***[451] the efforts of DGs EMPL, ENV, and GROW in assessing how and when OSH OELs could be considered as best Risk Management Option,[452] and the **EC proposal of 13 May 2016 to amend Directive 2004/37/EC**.[453] In this context it is important to note that the modernisation of existing Occupational Health and Safety legislation is amongst the priorities of the European Commission by the end of 2017.[454]

According to the EC[455] the aforementioned questions concerning the interface between OSH legislation and REACH authorisation (and restriction) are currently under discussion and therefore an official answer cannot be given at the moment. Currently, the EC is applying a 'case by case' analysis before it reaches an overall position of the relationship on these issues. In particular, the outcome of the VECCO court case (related to REACH Article 58(2)), that it is under appeal before the CJEU, is awaited.[456]

The **REFIT Platform Government Group**[457] has concluded that **REACH authorisation may not be necessary where** OSH legislation is shown to provide an appropriate, targeted, proportionate and mandatory regulatory control of risk. This should be decided on a case-by-case basis using ***"defined criteria"*** (which are proposed in the paper). It recommends further clarification by the EC to "address the confusion".

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[450] Such as currently proposed for NMP.

[451] http://www.cii-reach-osh.eu. The CII takes the position that when a substance poses a risk requiring further risk management, but authorities find that the concern is limited to the workplace, then workplace legislation is the more tailored and effective tool to address this concern. REACH Authorisation on top of workplace legislation would be unnecessary. Workplace legislation would benefit from the setting of an EU-wide OEL to ensure its harmonised implementation in the EU.

[452] EC/DG ENV, Christian HEIDORN, Linking REACH and OSH Legislation (16 – 17 May 2016), in particular slides 6 and 7.

[453] Proposal COM(2016) 248 final for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

[454] Jean-Claude JUNCKER, President of the European Commission, State of the Union 2016; *"-- Follow-up to the REFIT check, modernisation of existing Occupational Health and Safety legislation to better protect the safety and health of workers, through better implementation, an updated legislative framework and enhanced protection from the risks related to carcinogens and mutagens;"*

[455] Response by DG GROW and DG ENV in the frame of the study on 30 August 2016.

[456] See Section 4.2.3.5 and Annex J for further information on the VECCO court case related to REACH Article 58(2).

[457] REFIT Platform Opinion on the submission by the Cross Industry Initiative on the interface between REACH and the EU Occupational Safety and Health (OSH) legislation (27/28 June 2016), page 6.

In this context it has also been mentioned during the study consultation that substances have a relatively lower contribution to work related cancer.[458] This could support a more risk-based approach using the OSH regime for CMRs limited to the workplace, as long as sufficient risk management measures are in place. Further analysis is recommended, which could be part of the study proposal given in Section 9.2.3.

Overall, the study has clearly confirmed that both MoD and defence industry would like to see the relationship of REACH and OSH legislation clarified – in particular whether and when to use REACH authorisation as an additional risk management option on top of OSH (which already foresees the substitution principle and sets out a growing number of binding OELs including for candidate list substances) - in order to ensure a consistent application of both regimes.[459]

CRITICAL RAW MATERIALS (CRM) POLICY

Raw Materials are of high economic importance for the EU but some of them may be vulnerable to supply disruptions. In order to identify potential problems and shortages and to mitigate supply disruptions, the EC launched a **Critical Raw Materials Initiative (CRI)** in 2008. This initiative resulted in establishing a first list of CRMs (2011), followed by a second list of 20 CRMs (2014),[460] but it excluded the defence sector. In 2017, a third list based on a revised methodology will be published by the EC.

The Commission's action plan, in the form of a Communication *"Towards a more competitive and efficient defence and security sector"*[461] identifies the area of raw materials as one area where the Commission could contribute to reinforcing the EU's defence industry.

- An initial, non-exhaustive view on raw materials for defence supply chains and their criticality was described in the frame of producing the updated 2014 list of CRMs for the EU.[462]
- The EC's Joint Research Centre (JRC) has finalised but not yet published a study titled *"Raw materials in the European defence industry".* The outcome will be used for a **new raw material strategy in the defence sector** that is under development within the EC.[463]
- An EDA study on Raw Materials and the defence industry is ongoing.

This shows that a number of initial actions are undertaken to build a view of the use of raw materials in the defence industry and to identify potential gaps or problems. The present study

[458] It has been mentioned that the highest risk to work related cancer is asbestos, diesel fume particles (not covered under REACH) and building materials. See also European Agency for Safety and Health at Work, Exposure to carcinogens and work-related cancer: A review of assessment methods European Risk Observatory Report (2014), page 61 (Figure 2): Solar radiation, environmental tobacco smoke (ETS), silica, crystalline and diesel engine exhaust are the top 4 common agents to which workers were exposed.

[459] ECHA recommends that *"R19. The authorities should improve the interaction at an operational level between REACH and other legislation addressing chemicals, e.g. the Industrial Emissions Directive, the Chemical Agents Directive and waste legislation and to strengthen the potential links with company quality and environmental, health and safety management systems."*; see ECHA, Report on the Operation of REACH and CLP 2016 (May 2016), page 16.

[460] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52014DC0297.

[461] EC, Communication COM(2013) 542 final.

[462] Oakdene Hollins and Fraunhofer ISI, Study on Critical Raw Materials at EU Level, Final Report for DG Enterprise and Industry (16 December 2013), page 156-157.

[463] Publication is envisaged by the end of 2016.

has also identified a number of defence-critical CRM substances targeted by REACH authorisation considerations (such as beryllium) or which are linked to CRMs.[464]

The REACH Regulation does not contain any reference to CRMs and the related EC policy. At first glance, there is no apparent relationship between REACH (addressing safe use of chemicals) and the issue of Critical Raw Materials (addressing a supply risk). However, REACH constraints such as authorisation for CRMs or linked substances could impose an **additional hurdle to supply**,[465] for example in that it discourages the non-EU supplier from incurring the costs for supporting an application for authorisation, so that continued supply depends additionally on the EU downstream users' authorisation compliance. The supplier may even envisage complete cessation of EU business if the substance is promoted to Annex XIV.[466]

This shows that it is important to consider the possible impact on CRM supply when making REACH-related regulatory risk management decisions. In a first step, a closer examination of supply chain risks as a consequence of assumed REACH regulatory scenarios (such as Annex XIV inclusion) to clarify the link between CRM strategy and REACH would be recommended.

CIRCULAR ECONOMY

The Circular Economy Package[467] was adopted by the EC at the end of 2015. The related EU Action Plan for the Circular Economy of 2.12.2015[468] has clearly recognised the importance of addressing the link between chemicals, product and waste legislation (highlightings by the author):

*"Another **very important issue** for the development of secondary raw materials markets is the **link with legislation on chemicals**. A growing number of chemical substances are identified as being of concern for health or the environment and become subject to restrictions or prohibitions. However, these substances may be present in products sold before the restrictions applied, some of which have a **long lifetime**, and therefore chemicals of concern can sometimes be found in recycling streams. Such substances can be costly to detect or remove, creating obstacles in particular for small recyclers.*

*The **promotion of non-toxic material cycles** and **better tracking of chemicals of concern in products** will facilitate recycling and improve the uptake of secondary raw materials. **The interaction of legislations on waste, products and chemicals must be assessed in the context of a circular economy in order to decide the right course of action at EU level to address the presence of substances of concern, limit unnecessary burden for recyclers and facilitate the traceability and risk management of chemicals in the recycling process.** The Commission will therefore develop its analysis and propose options for action to overcome unnecessary barriers while*

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[464] See Chapter 6 with Table 9 and Annex D for more substance-specific information.

[465] Oakdene Hollins and Fraunhofer ISI, Study on Critical Raw Materials at EU Level, Final Report for DG Enterprise and Industry (16 December 2013), Section 5.5.2 (page 71-76) conclude that environmental legislation such as REACH may potentially influence the criticality of raw materials, especially where outright bans or restrictions on raw materials are in place (impact on the demand for substances derived from such raw materials). Overall, the study considers that the impact of environmental legislation on criticality is uncertain and would require a wider understanding of supply chains via application based criticality studies, or examinations of supply chain risk.

[466] This has been mentioned e.g. for diboron trioxide (borates are on the CRM list 2014), which was prioritised by ECHA for Annex XIV inclusion in 2015. Annex XIV inclusion would have a major impact on the main EU manufacturer, because the non-EU supplier does not wish to apply and would stop supply in that case, while the substance is not available from within EU in the quality required for semiconductors, see Annex D.8.

[467] http://ec.europa.eu/environment/circular-economy/index_en.htm.

