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REACHLaw webinar | 7 June 2017

REACH & CLP Impact on the Defence Sector

Results of the Study for the European Defence Agency

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Presenter

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REACH & CLP Impact on the Defence Sector
Registered Participants

- Over 200 participants, mainly from the Defence Industry
- A number of non-study participants (e.g. from the chemicals industry), in addition to stakeholders consulted
- EU (15 countries): Belgium, Czech Republic, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Luxembourg, Netherlands, Poland, Portugal, Spain, Sweden, UK
- Non-EU (13 countries): Australia, China, Hong Kong, India, Israel, Japan, Korea (South), Mexico, Saudi Arabia, Singapore, South Africa, Switzerland, US

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   - Questions you claim as confidential questions (*"this is CBI"*) may be answered after the webinar by e-mail.
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3. The presentation material will be available for download amongst the webinar participants. A link will be sent.
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Providing Chemical Regulatory Compliance

- REACH ONLY REPRESENTATIVE SERVICES
- 2018 REACH REGISTRATIONS
- REACH AUTHORISATION
- SDS/ESDS PREPARATION
- GLOBAL NOTIFICATIONS
- OUT-TASKING

Note to the Reader

This presentation is based on the Final Report of 16 December 2016 which has been published by the EDA on 26 January 2017:
https://www.eda.europa.eu/docs/default-source/documents/eda-reach-study-final-report-2016-december-16-p.pdf

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 REACHLaw, unless stakeholder opinions are explicitly quoted.

Defence Industry and REACH
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Introductions

About the European Defence Agency (EDA)

- An intergovernmental agency of the Council of the EU; established 2004, based in Brussels, 140 staff, budget of some 30 million €
- 27 Member States (MoDs): all EU members except Denmark
  - Administrative Arrangements with Norway, Serbia, Switzerland and Ukraine
- Mission: *to support the Council and the Member States in their effort to improve the European Union's defence capabilities for the Common Security and Defence Policy* (Treaty of Lisbon)
  - EDA's aim is to foster defence cooperation among European Member States
- Dialogue with defence and industrial stakeholders (ASD, NDIAs, Regional clusters, Large and SMEs, Think Tanks)
- Key measures in support of the *European Defence Technological and Industrial Base (EDTIB)* include developing tools regarding EU regulation → EDA facilitator role on REACH defence-related issues
- Further information: www.eda.europa.eu

Introductions
The EDA's Facilitator Role for REACH Support

See EDA REACH Project webpage:
http://eda.europa.eu/what-we-do/activities/activities-search/reach

- **Defence exemption: Harmonisation of national procedures**
  - EDA Code of Conduct on REACH Defence Exemptions (adopted 2015)
  - EDA REACH Portal: https://reach.eda.europa.eu
- **Ammunition Classification under REACH** (in progress)
- **EDA study on REACH and CLP impact to Defence sector** (concluded December 2016)
- **EDA's Capability Technology Groups (CapTechs):** REACH is increasingly taken into account in the R&T related activities (e.g. ECOCOAT, CCNS)

Prioritised **EDA REACH Roadmap**
- With Member States, in close cooperation with the EC, ECHA and industry
- To facilitate common coordinated action

Introductions
The EDA REACH Task Force

- Working group comprised by a number of EDA participating Member States (MoDs) REACH experts supporting EDA on specific REACH related issues of joint interest, at the technical level.
- A European Commission (DG GROW) representative is also attending on a regular basis

- The task force closely supported the EDA REACH study
  - Comments on draft study questionnaires and report
  - Study consultation input (on behalf of the experts' MoDs)
  - Monthly face-to-face progress meetings at the EDA in Brussels

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Study Background, Objectives and Methodology

Study Background

Creating a competitive European Defence Equipment Market (EDEM) and strengthening the European Defence Technological and Industrial Base (EDTIB) in view of sustaining existing and/or developing new defence capabilities for the benefit of EU MoDs is one of the main tasks ascribed to the EDA.

REACH and CLP 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 EDTIB. EU 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.

Further to REACH and CLP, other European Regulations on chemicals - such as BPR, ODS, POP – may also have an impact on European defence capabilities.

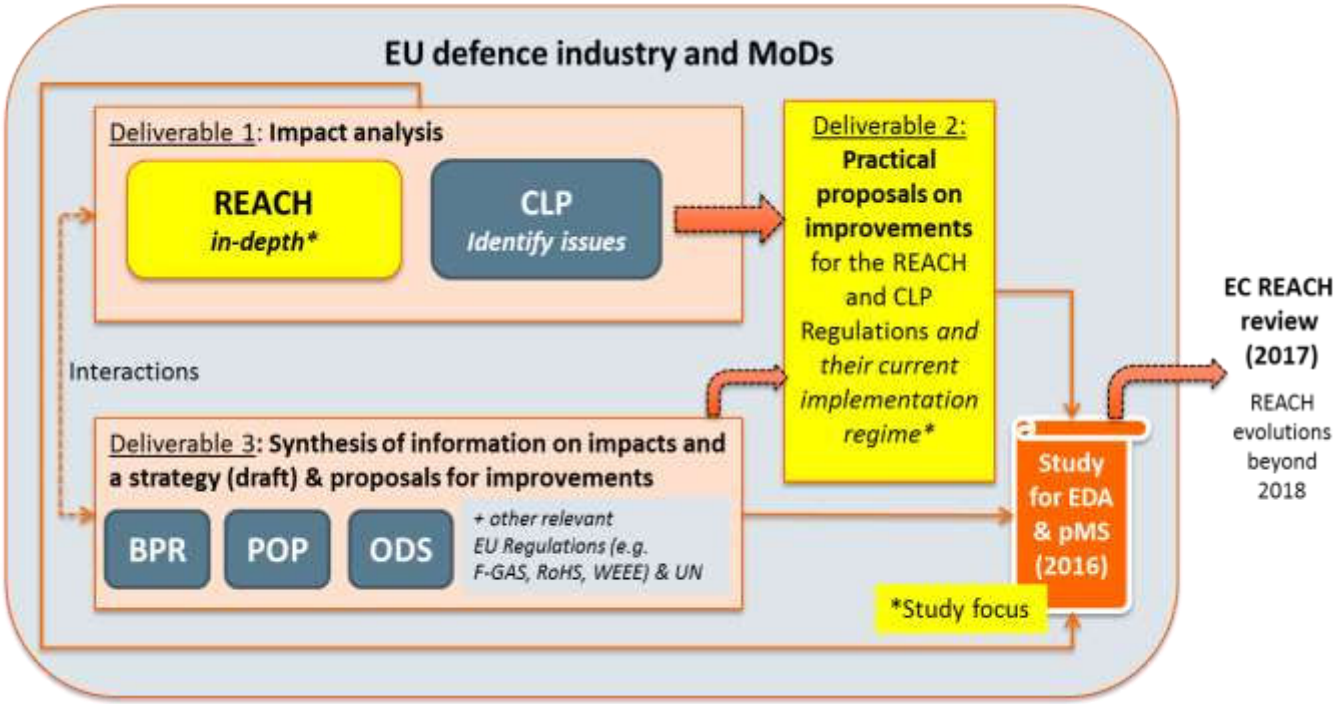
Study Background, Objectives and Methodology

Study Objectives

Through the study, EDA intended to serve two principles:

a) a high level of health and environmental protection **and**

b) operational effectiveness of Member States' Armed Forces, including through enhancing the competitiveness and innovation of the European Defence Technological and Industrial Base (EDTIB)



Study Background, Objectives and Methodology
The 2nd EC REACH Review 2017: Overview

A LEGAL REQUIREMENT

REACH Art. 117(4): *"**Every five years**, the Commission shall publish a **general report on: (a) the experience acquired with the operation of this Regulation**, […]"*

EDA Study

EVIDENCE GATHERING

- Reports from ECHA and EU Member States
- 17 thematic studies
- Stakeholder consultation (closed 28.01.2017)

METHODOLOGY

- Builds on the first REACH Review (2013)
- Carried out in the frame of **"REFIT"**: Regulatory Fitness and Performance Programme of the EC, evaluating Effectiveness, Efficiency, Relevance, Coherence and EU Added Value
- Parallel fitness check on the most relevant non-REACH chemicals legislation

INPUT FOR

Evidence base for **chemicals stock-taking report** mentioned in the 2014 REFIT communication, and, more generally, for developing by 2018 the **non-toxic environment strategy** as required by the 7th Environment Action Programme.

Study Background, Objectives and Methodology
Study Consultation

Stakeholders involved in consultation:

- EU MoDs: 13[*1]
- European Commission: DG GROW + DG ENV
- European Chemicals Agency (ECHA)
- EU MS REACH Competent Authorities: 17
- Industry (incl. Defence): 66 (incl. associations)
- Others: 3 (NATO, trade union)

[*1] representing 90.5% of EU MoDs expenditure *[EDA 2014 Defence Data] and* 91.3% of the EU defence industry annual turnover *[EDA 2015 Defence Industry Data]*.

Means:

- Targeted questionnaires
- Interviews

Duration:

7 months
(May – Dec 2016)

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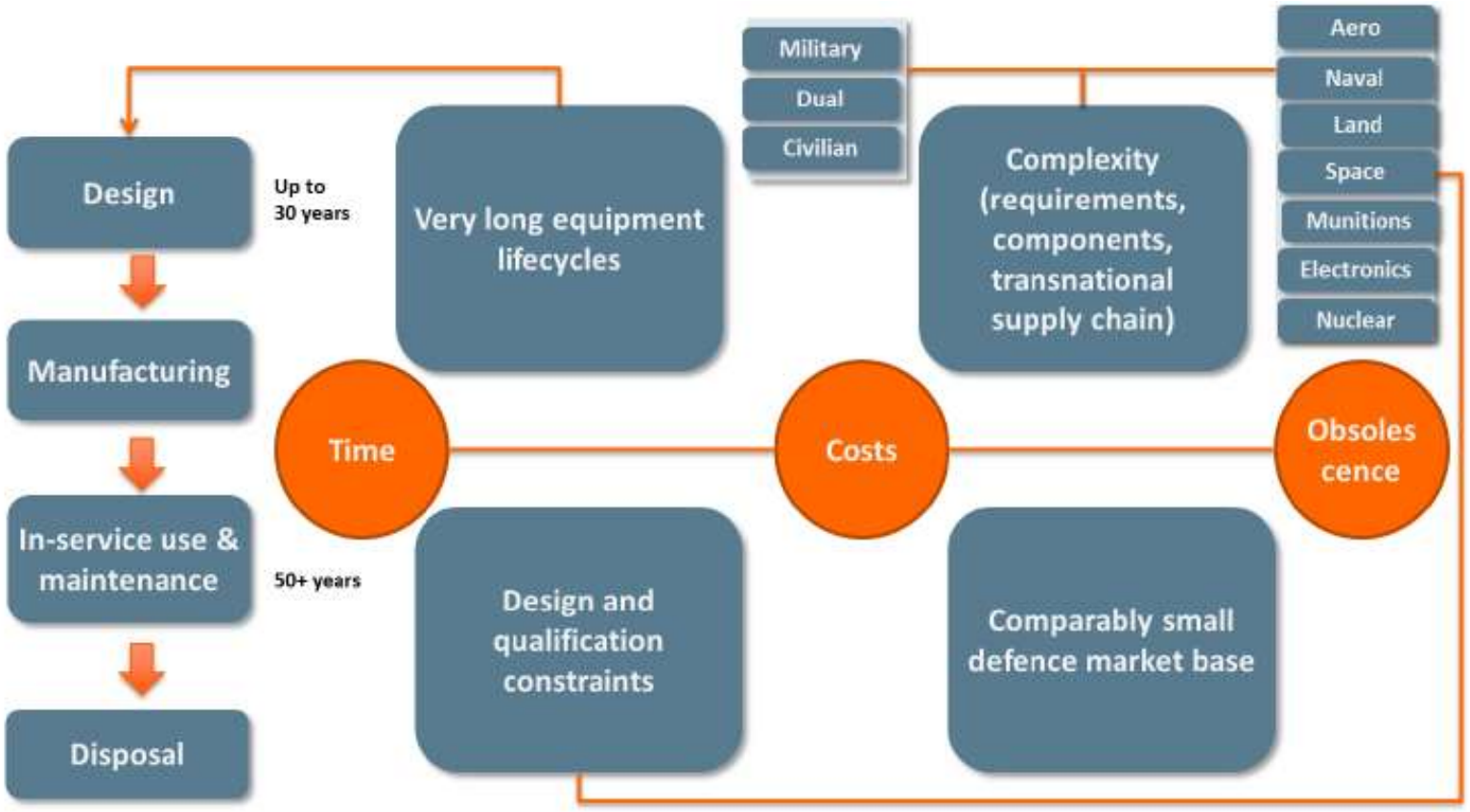
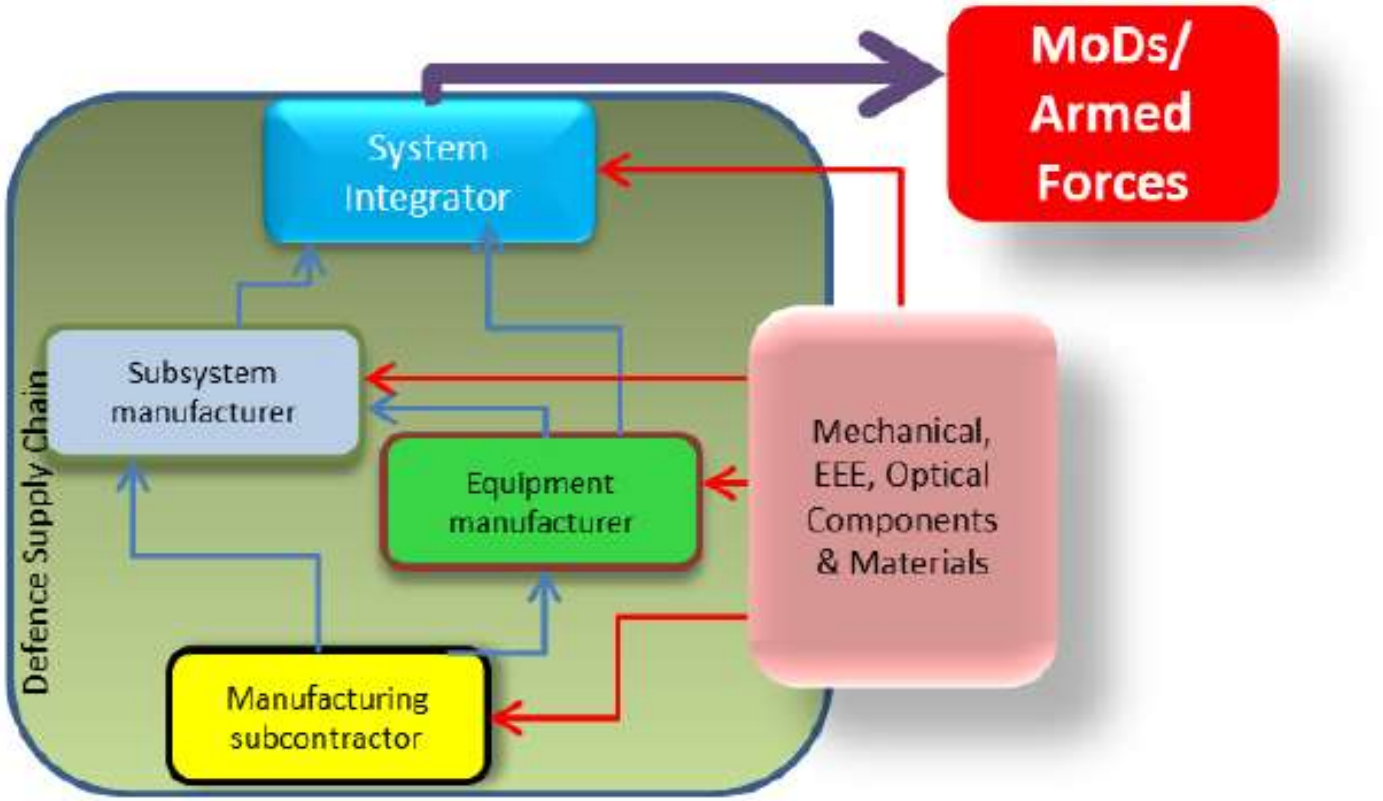
Findings of the Impact Assessment
Impact-Determining Specificities of Defence