[468] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52015DC0614; last accessed: 11.12.2016.

preserving the high level of protection of human health and the environment. This work will feed into the future EU strategy for a non-toxic environment."

Consequently, an action on the EC for 2017 includes:

"Analysis and policy options to address the interface between chemicals, products and waste legislation, including how to reduce the presence and improve the tracking of chemicals of concern in products"

The plan also highlights ***"facilitating substitution of chemicals of concern"*** as one of the actions.

This shows that the EC's Circular Economy package sees substitution of SVHCs as an activity that should be **encouraged** in terms of supporting industry in this challenging task rather than enforcing it within very short timeframes. In the Contractor's opinion this can be achieved especially by means of financial support and allowing more time to substitute, e.g. by means of applying the principle ***"innovate first, regulate later"*** as a possible outcome of an RMOA (see Sections 9.1 and 9.2.1 above).

The overall aim of the circular economy initiative, which is also supported by stakeholders in the defence sector, is to **minimize waste**. This can be achieved by ensuring **longevity of products** and **promotion of recycling / reuse**. As with CRMs, the REACH rules for SVHCs pose potential hurdles to the circular economy idea. Two examples shall be given:

- The defence sector is still dependent today on a number of SVHCs (such as chromates and cadmium) for maintenance activities to ensure performance and longevity of defence equipment. If the substance is listed in Annex XIV, an **authorisation** application is required. Today, this is still a significant hurdle for downstream users in the defence sector and maintenance activities are not covered by the envisaged simplification rules of the EC.
- Where a user of defence equipment has to make a decision whether to discard it as waste or recycle / resell it, **REACH Article 33** applies in principle when reselling the equipment / parts. MoDs have reported that the disposal of old aircraft results in removal of usable spare parts by qualified staff. These spare parts are then sold as second hand spare parts. However, as it has been shown (Section 4.2.2.1), due to the lack of knowledge (especially for legacy and imported systems), it is often not possible to tell for sure, which SVHCs are present in the product or spare part. Therefore the re-seller incurs a potential compliance risk with regard to REACH Article 33 or has to incur additional costs for the detection of possible SVHCs. This may discourage him from making a re-selling decision, even if the equipment could be used safely.

In a recent study prepared for the EC[469] the REACH Regulation was also considered as a possible regulatory barrier for the case of medical equipment and its remanufacturing. This case has a number of similarities to the issues for defence equipment, as shown in the info box below.

[469] Technopolis Group et al., Regulatory barriers for the Circular Economy: Lessons from ten case studies, Final report (13 July 2016), page 99 et seq. (especially page 102-104 and Table 40).

INFO BOX: Regulatory barriers to Circular Economy for Medical Equipment

Medical imaging devices are widely refurbished because of their high value and their design for repair and refurbishment. Medical imaging devices are reusable (and reused), highly recyclable and contain many tons of valuable materials (steel, copper, aluminium, pure lead, etc.). The devices are built to last 15 to 20 years, but are often not completely utilised in their first life cycle. Refurbishment can therefore extend the overall time of the equipment. Due to their specific properties needed for medical imaging, those devices often contain hazardous materials such as lead, cadmium and hexavalent chromium. High standards of end of life treatment of these substances reduce the risk for patients and environment. While the study has identified RoHS as main regulatory barrier that hinders circular economy, hampering the remanufacturing of medical equipment within the EU, other substance regulations like REACH have been highlighted as the first additional barrier, if substances used in medical devices would be added to them, with just the same problems like for RoHS: Restricted access to used parts/products; difficulties with selling refurbished equipment on EU market; uncertainty about future restrictions. As a possible (legal) solution the study indicates exclusion of the refurbishment of medical devices.

Thus, there appears to be a need to determine, how provisions / decisions under REACH (e.g. for RMOA) are to be interpreted / made in the light of the circular economy, and how hazardous substances (especially those with SVHC properties) are to be addressed in this context, especially where the use could be made safely (low risk). As mentioned, hazardous substances may well support longevity of equipment and hence the objectives of the circular economy. On the other hand, their continued use does not support the move towards a non-toxic environment. Therefore a risk-based trade-off seems to be required.

N.4 Possible elements of a fit-for-purpose simplified authorisation for military uses

A simplification is proposed for all elements of the authorisation dossier, i.e. Chemical Safety Report (**CSR**), Analysis of Alternatives (**AoA**) and Socio-Economic Analysis (**SEA**). Overall,[470] the application could possibly be limited to **existing data**, allowing a **simple referral statement by Ministries of Defence in AoA and SEA of an agreed need and criticality in the interests of defence/national security**. **It should not be limited to a tonnage threshold, since it is not adequate to cover military needs, which are volatile by nature.**

More specifically, possible elements of a simplified defence-specific AfA include:

- in the AoA:
  - limitation to alternatives expected to comply with **military standards/requirements**
  - possible need for customer qualifications/approval
  - consideration of **interoperability requirements** / joint design with non-EU partners
  - compatibility with legacy weapon systems
  - consideration of relevant **domain-specific aspects**, e.g. for explosives: how to address the risk of accidents during substitution (see Annex D.2); no/limited substitutability for MRO chemicals for aircraft (airworthiness, imported equipment with IPR/design restrictions)
  - how to make the case for novel uses?

[470] The simplification proposals are based on valid stakeholder suggestions identified during the study consultation.

- in the SEA:
  - **qualitative argumentation** with regard to the ***interest of defence***: description of military capabilities achieved with the defence product[471]
  - description of the **process of military qualification and certification** after substitution
  - consider relevant domain-specific aspects.
- in the CSR:
  - Simplifications similar to the ones currently underway for low volume uses. Identify higher volume cases for the military and study how these should be addressed.

The template should be fit for purpose to be used by eligible applicants, i.e.

- company DU
- MoD "DU" (if such exists, please refer to Section 9.3.5)
- upstream formulator (esp. to cover complex supply chain scenarios with many DUs)

The template is proposed to be accompanied by **guidelines for the processing of defence specific AfAs** foreseeing e.g. informal consultations by ECHA Committees/the EC of the **MoD** in case of intended deviations from the application (e.g. shorter review period). In relation to informal consultations of **other EU-level agencies** reports were made during the study consultation about an agreement between ECHA and the European Aviation Safety Agency (**EASA**) about civil aerospace. When ECHA and EASA prepared their common paper, it was discussed that EASA could act as an independent arbiter and verifier of claims made by industry should the ECHA Committees require this. It was suggested that **EDA** could play a similar role for the military domain. However, ECHA informed that such involvement of EASA in the AfA opinion-making process has not been confirmed and is not operational today. As of today, its workability in relation to the EDA, who may also need to consult with MS and/or industry in such cases, and given its current constraints in terms of the necessary resources and expertise required, can therefore not be fully assessed.

N.5 Review of opinions on REACH Article 33 interpretation / implementation

Today, different views of defence industry and authorities persist on the important question, whether / to what extent REACH Article 33 communication for (very) complex articles containing a candidate list substance above 0.1% should identify the component article(s) where it is present, regardless of the necessity for safe use ("**localisation information**"). A review of different opinions and proposed solutions is given hereafter:

- The **CJEU** judgment of 10 September 2015 has not unambiguously stated whether SVHCs also need to be declared on a component article level, i.e. whether **localisation information** should be given by default (see further information in Annex J).
- Defence industry stakeholders see a critical need to **streamline and simplify the application of Article 33** to ensure effective SVHC communication based on common, relevant and reasonable requirements for such articles and to avoid further excessive work and costs for the defence industry, which ultimately means a cost for the tax payer through price increases to national MoDs. They see it as the **most important short term action**

[471] It is difficult to quantify the benefits for continued use of a fighter jet, tank etc. to a Member State.

towards lowering the economic impact of REACH on defence industry. Some industry stakeholders also see a need for applying **"cut-off criteria"** for very complex articles such as many defence products, in order to reduce the communication obligations in the supply chain to a reasonable and proportional level. Those stakeholders would welcome if the EDA joined the discussions on the information duties of Article 33 and, e.g., provide examples on how a **reasonable level of reporting** might look like for very complex defence products.[472]