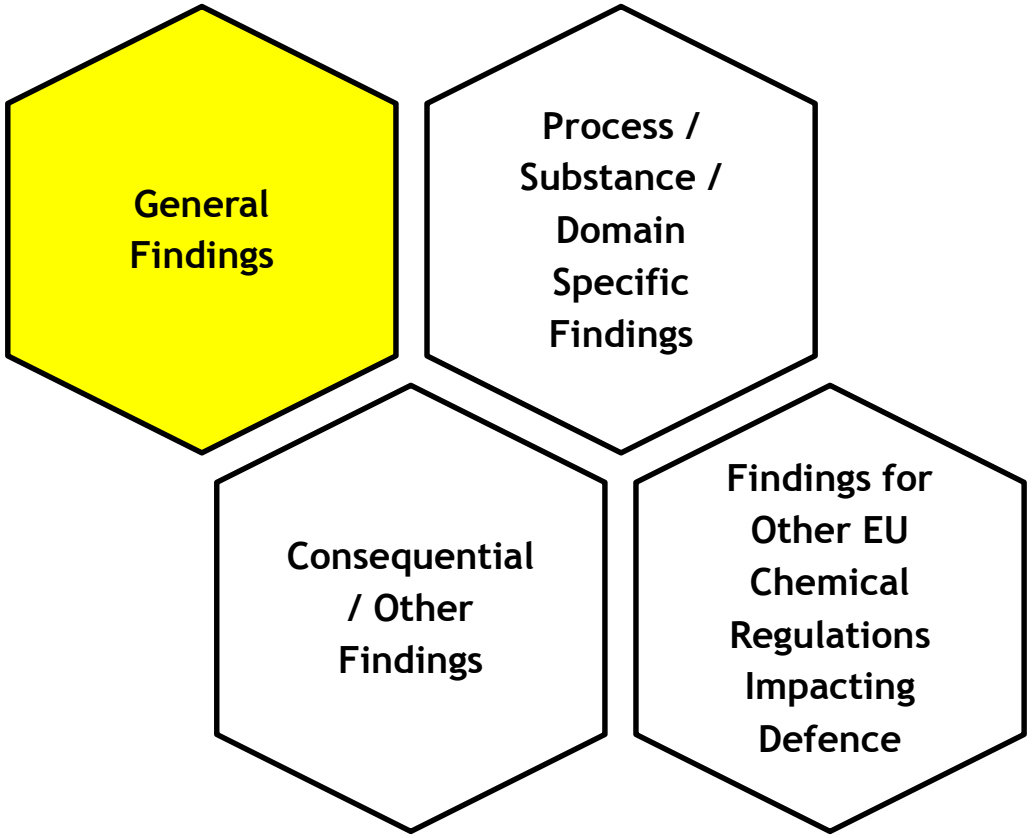


Findings of the Impact Assessment
Impact-Determining Specificities of Defence

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



Findings of the Impact Assessment
Categories of Findings



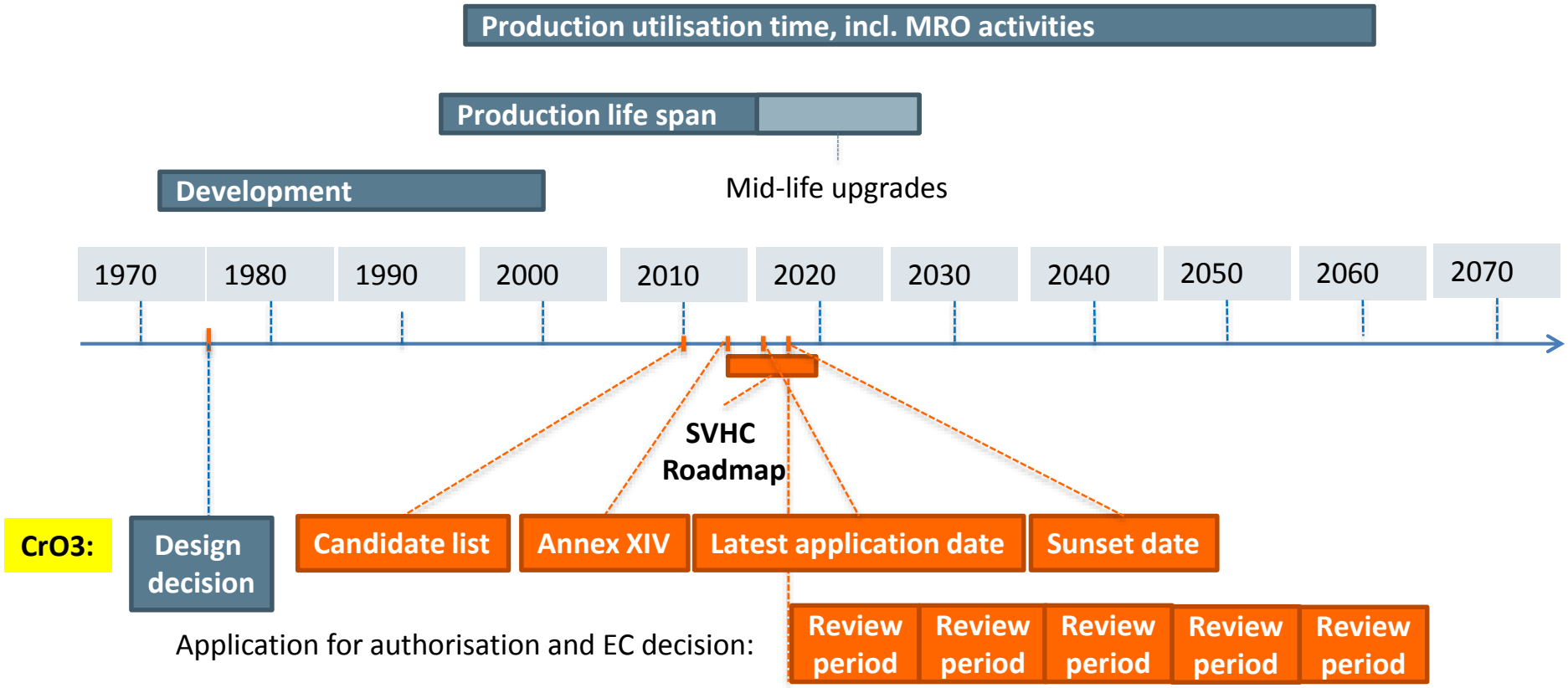
Findings of the Impact Assessment
General Findings

- REACH authorisation **timelines are strongly mismatched** to the defence sector (yrs vs decades).
- **Insufficient R&D funding** for the substitution of SVHC.
- REACH obsolescence causes **risks to Security of Supply**.
- **Unpredictability** of REACH SVHC regulation (risks of regrettable substitutions).
- Possible **EU policy conflicts** with regard to SVHC regulation (CRM, H&S, Circular Economy).
- **Legal uncertainty** whether MoDs / Armed Forces are addresses of REACH.

General Findings on REACH/CLP

Strong Mismatch of Timelines: Decades vs. Years

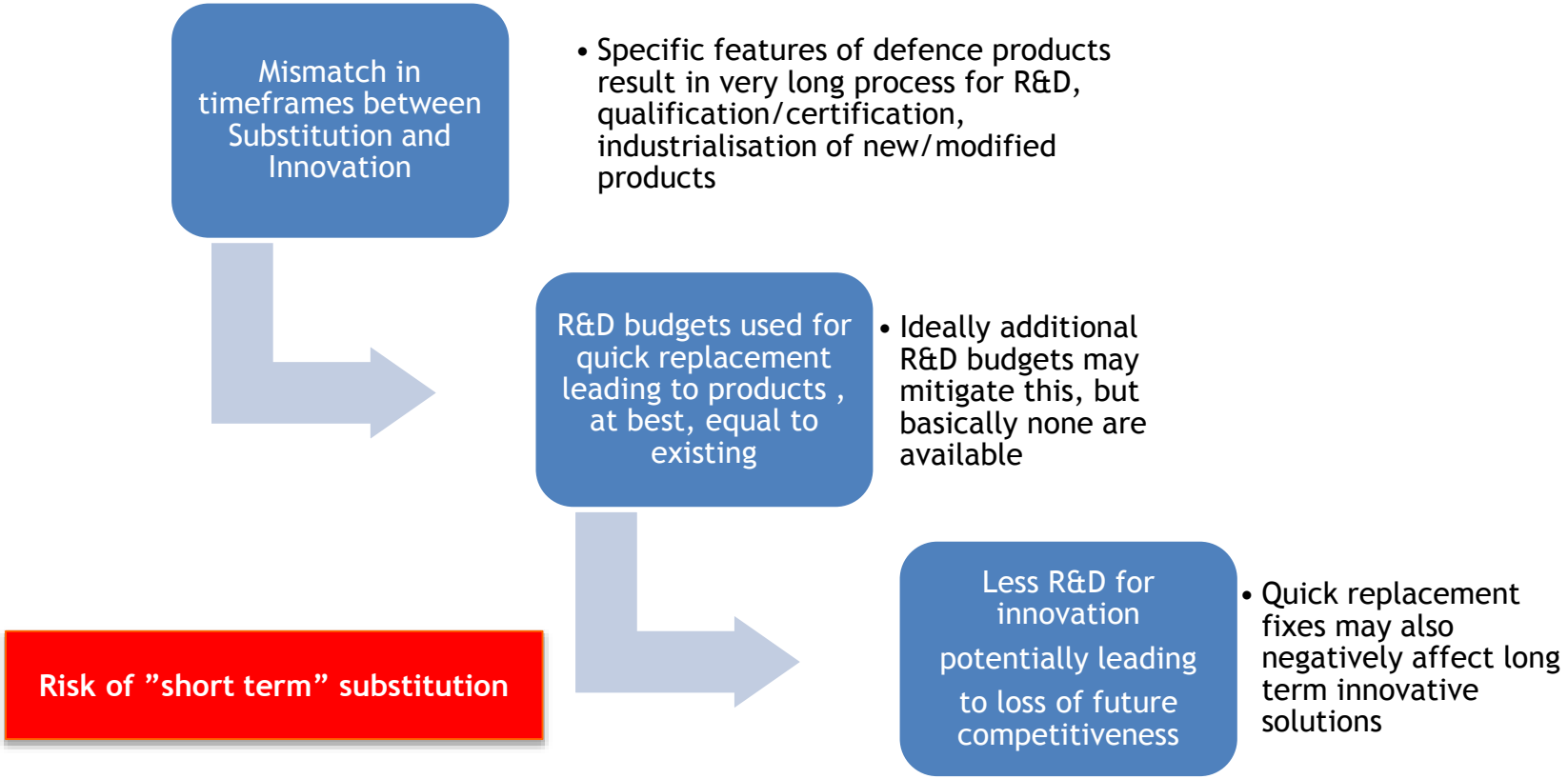
- A typical defence product lifecycle vs. REACH authorisation timelines:



General Findings on REACH/CLP

Strong Mismatch of Timelines: Consequences

Where possible, industry wants to avoid the double effort of authorisation and replacement:



General Findings on REACH/CLP
Insufficient R&D Funding for SVHC Substitution

- Clear REACH-induced increase of SVHC substitution R&D activities:
  - Confirmed by 78.6% of the defence industry for their organisation or supply chain
  - About half of MoDs (45.5%) are performing, financing or promoting R&D activities for SVHC substitution, including through the EDA CapTechs and NATO.

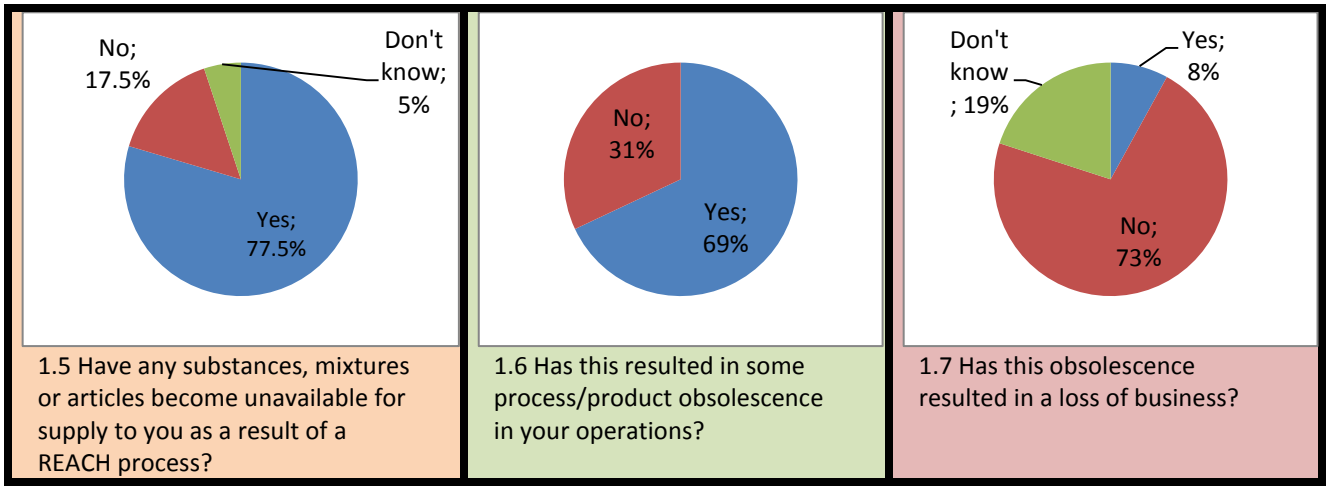
- However, the budgets of both defence industry and MoDs have not increased
  - The R&D for substitution is performed to the detriment of other R&D activities.
  - There is insufficient R&D funding for substitution at all levels: industry, Member States and EU. R&D policy makers at national (Member State, defence industry) or EU level often consider REACH related substitution as a regulatory cost issue and not as innovative R&D.

- There is a strong willingness, both within industry and MoDs, to perform the substitution R&D in a collaborative approach, at least at low Technology Readiness Levels.