- According to **ASD** Article 33 reporting should not legally require localisation information except where necessary for safe use under reasonably foreseeable conditions, as judged by the product manufacturer.
- The majority of **MoDs** consulted **prefer to receive localisation information** and that the safe use information provided would cover service, maintenance and repair as well as the disposal phase. With regard to ASD's position, those MoDs are concerned that the supplier's assessment might not be readily validated from the buyer (MoD's) or the enforcement authority's point of view.
  More specific solutions have been proposed by the FR and ES MoD:
  - The **FR MoD** proposal of having a **complexity/domain-specific communication scope** is supported by several other MoDs.[473] According to the FR MoD, localisation information for SVHCs should be reported, where it has been identified somewhere in the supply chain provided that the **complexity of the object is manageable**, in order to have useful info for maintenance scenarios and for end of life, e.g. for **ammunition, (land) vehicles and ships**. For **really complex objects such as airplanes,** with several millions of parts, information about the manufacturing and maintenance processes associated with the listed SVHC (e.g. (theoretical examples) "surface treatment (or paint) of this particular type of structural parts has Cr(VI)", "all connectors of this type in this subsystem have Cr(VI)+Cd"…) and codes sufficient to manage complexity while providing localisation information to experts should be provided together with the SVHC list and safe use documentation - even if beyond current use and maintenance activities by the MoDs, because one day unexpected maintenance might be required.
  - The **ES MoD** proposal is to use the **NATO Stock Number (NSN)** to include information of SVHC substances in articles to keep the whole supply chain informed about the risk management as needed for SHVC substances in an article using the NSN data base (used by more than 70 countries, not only NATO countries). According to STANAG´s 4427 and 4728 and ACMP-2000 publication, the Configuration Management (CM) is mandatory for the big armament platforms and systems, and NSN of the parts could be used to know the place of the article where the SVHC substances are located in those cases where this information is considered important to control the risk. Localisation information should be provided at least for spare parts, maintenance and disposal tasks.
- **MSCAs** consulted on the interpretation of REACH Article 33 have expressed different opinions as to whether localisation information should be given by default, or whether this

[472] Note: As of today the EDA does not have the level of technical expertise available to provide own opinions on such matters.
[473] DE MoD refers to the statements of the DE MSCA (BAuA).

is the supplier's responsibility (supplier risk assessment). It appears from the Contractor's assessment that the overall difference of views which existed before the CJEU judgment still persists, but now with regard to the required level of reporting.

- The **comparison of responses by MSCAs and MoDs** has shown that their opinions do not always match. The complexity/domain-specific opinion of the FR MoD, which is supported by most other MoDs responding, is not reflected in MSCA responses. This may be explained by the fact that MSCAs have provided a **legal interpretation** of REACH Article 33, while MoD responses rather reflected **practical information needs.** However, these two issues need to be clearly separated.

The question whether **ECHA** will take a clear stand on the localisation issue in the update of the *Guidance on requirements for substances in articles* (Guidance for Articles), is open today. The current draft Guidance for Articles for consultation of the Partner Expert Group (PEG)[474] is not explicit in terms of a mandatory localisation requirement.[475] The content of the revised ECHA guidance on requirements for substances in articles following the O5A judgment, and especially how the localisation issue will be addressed, will have a great influence on the further impact for the A&D industry. Defence industry suggestions in this regard are followed up by ASD within the PEG.

N.6 Ammunition safety: Study and possible legislative action

Description of proposal	Addressee
(1) Study on co-existing safety requirements for military ammunition, highlighting potential improvement ideas	EDA with MoDs, supported by the EC
(2) *Depending on the outcome of (1)*: Dedicated legislative action / provision on ammunition safety (amending CLP), to make it coherent with existing EU and national regulation on pyrotechnical products / energetic materials for use, transportation, storage, dismantling, etc..	EC

RATIONALE

MoDs and defence industry largely agree that CLP labelling for military ammunition adds little value (if any) to the trained user, or is even further regarded as a disruptive element negatively affecting on the defence capability. At the same time there are already a number of **co-existing requirements on ammunition safety**, which include labelling and supplied documents, and which are quite sophisticated. For further information see Section 4.2.5.

PROPOSAL IMPLEMENTATION

[474] The following MSCAs are PEG participants: DK, DE, IE, FR, IT, LT, NL, AT, SE, UK, NO.

[475] ECHA, Guidance on requirements for substances in articles, draft (July 2016), Version 4.0, Section 3.4.1: *"This means that the obligatory additional information depends on what a user needs to know to be able to use the article safely and not on how available this safety information is. Providing only the name of the substance is unlikely to be sufficient to allow safe use of the article in many cases. Any downstream supplier must pass the information that has been provided to him on down the supply chain or, upon request, to consumers."*

A study on co-existing ammunition safety rules could be the first step towards a longer term solution,[476] potentially leading to a dedicated legislative revision of the safety regime for military ammunition (amending CLP); this is supported by several MoDs.[477] EL MoD proposes to conduct this study in the frame of the EDA REACH Task Force, as an extension to its work on ammunition classification.

N.7 Transparency issues for REACH (etc.) and substance-level information

EC WEBPAGES

Today, it is very challenging for industry to find information about the EC's activities on REACH and CLP, including CARACAL, REACH Committee and EC (draft / final) amendments of REACH and CLP. There are different REACH-related websites for

- DG GROW: https://ec.europa.eu/growth/sectors/chemicals/reach_en
- DG ENV: http://ec.europa.eu/environment/chemicals/reach/reach_en.htm
- CARACAL: http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2385
- Committee established under the Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Code: C34200): http://ec.europa.eu/transparency/regcomitology/index.cfm
- Draft amendments of REACH Annexes (WTO notification), e.g. for the proposed Annex XIV update in 2017 http://ec.europa.eu/growth/tools-databases/tbt/nview.cfm?p=EU_407_EN
- Information on the streamlining and simplification of authorisation for low volumes: http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8081

It would be very helpful to enhance transparency in this regard, so that industry can keep better track of the various and dynamic evolutions of REACH and CLP.

ECHA WEBPAGES – RATIONALE FOR A REGULATORY SUBSTANCE TRACKING TOOL

Today substance-level monitoring of regulatory activities for obsolescence risk assessment and management is arduous and highly resource intensive for industry, also given the dynamic nature of the various REACH substance lists. Each organisation needs to create or buy its own tracking tool instead of having a global one to rely on; thus the spending of resources is unnecessarily multiplied. End users like the defence sector are affected simultaneously by a high number of substances which are in the "pipeline" for REACH candidate list and authorisation, restrictions or CLP harmonised classification and labelling, to mention only a few processes.

ECHA has introduced ***"infocards"***[478] for substances, which provide – among others – information about the most relevant regulatory activities and outcomes associated with the substance, with links to each regulatory process under which the substance is dealt at a given time.[479] However, this still requires the user to investigate deeper into each process and to manually track its

[476] The CLP defence exemption was not foreseen to be used to exempt from a requirement that does not add value.

[477] One MoD added, that both use by MoD and police (national security) should be addressed in any improvement activtity.

[478] https://echa.europa.eu/documents/10162/22177693/what_is_an_infocard_en.pdf.

[479] See e.g. for Bisphenol A: https://echa.europa.eu/substance-information/-/substanceinfo/100.001.133.

evolution from an initial proposal through to the final decision (often outside of ECHA by the EC) on a regular basis.

A regulatory substance tracker, to which the user can sign-up, and which highlights the implications of the current process step (e.g. the meaning of inclusion in the candidate list), could save a lot of unnecessary costs for industry, improve transparency and help industry take the corresponding decisions at the right moment in time. It would be particularly helpful for SMEs, who often do not have the competence and resources to track the regulatory progress manually and interpret the implications of a given process step.

As an example, if the user signs up for specific alerts for substance A, he or she would be informed at the earliest possible moment about key procedural milestones and their meaning such as

- initiation of an RMOA
- a stakeholder consultation on the RMOA
- the conclusion of the RMOA
- the submission to the Registry of Intentions (RoI)
- etc.

Importantly, the tool would comprise both the process steps on the ECHA **and the EC side** (e.g. REACH Committee vote, WTO notification, publication in the Official Journal of the European Union).

A major uncertainty for industry today relates to the fact that it is not known whether a candidate list substance will be eventually included in Annex XIV. Due to this uncertainty the market often overreacts with a precautionary "blacklisting" (stigmatisation effect of candidate listing, esp. at DU level). **Therefore it is important for industry to know not only if a substance will be regulated, but also, if it will <u>not</u> be promoted to a given list in the foreseeable future - unless new information comes to the light - and why (e.g. no Annex XIV inclusion for the time being because restriction route has been taken). This information should be given as well.**

This also applies to those candidate list substances recommended by ECHA for Annex XIV inclusion, where the EC proposes not to include them into Annex XIV for the time being (recent examples are ADCA, borates and RCF's). The uncertainty associated with this 'limbo' situation is very difficult to manage for the industry.

N.8 Additional improvement proposals discussed

Below is a list of some other major **stakeholder proposals** made during the course of the study, where either the time constraints, study specifications and/or the gathered data from the impact assessment did not allow further debate with stakeholders and elaboration of formal improvement proposals.

- **Question of the usefulness of authorisation altogether** compared to restriction, special dispositions for inorganic substances and/or substances in articles compared to substances in mixtures and/or substances for articles (maybe even mixtures) for professional use only, in relation with their regulatory process.
    - In particular: Change the current restriction and authorisation systems for a **single restriction system, with authorisation integrated within it** to allow essential uses until acceptable alternatives can be found.
- **ECHA Annex XIV recommendations**:
    - The prioritisation method is not meaningful (a sum, with inadequate thresholds for the rating for each of the 3 parameters. In risk analysis, we multiply a probability of occurrence by the severity of impact if the feared event happens).
    - After a substance has been added to the candidate list - instead of the current prioritisation approach – ECHA and industry jointly start to undertake a **high quality risk assessment**, where all relevant aspects are assessed such as:
        - the uses and level of exposure;
        - the current situation regarding development of alternatives;
        - the effects on circular economy.

      After this assessment, a knowledge-based decision can be made on the best way forward to control the risks causes by the uses of this substance.
- **REACH as a single "mother regulation"**, integrating also other EU chemicals / product regulations dealing only with a limited number of substances (BPR, ODS, POP, RoHS). It was noted by one MoD of a Member State with strong DTIB that while there was not so much information about other regulations' impacts available from this study, they see that they do happen and MoDs and industry are ill prepared to deal with their specific rules and impacts, which, according to this MoD is the primary reason for delocalisation and lack of entrepreneurship. There should be consistent objectives and processes across chemicals regulations (align and ideally integrate all within REACH).
- **Regulatory substance tracker for all EU chemicals regulations**: According to one stakeholder proposal the tracker (see Section 9.4.2) should cover all EU substances regulations (whether or not these regulations would be merged in 1 single regulation like REACH).
- **Improve Article 33:** Differentiate between *"antechamber"* for authorisation or restriction (candidate list) and a more stable notification list (including a wider range of substances based on CLP such as CMR and what is being done in automobile industry with GADSL)

- **ECHA IT-tool to create (save /& access) e-SDS / SDS** according to REACH to facilitate the transmission of information up / down the supply chain, minimize risk and promote transparency.
- **Amend REACH Article 2(3) to clarify** that *"Member States may allow for exemptions from this Regulation in specific cases for certain substances, on their own, in a mixture or in an article, where necessary in the interests of national or European defence and security."*
- **eSDS** not the answer to legal requirement to assess the nature, degree and duration of exposure to a substance:
    - Replace eSDS by TIER 1 and/or TIER 2 risk assessment instrument.
    - Open source EH&S data available to use in TIER 1 and/or 2 risk assessment instrument.
    - Ideal solution, when supplier supplies end-user with ready to use instrument.

  Replaces need to do CSR in case use is not in line with recommended use and/or RMM.

O. REFERENCES

Table 26 List of published references

Title	Author	Date (& place) of publication	WWW-Address of publication	Other identifiers (e.g. vol.)
Council conclusions on implementing the EU global strategy in the area of security and defence	Council of the European Union, Foreign Affairs Council	14 November 2016	http://www.consilium.europa.eu/en/press/press-releases/2016/11/14-conclusions-eu-global-strategy-security-defence/	14149/16
Aerospace and Defence Industries Key Facts & Figures 2015	ASD	November 2016	http://www.asd-europe.org/fileadmin/user_upload/ASD_F_F2015_web.pdf	
Annex XV Restriction Report – Proposal for a Restriction: Diisocyanates	Germany REACH Comptetent Authority (BAuA)	6 October 2016	https://echa.europa.eu/documents/10162/f210a2bf-bc8f-4a1c-b532-8a8fe3682321	
State of the Union 2016	Jean-Claude Juncker, President of the European Commission	14 September 2016	https://ec.europa.eu/priorities/state-union-2016_en#/documents	
Substance Evaluation Conclusion document for ammonium perchlorate	Germany REACH Comptetent Authority (BAuA)	10 August 2016	https://echa.europa.eu/documents/10162/5a24f238-6d61-4d67-948d-eba568e9d9ea	
Improving the Identification, Evaluation, Adoption and Development of Safer Alternatives: Needs and Opportunities to Enhance Substitution Efforts within the Context of REACH; An evaluation and report commissioned by the European Chemicals Agency	Joel Tickner and Molly Jacobs University of Massachusetts Lowell, Lowell Center for Sustainable Production	August 2016	https://echa.europa.eu/documents/10162/13630/substitution_capacity_lcsp_en.pdf/2b7489e1-6d96-4f65-8467-72974b032d7b	

Commission Regulation (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures	European Commission	19 July 2016	http://eur-lex.europa.eu/eli/reg/2016/1179/oj	
Regulatory barriers for the Circular Economy: Lessons from ten case studies	Technopolis Group in consortium with Fraunhofer ISI, Thinkstep and Wuppertal Institute	13 July 2016	http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8986&lang=en	
Economic Impact Authorisation Chrome VI	Panteia	July 2016	http://vereniging-ion.nl/system/files/nieuwsberichten/bijlages/Panteia%20Final%20Report%20Economic%20Impact%20%20Chrome%20VI.pdf	
Draft Guidance on requirements for substances in articles	ECHA	July 2016	https://echa.europa.eu/documents/10162/13643/peg_sia_guidance_en.pdf/fe8f10c8-bbdf-430c-af7d-315d2f7be7ac	Version 4.0
REFIT Platform Opinion on the submission by the Cross Industry Initiative on the interface between REACH and the EU Occupational Safety and Health (OSH) legislation	REFIT Platform	27/28 June 2016	http://ec.europa.eu/smart-regulation/refit/refit-platform/docs/recommendations/opinion_chemicals.pdf	
Information note from the Presidency for the Environment Council of 20 June 2016: Policy conference "REACH Forward" (Brussels, 1 June 2016)	Council of the European Union (General Secretariat of the Council)	9 June 2016	http://data.consilium.europa.eu/doc/document/ST-10098-2016-INIT/en/pdf	10098/16
Improving Substitution and Innovation	Health and Safety Authority, Sharon McGuinnes	1 June 2016	http://www.reachhelpdesk.nl/dsresource?objectid=rivmp:317976&type=org&disposition=inline&ns_nc=1	

Joint Service Publication (JSP) 418, leaflet 5, Management of Hazardous Substances and Restricted Materials	UK Ministry of Defence	June 2016	https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/561505/20160523-JSP_418_Lft_05_Hazardous_Materials_Final-.pdf	
The decision of the ECHA Board of Appeal of 25 May 2016 in case A-010-2014 (Nordenhamer Zinkhütte GmbH, diarsenic trioxide)	ECHA	25 May 2016	https://echa.europa.eu/documents/10162/3ddab5ca-db7a-4e85-8bfe-65e6bc2c8cf4	
Evaluation and Fitness Check (FC) Roadmap	European Commission	18 May 2016	http://ec.europa.eu/smart-regulation/roadmaps/docs/2017_env_005_reach_refit_en.pdf	Modified : 23/05/2016
Commission Staff Working Document Impact Assessment	European Commission	13 May 2016	http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016SC0152&qid=1472733006686&from=EN	
Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work	European Commission	13 May 2016	http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016PC0248	
Draft Commission Regulation (EU) amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards bis(pentabromophenyl)ether (5 pages + Annex 2 pages, in English)	European Commission	4 May 2016	https://members.wto.org/crnattachments/2016/TBT/EEC/16_1812_00_e.pdf https://members.wto.org/crnattachments/2016/TBT/EEC/16_1812_01_e.pdf	
Linking REACH and OSH Legislation Activities of the European Commission and latest developments	European Commission, DG Environment Chemicals Unit, Christian Heidorn	May 2016	http://reachconference.eu/images/presented2016/d2_l4_christian_heidorn_losh_reach_17_may_2016_prague.pdf	
Concerns, observations and suggestions for the EDA to consider on the application of CLP regulation to ammunition (as „explosive	ASD	May 2016	http://www.asd-europe.org/fileadmin/user_upload/ASD_Concerns__observations_and_suggestions_for_the_EDA_to_con	KOM