General Findings on REACH/CLP

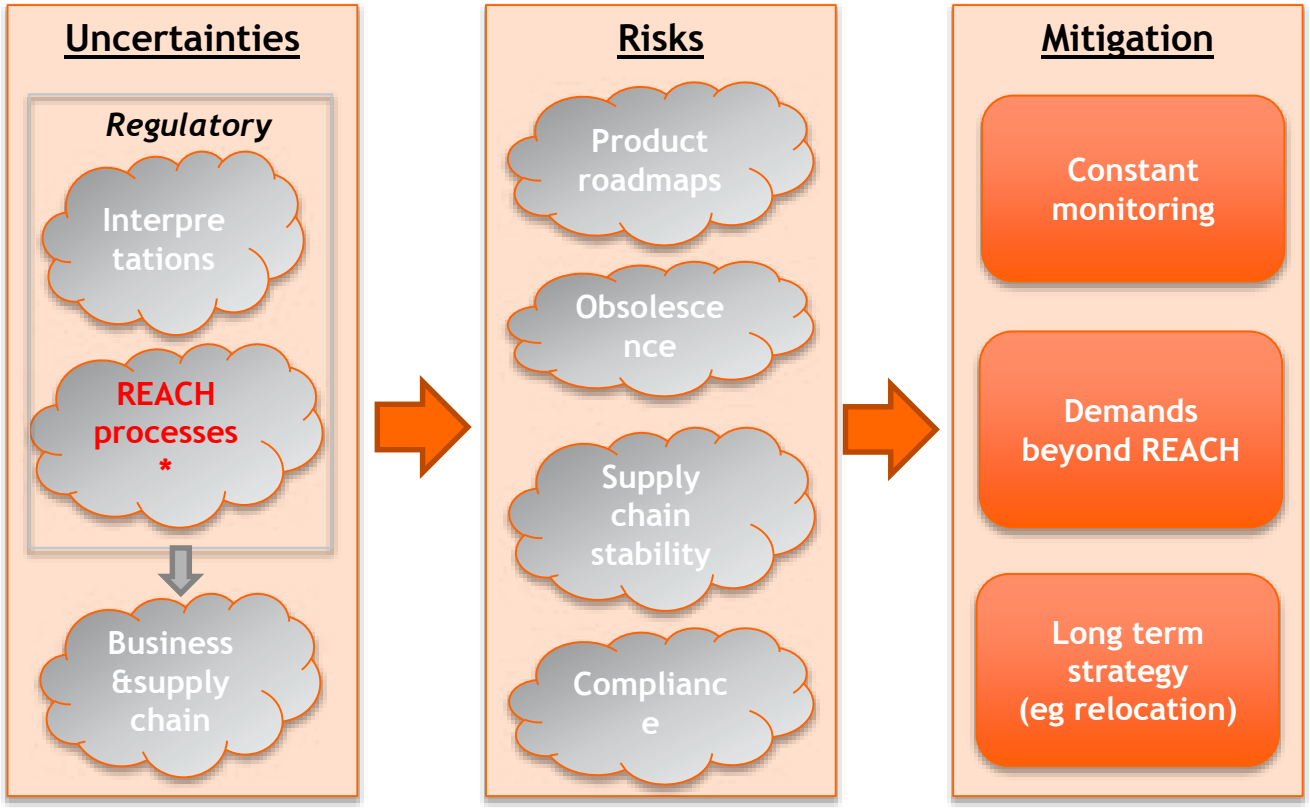
Obsolescence causes Risks to Security of Supply (SoS)

- A major REACH-related concern for industry and MoDs due to lack of control, limited visibility and accumulation of obsolescence impact at the end user level
- Defence industry survey results:



- The majority of MoDs believe that REACH is a challenge to maintain SoS, with obsolescence seen as the main REACH related challenge to SoS. MoDs have reported occurrences of shrinking supplier base, monopoly situations or complete cessation of production by single source suppliers due to costly REACH compliance requirements.

General Findings on REACH/CLP
Unpredictability



*In particular: Unpredictability surrounding the regulatory fate of SVHCs: whether, when and in which process(es) they will be further regulated under REACH

Risk of "regrettable" substitution

General Findings on REACH/CLP I Possible EU Policy Conflicts with regard to SVHC Regulation

- Possible conflicts between SVHC Regulation under REACH and other EU Laws and Policies have been determined for:

EC's Critical Raw Materials Policy

- **Defence applications rely on the use of various substances linked to a number of CRMs from the current 2014 list (e.g. beryllium, borates, cobalt)**
- **REACH authorisation process could be an additional hurdle to supply**

EU Workplace Legislation

- Directives 98/24/EC and 2004/37/EC also oblige to substitution with safer alternatives
- A number of EU-wide binding Occupational Exposure Limits is being proposed (e.g. for beryllium, Cr(VI), hydrazine, RCF)
- Interface with Authorisation unclear

EC Circular Economy Package

- Aims to minimise waste through long product life and recycling/reuse
- REACH Article 33 and authorisation are potential hurdles for the circular economy idea, especially for products with long lifecycles

General Findings on REACH/CLP I Legal uncertainty Are MoDs/Armed Forces Addressees of REACH? (1/2)

- Consulted MoDs (or their subordinate agencies) procure defence materiel for use by their Armed Forces: especially complex articles, as well as substances (often mixtures) for the continued maintenance; also from non-EU sources.

- It is not clear today whether government bodies/MoDs/Armed Forces may themselves be addressees of REACH according to the definitions of REACH Art. 3 (e.g. as “Importers”, “Downstream users”).

  - Based on their legal analysis the representatives of the DE MoD 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 REACH Article 3).

    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 obligations may apply.

General findings on REACH/CLP I Legal uncertainty
Are MoDs/Armed Forces Addressees of REACH? (2/2)

- The 11 other MoDs consulted on the question (BE, EL, ES, FI, FR, IT, NL, NO, PT, SE, UK) consider that they/their Armed Forces *may* be REACH addressees
  - Some MoDs have made submissions to ECHA (e.g. pre-registration as "Importer").
  - In one case defence exemptions have already been granted to the benefit of national Armed Forces, as REACH "Importer".

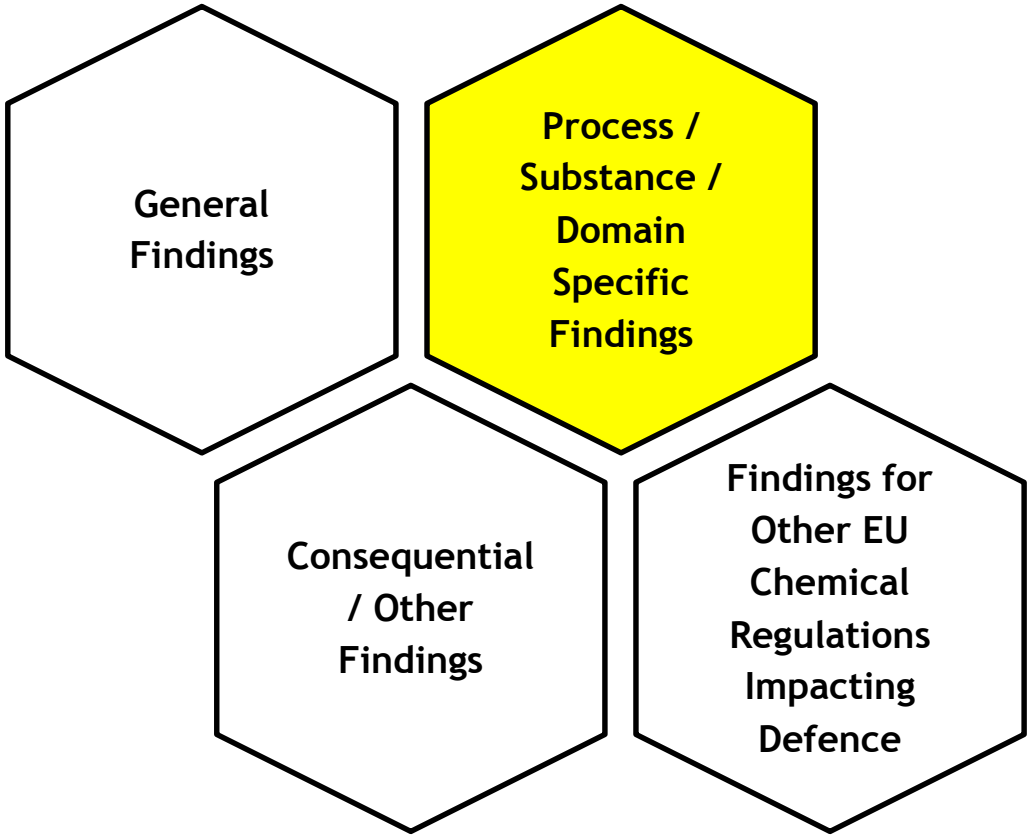
REASONS FOR DIFFERENCES IN MoD OPINIONS

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.