articles")			sider_on_the_application_of_CLP_regulation_to_ammunition_-_April_2016_-_final.pdf	
Report on the Operation of REACH and CLP 2016	ECHA	May 2016	https://echa.europa.eu/documents/10162/13634/operation_reach_clp_2016_en.pdf	Reference: ECHA-16-R-08-EN
The future of EU defence research	Me Frédéric Mauro, Professor Klaus Thoma, paper requested by the European Parliament's Sub-Committee on Security and Defence	March 2016	http://www.europarl.europa.eu/RegData/etudes/STUD/2016/535003/EXPO_STU(2016)535003_EN.pdf	Reference: EP/EXPO/B/SEDE/2015-02
Roadmap for SVHC identification and implementation of REACH risk management measures - Annual Report 2016	ECHA	4 April 2016	https://echa.europa.eu/documents/10162/19126370/svhc_roadmap_2016_en.pdf	Reference: ECHA-16-R-06-EN
Annex XV Restriction Report: Proposal for a Restriction: Substance Names: Four Phthalates (DEHP, BBP, DBP, DIBP)	ECHA	1 April 2016	https://echa.europa.eu/documents/10162/e06ddac2-5ff7-4863-83d5-2fb071a1ec13	Version number 1
Cumulative Cost Assessment for the EU Chemical Industry	technopolis group	April 2016	http://ec.europa.eu/DocsRoom/documents/17784/attachments/1/translations/	
REACH-Info 6 Erzeugnisse – Anforderungen an Produzenten, Importeure und Händler	Germany REACH Comptetent Authority (BAuA)	April 2016	http://www.baua.de/de/Publikationen/Broschueren/REACH-Info/REACH-Info-06.pdf?__blob=publicationFile&v=25	3., überarbeitete und erweiterte Auflage
Guidelines for an Industry Risk Management Options Analysis (RMOA)	Eurometaux	January 2016	http://www.reach-metals.eu/index.php?option=com_content&task=view&id=211&Itemid=319	
Chemicals legislation and the circular economy	European Commission, Bjørn Hansen, Head of the Chemicals Unit, DG	9 December 2015	http://ecostandard.org/wp-content/uploads/Hansen_Chemicals-and-circular-economy.pdf	

	Environment			
Background information on bisphenol A and thermal paper	ECHA	7 December 2015	https://echa.europa.eu/documents/10162/13580/annex_bpa_pr_15_16.pdf	Annex to ECHA/PR/15/16
Study on "Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs"	European Commission (DG GROW)	December 2015	http://ec.europa.eu/DocsRoom/documents/14581/attachments/1/translations/en/renditions/native	Ref. Ares(2015)5889146 - 16/12/2015
Guidance on requirements for substances in articles	ECHA	December 2015	https://echa.europa.eu/documents/10162/13632/articles_en.pdf	V. 3.0
ECHA's general responses on issues commonly raised in public consultations on draft recommendations	ECHA	18 November 2015	https://echa.europa.eu/documents/10162/13640/recom_general_responses_doc_en.pdf	
Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV – General Approach	ECHA	18 November 2015	https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf	
Recherche des origines de la pollution en perchlorate impactant des captages d'eau potable au sein des AAC de la région de Nemours et Bourron-Marlotte (77) et (45)	BRGM	November 2015	http://infoterre.brgm.fr/rapports/RP-64840-FR.pdf	BRGM/RP-64840-FR
European Defence Action Plan	European Commission	November 2015	http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_grow_006_cwp_european_defence_action_plan_en.pdf	
Comments on the CTAC(Sub) application for authorisation in public consultation	Space Chromates Task Force	6 October 2015	https://echa.europa.eu/documents/10162/18074545/a4a_comment_665_1_attachment_en.pdf	
Judgment of the General Court (Fifth Chamber) in case T-360/13	Court of Justice of the EU (CJEU)	25 September 2015	http://curia.europa.eu/juris/document/document.jsf?text=&docid=168623&pageIndex=0&doclang=en&mode=req&dir=&occ=first&part=1&cid=771177	

Judgment of the Court (Third Chamber) in case C-106/14	Court of Justice of the EU (CJEU)	10 September 2015	http://curia.europa.eu/juris/document/document.jsf;jsessionid=9ea7d2dc30d5d17a25a482df4777be19b722670fc3ea.e34KaxiLc3qMb40Rch0SaxuTa3f0?text=&docid=167286&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=1125929	
Summary of European Commission Decisions on authorisations for the placing on the market for the use and/or for use of substances listed in Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	European Commission (Official Journal of the European Union)	2 September 2015	http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52015XC0902(01)&from=EN)	
Analysis of the most appropriate risk management option (RMOA) for 1,2-dibromoethane	ECHA	16 July 2015	https://echa.europa.eu/documents/10162/e097e2c0-903c-41aa-8040-5fe0d6262222	
REACH position paper - Annex I: SVHC Roadmap	FuelsEurope	July 2015	https://www.fuelseurope.eu/uploads/Modules/Resources/fuelseurope-position-paper-on-reach_annex-i_svhc-roadmap.pdf	
Opinion on an Annex XV dossier proposing restriction on Bis(pentabromophenyl) ether (DecaBDE)	ECHA (RAC & SEAC)	2 June 2015 and 10 September 2015	https://echa.europa.eu/documents/10162/b5ac0c91-e110-4afb-a68d-08a923b53275	
ANALYSIS OF ALTERNATIVES non-confidential report Use number: 5	CTAC Submission Consortium	May 2015	https://echa.europa.eu/documents/10162/abfeff08-5b9e-4e89-8296-8d8f08c1aac7	
Joint ASD/AEA Position Paper REACH Authorisation Consultation on Applications for Low Volumes and an Extension of Transitional Arrangements for Uses in Legacy Spare Parts	ASD, AEA	17 April 2015	http://ec.europa.eu/DocsRoom/documents/10710/attachments/1/translations/en/renditions/native	
Technical Barriers to Trade (TBT) Inquiry on Proposed German Regulations on Beryllium	Materion	15 April 2015	-	

Community rolling action plan (CoRAP) update covering years 2015, 2016 and 2017	ECHA	17 March 2015	https://echa.europa.eu/documents/10162/13628/corap_list_2015-2017_en.pdf	
Justification for the selection of a substance for CoRAP inclusion	Germany REACH Comptetent Authority (BAuA)	17 March 2015	https://echa.europa.eu/documents/10162/63aae2e2-3a13-481b-8fbc-9e53c9cfcbd2	
EDA Code of Conduct on REACH Defence Exemptions	EDA	March 2015 (Brussels)	https://www.eda.europa.eu/docs/default-source/documents/eda-code-of-conduct-on-reach-defence-exemptions.pdf	
Annex to Code of Conduct on REACH Defence Exemptions - Framework for Applying for a Defence Exemption from a Requirement of REACH	EDA	March 2015 (Brussels)	https://www.eda.europa.eu/docs/default-source/documents/annex-to-EDA CoC---framework-for-applying-for-a-defence-exemption-from-a-requirement-of-reach.pdf	EDA documentation for Government use only
Critical Space Technologies for European Strategic Non-Dependence Actions for 2015/2017	EC, ESA, EDA	March 2015	https://ec.europa.eu/research/participants/portal/doc/call/h2020/compet-1-2016/1682606-european_non-dependence_items_2015_2017_v1_16_en.pdf	V1.16
Military Challenged to Maintain Decades-Old Aircraft	Sandra I. Erwin	January 2015	National defense magazine http://www.nationaldefensemagazine.org/archive/2015/January/Pages/MilitaryChallengedtoMaintainDecadesOldAircraft.aspx	
On the Materials basis of Modern Society	Graedel T.E., Harper E.M, Nassar N.T., Reck K.R.	2015	Proceedings of the National Academy of Science: http://www.pnas.org/content/112/20/6295.full.pdf?sid=5e6b0fe4-7720-4114-a1ad-f8af81f5e032	112(20)
Guidance on Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD)	ECHA	November 2014	https://echa.europa.eu/documents/10162/13632/pord_en.pdf	Version 2.0
Report of the Task Force on Restriction Efficiency	ECHA	21 October 2014	https://echa.europa.eu/documents/10162/13641/report_task_force_on_restriction_efficiency_en.pdf	
Scientific Opinion on the risks to public health related to the presence of perchlorate in food, in particular fruits and vegetables	European Food Safety Authority	17 October 2014	https://www.efsa.europa.eu/en/efsajournal/pub/3869	EFSA Journal 2014;12(10)