With a view to the upcoming 2018 registration deadline and 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.**

Findings of the Impact Assessment
Categories of Findings



Findings of the Impact Assessment

Process / Substance / Domain Specific Findings

Substance criticality for defence coupled with **limited substitution of inorganic substances**.

AfA process not fully fit for military purpose.

Challenges for REACH **defence exemption** implementation **across national borders**.

Emerging security issues: unclear relationship with defence - possible regulatory gap.

Major **challenges on duty to communicate information (Art. 33)** on substances in complex defence equipment.

Difficulties to establish **general exemptions** from authorisation.

Cumulative impacts of REACH & CLP on the defence sector (substitution of substances - labelling).

REACH Defence Exemption Implementation

LEGAL TEXT

REACH Article 2

Application

[…]

3. 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.

[…]

Process Specific Findings
REACH Defence Exemption Implementation

NUMBER OF REACH DEFENCE EXEMPTIONS

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

Process Specific Findings
REACH Defence Exemption Implementation

THE EDA CODE OF CONDUCT ON REACH DEFENCE EXEMPTIONS (EDA CoC 2015)*

https://www.eda.europa.eu/docs/default-source/documents/eda-code-of-conduct-on-reach-defence-exemptions.pdf

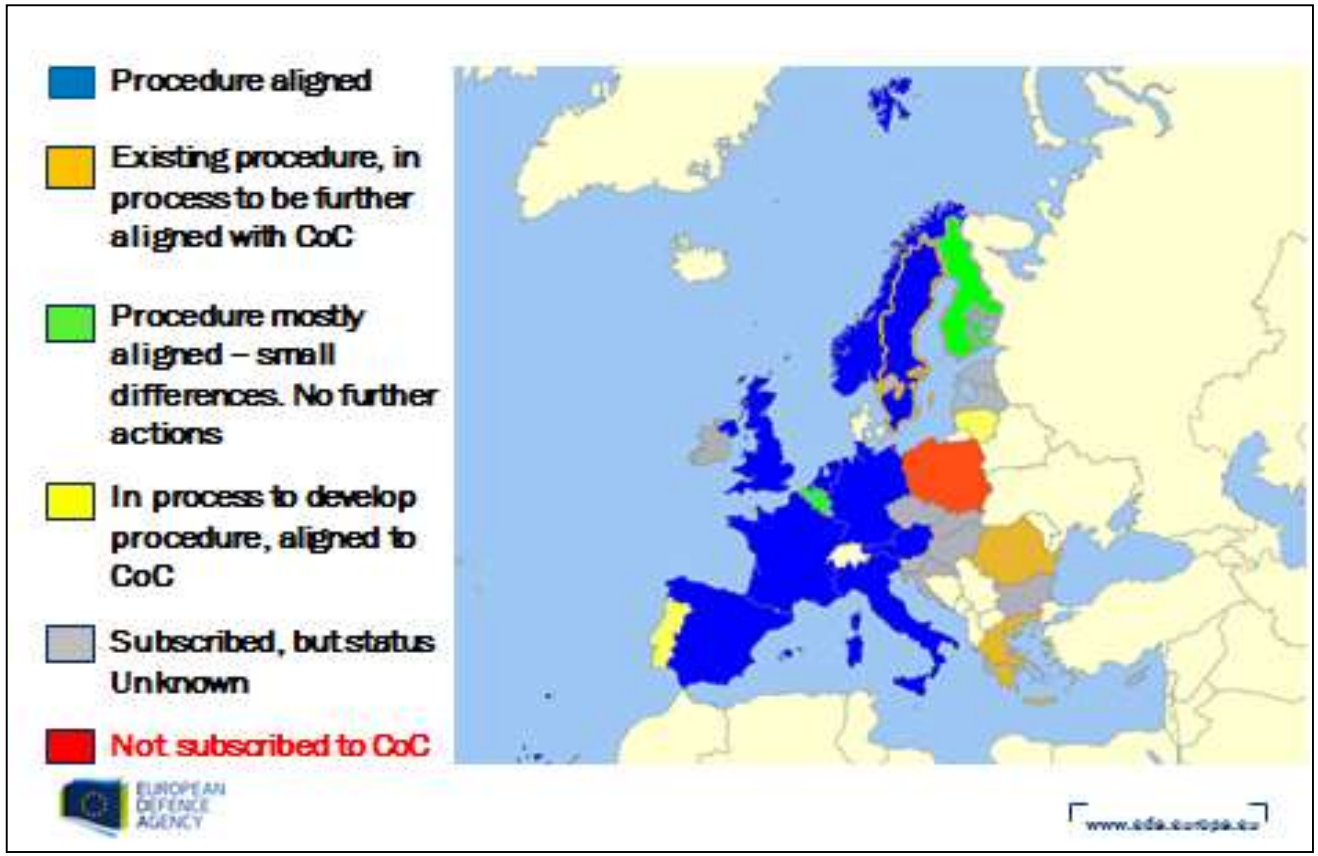
Aim
harmonise the handling of national defence exemptions in the area of REACH at the European level

Participants	Last-resort approach	Annex to the EDA CoC	Not (yet) part
All EDA participating Member States except Poland (analysis ongoing) + Norway	The granting of the defence exemptions should be considered only after the alternative methods have been examined: - complying with REACH and - substitution with more benign alternatives.	*"Framework for Applying for a Defence Exemption from a Requirement of REACH"* Minimum standards for an exemption dossier	- Requirement for reciprocal acknowledgment of defence exemptions, - joint exemption process, - Non-REACH Regulations

**The CoC is voluntary, i.e. legally non-binding, as all EDA intergovernmental instruments*

Process Specific Findings
REACH Defence Exemption Implementation

HARMONISATION OF EXEMPTION PROCEDURES – STATUS (EDA, NOVEMBER 2016)



Process Specific Findings
REACH Defence Exemption Implementation

ISSUE OF TRANSNATIONAL USE

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.