				:3869
Discussion REACH - Classification of ammunition as articles with an integral substance / mixture	BDSV	September 2014		
Risk Management Options Analysis Conclusion for Diisocyanates	Germany REACH Comptetent Authority (BAuA)	29 August 2014	http://www.reach-clp-biozid-helpdesk.de/de/REACH/SVHC-Roadmap/Downloads_RMOA-Conclusion/MDI-Gruppe.pdf?__blob=publicationFile&v=4	
Application of the REACH Regulation to Ammunition - Professional Guidance	GICAT	28 August 2014		Version 2 issue c
Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the review of the list of critical raw materials for the EU and the implementation of the Raw Materials Initiative	European Commission	26 May 2014	http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52014DC0297	COM/2014/0297 final
REACH Interpretation Guidelines	ASD	May 2014	http://www.asd-europe.org/fileadmin/user_upload/Client_documents/ASD_Contents/7_CROSS-FUNCTIONS/7.4_Environment/REACH_Interpretation_Guidelines_v3_May_2014.pdf	
DRAFT ANALYSIS OF THE MOST APPROPRIATE RISK MANAGEMENT OPTION FOR NICKEL SULPHATE	FRANCE (Anses - French Mandated National Institute)	April 2014	https://www.nickelinstitute.org/~/media/Files/Sustainability/RMOAsSection/RMOA_NiSO4_PUBLIC.ashx?la=en	
An elaboration of key aspects of the authorisation process in the context of aviation industry	ECHA, EASA	April 2014	https://www.easa.europa.eu/system/files/dfu/20140415%20Published%20report.pdf	ECHA-14-R-09-EN

Exposure to carcinogens and work-related cancer: A review of assessment methods European Risk Observatory Report	European Agency for Safety and Health at Work	2014	https://osha.europa.eu/en/tools-and-publications/publications/reports/report-soar-work-related-cancer	ISSN: 1831-9343
Study on Critical Raw Materials at EU Level Final Report for DG Enterprise and Industry	Oakdene Hollins and Fraunhofer ISI	16 December 2013	http://ec.europa.eu/DocsRoom/documents/5605/attachments/1/translations	EC—11 315 –Final Report Issue 3.docx
SVHC Roadmap to 2020 Implementation Plan	ECHA	9 December 2013	https://echa.europa.eu/documents/10162/19126370/svhc_roadmap_implementation_plan_en.pdf	
Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Towards a more competitive and efficient defence and security sector	European Commission	24 July 2013	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2013:0542:FIN:EN:PDF	COM(2013) 542 final
The development of a European Defence Technological and Industrial Base (EDTIB)	Valerio BRIANI, Istituto Affari Internazionali (IAI), ITALY Alessandro MARRONE, Istituto Affari Internazionali (IAI), ITALY Christian MÖLLING, German Institute for International and Security Affairs (SWP), GERMANY (LEAD) Tomas VALASEK, Central European Policy Institute (CEPI), SLOVAKIA	June 2013	http://www.europarl.europa.eu/RegData/etudes/etudes/join/2013/433838/EXPO-SEDE_ET(2013)433838_EN.pdf	
Judgment of the General Court (Seventh Chamber, Extended Composition) in case T-93/10	Court of Justice of the EU (CJEU)	7 March 2013	http://curia.europa.eu/juris/document/document.jsf?text=REACH%2BRegulation%2Bcandidate%2Blist%2Bproportionality&docid=134564&pageIndex=0&docl	

			ang=EN&mode=req&dir=&occ=first&part=1&cid=881558#ctx1	
Roadmap on Substances of Very High Concern	European Commission	5 February 2013	http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%205867%202013%20INIT	
REACH Aerospace Supply Continuity Management	ASD	23 January 2013	https://echa.europa.eu/documents/10162/13637/aviation_industry_and_reach_en.pdf	
The French White Paper on defence and national security	Présidence de la République	2013	http://www.cfr.org/content/publications/attachments/Dossier_de_presse_LBlanc_DSN_en_anglais.pdf	
Position Paper Exemption of propellant-related use of hydrazine from REACH authorisation requirement	ASD-Eurospace	14 June 2012	http://www.eurospace.org/Data/Sites/1/pdf/positionpapers/hydrazinereachpositionpaper_final_14june2012.pdf	
Main concerns resulting from the implementation of REACH within the Aerospace Defence and Security business	ASD	30 May 2012	http://www.asd-europe.org/fileadmin/user_upload/Client_documents/ASD_Contents/7_CROSS-FUNCTIONS/7.4_Environment/REACH_14.pdf	Version 1.4
Addressing key European Defence Technology and Industrial Dependences 10-R&T-OP-33	FOI/ONERA/RAND	11 May 2012	http://eda.europa.eu/docs/default-source/procurement/14-cps-op-030-q-a-nr1-annex-3-edtid_-executive_summary.pdf	
Position Paper: Exemption of propellant-related use of hydrazine from REACH authorisation requirement	ASD, Eurospace	9 May 2012	http://www.eurospace.org/Data/Sites/1/pdf/positionpapers/hydrazinereachpositionpaper_final_14june2012.pdf	
Technical assistance related to the scope of REACH and other relevant EU legislation to assess overlaps	Milieu Ltd.	12 March 2012	http://ec.europa.eu/environment/chemicals/reach/pdf/studies_review2012/report_study8.pdf	Final Report (revised)
Commission Regulation (EU) No 143/2011 of 17 February 2011 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH')	European Commission	17 February 2011	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:044:0002:0006:en:PDF	

Guidance on Registration, Evaluation and Authorisation of Chemicals (REACH)	UK MOD	1 July 2010	https://www.gov.uk/government/publications/reach	Last update on 29 August 2014
A comprehensive analysis of emerging competences and skill needs for optimal and skill needs for optimal preparation and management of change in the EU defence industry, Final Report	Eurostrategies (Francois CAUZIC, Hélène COLAS, Nathalie LERIDON, Sofiène LOURIMI, Elisabeth WAELBROECK-ROCHA)	20 May 2009	https://www.eda.europa.eu/docs/default-source/procurement/14-cps-op-030-q-a-nr1-annex-1-97-skills-report-vf-1.pdf	
Oslo Manual – Guidelines for Collecting and Interpreting Innovation Data	OECD, European Commission	2005	http://www.oecd-ilibrary.org/docserver/download/9205111e.pdf?expires=1470495870&id=id&accname=guest&checksum=A619F98E659909594E8EF1104106F970	3rd edition
Council Directive 98/24/EC of 7 April 1998	European Council	7 April 1998	http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01998L0024-20140325&from=EN	
Innovative substances in the spotlight of chemicals legislation REACH	Industry initiative „IMAT“		https://indico.esa.int/indico/event/81/material/slides/4.pdf	
FuelsEurope position paper on REACH and the Refining industry	FuelsEurope		https://www.fuelseurope.eu/uploads/Modules/Resources/fuelseurope-position-paper-on-reach-and-the-refining-industry.pdf	

P. DEFINITIONS

Table 27 List of definitions

Actors in the supply chain	All manufacturers and/or importers and/or downstream users in a supply chain (REACH Article 3(17)
AfA Task Force	Task Force on the Workability of Applications for Authorisation, comprising representatives of the EC, ECHA and some MS
Annex XIV	List of substances subject to REACH Authorisation
Authorisation under REACH	Decision by the European Commission addressed to the applicant (manufacturer, importer or downstream user) granting him the right to continue use(s) applied for of a substance included in Annex XIV of the REACH Regulation after the sunset date. Each authorisation shall specify a time-limited review period.
CapTech	EDA promotes, facilitates and manages Research and Technology activities in 12 technology domains ('CapTechs') in order to develop knowledge and technologies needed for future defence capabilities. The purpose of a 'CapTech' working group is to generate collaborative R&T Projects within its technological scope, and to support EDA participating Member States in the preparation of wider programmes.
CARACAL	CARACAL (Competent Authorities for REACH and CLP) is an expert group which advises the European Commission and ECHA on questions related to REACH and CLP. CARACAL is composed of representatives of Member States competent authorities for REACH and CLP, representatives from competent authorities of EEA-EFTA countries as well as a number of observers from non-EU countries, international organisations and stakeholders.
Chemicals	Substances and mixtures of substances as defined in REACH Article 3 No. 1 and 2
Consumer	The term is not defined in the REACH Regulation, but referred in various REACH provisions, such as Article 3(13) ["…a consumer is not a downstream user"] and Article 33(2) [Article supplier's duty to communicate information on substances in articles "on request by a consumer…"]. Consumers do not have obligations under REACH.
Distributor	Any natural or legal person established within the Community [EU], including a retailer, who only stores and places on the market a substance, on its own or in a mixture, for third parties (REACH Article 3(14))
Downstream user	Any natural or legal person established within the Community, [EU] other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream

	user. (REACH Article 3(13))
Dual use	Dual use is not legally defined. For the purpose of this study dual use refers to any programme, system, component, technology, product, process or service that can be used for both military and civil purposes.
Exemption **(vs. exclusion)**	For the purpose of this study "exemption" refers to any exception from the application of standard requirements of the legislation in question for certain cases foreseen in the legal text, be it in full, with respect to specific requirements, or subject to a case-by-case decision by an authority (such as in case of REACH Article 2(3) or 58(2)). However, for the purpose of RoHS Article 2(4) the term "disapplication" as the common denomination by some MoDs is used for lit. (a) and "exclusion" for the other cases listed. The term "exclusion" is also used in relation to the stakeholder proposal to take military uses out of the REACH scope fully or partly (without the need to grant case-by-case exemptions).
European Economic Area (EEA)	All Member States of the European Union (EU) incl. French Guiana, as well as in Norway, Iceland and Liechtenstein. REACH applies in the EEA territory. Switzerland, Turkey or Russia are not part of the EEA. *References to "EU" in this study shall be understood to comprise also the EEA countries Norway, Iceland and Liechtenstein.*
Importer	Any natural or legal person established within the Community [EU] who is responsible for import; import means the physical introduction into the customs territory of the Community (REACH Article 3(11) and (10))
Latest application date	The date at least 18 months before the sunset date by which applications must be received by ECHA if the applicant wishes to continue to use the substance or place it on the market after the sunset date; this date is specified in Annex XIV
Manufacturer	Any natural or legal person established within the Community [EU] who manufactures a substance within the Community; 'manufacturing' means production or extraction of substances in the natural state (REACH Article 3(9) and (8))
Materials and Processes	Material: Raw, semi–finished or finished substance (gaseous, liquid, solid) of given characteristics from which processing into a component or part is undertaken Process: Set of inter-related resources and activities which transforms a material or semi-finished product into a semi-finished product or final product
Materiel	Military equipment and supplies
Member State Competent Authority (MSCA)	National competent authority or competent authorities by a Member State, which is responsible for performing the tasks allotted to competent authorities under the REACH (CLP, etc.) Regulation and for cooperating with the EC and the ECHA in the implementation of the

	Regulation (see for REACH: Article 121)
National Enforcement Authority (NEA)	National authority or authorities responsible for enforcement of the Regulation. National Enforcement Authorities are typically different from their Member State Competent Authority/Authorities. For REACH each EU MS has already designated the authority to deal with REACH enforcement.
Only Representative	A natural or legal person established outside the Community [EU] who manufactures a substance on its own, in mixtures or in articles, formulates a mixture or produces an article that is imported into the Community [EU] may by mutual agreement appoint a natural or legal person established in the Community [EU] to fulfil, as his only representative, the obligations on importers under this Title [Title II: Registration of substances]. The representative shall also comply with all other obligations of importers under this Regulation. (REACH Article 8(1) and (2)1)
Placing on the market	Supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market (REACH Article 3(12))
Producer of an article	Any natural or legal person who makes or assembles an article within the Community [EU] (REACH Article 3(4))
REACH Committee	Committee established under REACH Article 133 (Joint responsibility of DG GROW and DG ENV)
Regulations	The term "regulations" as uses in this report may refer both to "Regulations" (such as BPR, CLP, ODS, POP and REACH) and "Directives" (such as RoHS and WEEE) as distinct pieces of EU legislation in terms of EU law. *Regulations* as defined in Article 288 of the Lisbon Treaty are of general application, binding in their entirety and directly applicable in all Member States. *Directives* are binding, as to the result to be achieved, upon any or all of the Member States to whom they are addressed, but leave to the national authorities the choice of form and methods.
Research & development (R&D)	Directive 2009/81/EC (Defence and Security Procurement Directive), Article 1, par 27: *Research and development means all activities comprising fundamental research, applied research and experimental development, where the latter may include the realisation of technological demonstrators, i.e., devices that demonstrate the performance of a new concept or a new technology in a relevant or representative environment;* Research and Development includes Research and Technology Development (R&T or RTD).
SME	Small and medium-sized enterprises as defined in the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

Substance of Very High Concern (SVHC)	Substances with certain dangerous properties, which may be included in Annex XIV of REACH (see REACH Article 57)
Sunset date	The date from which placing on the market and use of the substance shall be prohibited, unless an authorisation is granted; this date is specified in Annex XIV
Supplier of an article	Any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market (REACH Article 3(33)
Use	Any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation (REACH Article 3(24))

Q. GLOSSARY OF TERMS

Table 28 List of acronyms

A&D	Aerospace & Defence
AC326	NATO Ammunition Safety Group
ACWS	Antifouling Coatings for War Ships
ADCA	Azodicarbonamide
ADR	International Carriage of Dangerous Goods by Road
AEP	Allied Engineering Publications
AF	Armed Forces
AfA	Application for Authorisation
AFV	Armoured Fighting Vehicles
AIA	US Aerospace Industries Association
AIAD	Italian Industries Federation for Aerospace, Defence and Security
Al-RCF	Aluminosilicate Refractory Ceramic Fibres
AoA	Analysis of Alternatives
AOP	Allied Ordnance Publications
Art.	Article
ASD	Aerospace and Defence Industries Association of Europe
ASD RIWG	ASD REACH Implementation Working Group
AT	Austria
ATP	Adaptation to Technical Progress
AVT	Applied Vehicle Technologies
BAuA	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin
BBP	Butyl benzyl phthalate
BDI	German Federation of Industries
BDSV	Bundesvereinigung Deutscher Stahlrecycling- und Entsorgungsunternehmen

BE	Belgium
BeST	Beryllium Science and Technology Association
BG	Bulgaria
BoA	Board of Appeal
bOEL	binding Occupational Exposure Limit
BPA	Bisphenol A
BPR	Biocidal Products Regulation (Regulation (EC) No 528/2012)
B2B	Business to Business
CA	Competent Authority
CAA	Chromic Acid Anodising
CAD	Chemical Agents Directive (Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work)
CapTech	Capability Technology Group(s) at the EDA
CARACAL	Competent Authorities for REACH and CLP
Carc.	Carcinogenicity (according to CLP)
CAS	Chemical Abstracts Service
CBI	Confidential Business Information
$CBrF_3$	Bromotrifluoromethane
$C_2Br_2F_4$	Dibromotetrafluoroethane
$CBrClF_2$	Bromochlorodifluoromethane
CCC	Chromate conversion coating
CCNS	Corrosion Control on Navy Ships
CCST	Chromium VI Compounds for Surface Treatment (REACH Authorisation Consortium)
Cd	Cadmium
CDI	Cobalt Development Institute
CFC	Chlorofluorocarbon

CIDEF	Conseil des Industries de Défense Françaises
CII	Cross-Industry Initiative
CJEU	Court of Justice of the European Union
C&L	Classification and Labelling of substances and mixtures
CLH	Harmonised Classification and Labelling according to CLP
CLP	Classification, Labelling and Packaging according to Regulation (EC) No 1272/2008
CMD	Carcinogens or Mutagens Directive (Directive 2004/37/EC)
CMR	Carcinogenic, Mutagenic, toxic to Reproduction
CNAD	Conference of NATO Armament Directors
Co	Cobalt
CoC	EDA Code of Conduct on REACH Defence Exemptions (March 2015)
CoRAP	Community Rolling Action Plan
CoRC	Cobalt REACH Consortium Ltd
CrO_3	Chromium trioxide
CSDP	Common Security and Defence Policy
CSR	Chemical Safety Report
CRM	Critical Raw Material
Cr(VI)	Hexavalent Chromium
CS gas	2-chlorobenzalmalononitrile
CSES	Centre for Strategy and Evaluation services L.p.p.
CSM	Centro Sviluppo Materiali
CSMU	Crash-Survivable Memory Unit
CTAC	Chromium Trioxide Authorisation Consortium
CTACSub	Chromium Trioxide Authorisation Submission Consortium
Cu	Copper
CY	Cyprus

CZ	Czech Republic
CZT	Cadmium zinc telluride
D	Deliverable
DARPA	Defense Advanced Research Projects Agency
DBP	Dibutyl phthalate
DE	Germany
DecaBDE	Bis(pentabromophenyl) ether (decabromodiphenyl ether)
DefCon	Defence readiness Condition
DEHP	bis(2-ethylhexyl)phthalate
DE&S	Defence Equipment and Support
DGA	Direction Générale de l'Armement
DGAM	National Armament Directorate
DG EMPL	Directorate-General for Employment
DG ENV	Directorate-General for the Environment
DG GROW	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
DIPB	1,4-DIISOPROPYLBENZENE
DK	Denmark
DNEL	Derived No-Effect Level
DNT	Dinitrotoluene
DSCA	Defense Security Cooperation Agency (http://www.dsca.mil)
DTIB	Defence Technological and Industrial Base
DU	Downstream User
EADS	European Aeronautic Defence and Space Company
EASA	European Aviation Safety Agency
EATC	European Air Transport Command
EC	European Commission

ECFIA	European Ceramic Fibre Industry Association
ECHA	European Chemicals Agency
ECJ	European Court of Justice
ECOCOAT	Environmentally Compliant Coating in Aeronautic
ED	Endocrine Disruptor
EDA	European Defence Agency
EDEM	European Defence Equipment Market
EDIA	European Defence Industry Association (i.e. ASD)
EDRP	European Defence Research Programme
EDTIB	European Defence Technological and Industrial Base
EE	Estonia
EEA	European Economic Area
EEE	Electrical and Electronic Equipment (ROHS)
EFTA	European Free Trade Association
EHS or EH&S	Environment, Health and Safety
EHSM	Environment, Health, and Safety Management
EL	Greece
EPIC	Electric Propulsion project of Horizon 2020
EPMF	European Precious Metals Federation
ERB	Expositions-Risiko-Beziehung
ERDF	European Regional Development Fund
ERM	Environmental Release Measures
ERP	Enterprise Resource Planning
eSDS	extended Safety Data Sheet
ES	Spain
ESA	European Space Agency

ESIF	European Structural and Investment Funds
ETS	Environmental Tobacco Smoke
EU	European Union
EUROBAT	Association representing all battery technologies in Europe
F4P	Fit for Purpose
F-GAS	Fluorinated greenhouse gases (Regulation (EU) No 517/2014)
FI	Finland
FiCS	Fuels in Closed System
FMS	Foreign Military Sales
FMV	Swedish Defence Materiel Administration
Fn	Footnote
FOI	Swedish Defence Research Agency
FR	France
GaAs	Gallium arsenide
GADSL	Global Automotive Declarable Substance List
GHS	Globally Harmonised System
GIFAS	Groupement des industries françaises aéronautiques et spatiales
GMES	Global Monitoring for Environment and Security
GRAIL	Green advanced High Energy Propellants for Launchers
GRASP	Green Advanced Space Propulsion
Hazmat	Hazardous Materials
HCFC	Hydrochlorofluorocarbon
HDI	Hexamethylene diisocyanate
HFC	Hydrofluorocarbon
HFO	Hydrofluoroolefin
HR	Croatia

HSE	Health and Safety Executive
HU	Hungary
IAEG	International Aerospace Environmental Group
ICAO	International Civil Aviation Organization
IE	Ireland
ILA	International Lead Association
IMAT	Innovative Semiconductor Materials
IMDG	International Maritime Dangerous Goods
INEA	Innovation and Networks Executive Agency
InSb	Indium antimonide
IOM	Institute of Occupational Medicine
IPC	Association Connecting Electronics Industries
IPDI	Isophorone diisocyanate
IPR	Intellectual Property Rights
IT	Italy or Information Technology
ITAR	The International Traffic in Arms Regulations
LEV	Local Exhaust Ventilation
LoI	Letter of Intent Framework Agreement Treaty of 27 July 2000 between France, Germany, Italy, Spain, Sweden and UK
LoR	Letter of Request
LT	Lithuania
LU	Luxemburg
LV	Latvia
KemI	Swedish Chemicals Agency
MCT	Medium-chain triglyceride
MDA	4,4'-Diaminodiphenylmethane
MDI	Methylene Diphenyl Diisocyanate

MMH	Monomethylhydrazine
M&P	Materials and Processes
MoD	Ministry of Defence
MoEnv	Ministry of Environment
MRO	Maintenance, Repair and Overhaul
MS	Member State
MSCA	Member State Competent Authority
MT	Malta
NATO	North Atlantic Treaty Organization
NAS	National Aerospace Standards
NDI	Naphthalene diisocyanate
NDIA	National Defence Industry Association
NEA	National Enforcement Authority
Ni	Nickel
NL	Netherlands
NMP	1-methyl-2-pyrrolidone
NO	Norway
NOx	Nitrogen oxides
NSO	NATO Standardisation Office (http://nso.nato.int/nso)
NSPA	NATO Support and Procurement Agency
OCCAR	Organisation Conjointe de Coopération en matière d'ARmement
ODS	Ozone Depleting Substances (Regulation (EC) No 1005/2009)
OECD	Organisation for Economic Cooperation and Development
OEL	Occupational Exposure Limit
OEM	Original Equipment Manufacturer
OMP6	OCCAR Management Procedure 6

ONERA	Office National d'Etudes et de Recherches Aérospatiales
O5A	“Once an article, always an article”
OSH	Occupational Safety and Health
OSHA	Occupational Safety and Health Administration (US)
OR	Only Representative (REACH Article 8)
PACT	Public Activities Coordination Tool (maintained by ECHA)
Pb	Lead
PBHT	Hydroxyl-terminated polybutadiene
PBT	Persistent, bioaccumulative and toxic
PCB	Polychlorinated biphenyl
PEG	Partner Expert Group
PETCO	Petroleum and Coal stream substances
PFC	Perfluorinated Compound
PFOA	Perfluorooctanoic acid
PL	Poland
PLM	Product lifecycle management
pMS	participating Member State
PoC	Point of Contact
POP	Persistent Organic Pollutants (Regulation (EC) No 850/2004)
PPORD	Product and Process Orientated Research and Development
PT	Portugal
PULCHER	Pulsed Chemical Rocket with Green High Performance Propellants
PZT	Lead titanium zirconium oxide
RO	Romania
Q&A	Questions & Answers
QSEP	Quality, safety and environmental protection

RAC	Risk Assessment Committee
RAND	RAND Corporation
RCF	Refractory Ceramic Fibres
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals according to Regulation (EC) No 1907/2006
REFIT	Regulatory Fitness and Performance Programme
Repr.	Reproductive toxicity (according to CLP)
RETF	Restriction Efficiency Task Force
RHEFORM	Replacement of hydrazine for orbital and launcher propulsion systems
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
RMM	Risk Management Measure
RMO	Risk Management Option
RMOA	Risk Management Option Analysis
RO	Romania
RoHS	Restriction of the use of certain Hazardous Substances in electrical and electronic equipment (Directive 2011/65/EU)
R&D	Research and Development
R&T(D)	Research and Technology (Development)
RTG	Research Technology Group
SAF	Swedish Armed Forces
SCL	Specific Concentration Limit
SCOEL	Scientific Committee on Occupational Exposure Limits
SDGINREID	Subdirectorate of Inspection, Regulation and Industrial Strategy of Defence
SDS	Safety Data Sheet
SE	Sweden
SEA	Socio-Economic Analysis
SEAC	Socio-Economic Analysis Committee

SESAR	Single European Sky ATM Research
SI	Slovenia
SIEF	Substance Information Exchange Forum
SIN	Substitute It Now
SK	Slovakia
SME	(Micro,) Small and Medium-sized Enterprise
sMS	subscribing Member State
SnPb	Tin-lead
SoS	Security of Supply
SofS	Secretary of State
$SrCrO_4$	Strontium Chromate
SRD or SR&D	Scientific Research & Development (REACH Article 3(23))
STANAG	NATO Standardisation Agreements
STF	Space Chromate Task Force
STOT	specific target organ toxicity
SVHC	Substance of Very High Concern (REACH Article 57)
SWD	Staff Working Document
S&T	Science and Technology
TBT	Tributyltin
TDI	Toluene diisocyanate
TF	Task Force
Ti	Titanium
TRL	Technology Readiness Level
TSCA	Toxic Substances Control Act (US)
UDMH	Unsymmetrical dimethylhydrazine
UER	special Unit of REACH exemption

UK	United Kingdom
UN	United Nations
UN RTDG	UN Recommendations on the Transport of Dangerous Goods
US(A)	Unites States (of America)
UVCB	Substances of Unknown or Variable composition
VDA	German Automotive Association
VECCO	Verein zur Wahrung von Einsatz und Nutzung von Chromtrioxid und anderen Chrom-VI-verbindungen in der Oberflächentechnik eV
VOC	Volatile Organic Compounds
vPvB	Very persistent and very bioaccumulative
VTT	Technical Research Centre of Finland
WEEE	Waste Electrical and Electronic Equipment (Directive 2012/19/EU)
WG	Working Group
WP	Work Package
WPC	Working Party on Chemicals
Zn	Zinc
Zr-RCF	Zirconia Aluminosilicate Refractory Ceramic Fibres

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