Challenges

According to the interpretation of REACH Article 2(3) by EDA pMS, as 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; the "interests of defence" in REACH Article 2(3) were meant strictly at national level.

No documented process yet to address an exemption jointly

Recent developments

During the study consultation one MoD suggested that the allowance of an exemption is valid for the REACH Regulation and its pan-European area of application, regardless of the interpretation of the "interests of defence".

Some related discussions have started.

Conclusion: Today, cross-border issues related to REACH Article 2(3) are still largely unresolved and/or subject to different MS views, and would benefit from further clarification in the EDA framework.

Process Specific Findings
REACH Defence Exemption Implementation

Question asked in the study survey to MoDs and defence industry:

"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 the defence industry (90%) responding would be in favor of an exclusion of defence from the REACH scope (fully or partly), whatever its form.**

- Further national examination of this finding is recommended (dedicated study proposal)

Substance Specific Findings
Substance Criticality for Defence

Important note: Substances were discussed for illustrative purposes only (no exhaustive list). Their discussion does not imply that they will be targeted for further prioritisation actions at EU level.

Substance / substance group	Air-Naval-Land	Space	Electronics	Nuclear	Munitions	CRM	R&T ongoing*
Phthalates	+				+		YES
Lead chromate (CAS 7758-97-6)	+				+		YES
Trichloroethylene (CAS 79-01-6)	+				+		YES
Cr(VI) compounds	+	+	+		+	Chromium	YES (high)
Cobalt salts	+	+				Cobalt	Not known
ADCA (CAS 123-77-3)					+		Not known
Refractory ceramic fibres	+					Silicon metal	Not known
Boric Acid (CAS 10043-35-3)	+	+		+		Borates	YES (some)
Lead and its compounds	+	+	+		+		YES
Hydrazine (CAS 302-01-2)	+	+		+	+		NO (F-16)
Lead titanium zirconium oxide (CAS 12626-81-2)	+		+	+			YES
Cadmium (CAS 7440-43-9)	+	+	+	+	+		YES (some)
Ammonium perchlorate (CAS 7790-98-9)		+			+		YES
Beryllium (CAS 7440-41-7)	+	+	+	+	+	Beryllium	Not known
Bisphenol A (CAS 80-05-7)	+						Not known
Diisocyanates	+	+	+	+	+		Not known
Gallium Arsenide (CAS 1303-00-0)			+			Gallium	YES
Nickel salts	+	+	+		+		YES (some)
Petroleum substances, e.g. in NATO fuel	+						YES (some)

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

Process Specific Findings

AfA = Application for Authorisation

Military Application for Authorisation Challenges

Based on an analysis of AfAs covering military uses and study consultation

- Vast majority (89%) of AfAs are for inorganic substances (Cr(VI) substances)
- (only) 16% of AfAs with military use potentially covered by the EC's low volume rules (100 kg threshold); lowest tonnage applied for is 10 kg/a*
- Average cost to benefit ratio: 1.77 million : 1 *
- Need to maintain equipment to standard throughout its lifecycle
- Scope for substitution in defence equipment is limited
- "Niche" sector: risk of being "overshadowed" by other – bigger – sectors in upstream AfAs / Non-Air domains → risk of too short review periods
- Shrinking numbers of suppliers. Monopoly situations developing e.g. DBP
- Resulting business uncertainty within the defence industry

→ Need for fit-for-purpose simplified military specific AfA. To consider: "dual use" scenario, need for continued maintenance

*Based on downstream applications covering military uses, either exclusively or in a dual use

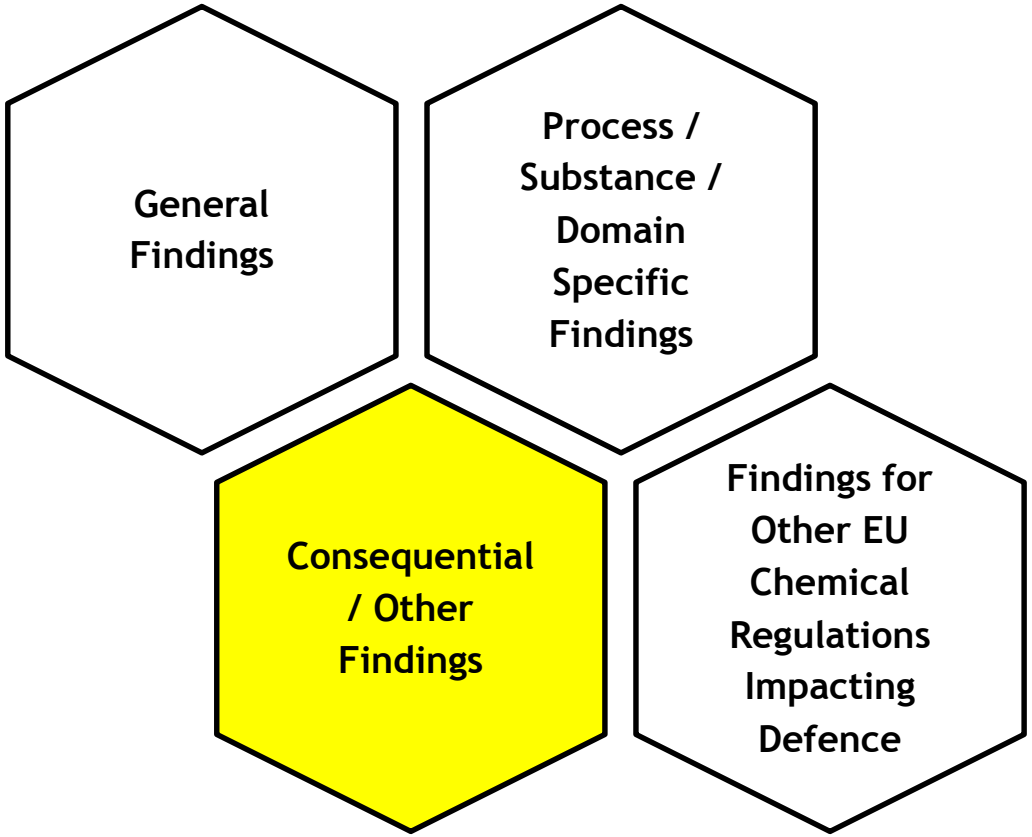
Process Specific Findings
REACH Article 33 Compliance Challenges

- Article 33 Compliance (*Duty to communicate information on substances in articles*) is very difficult & costly for very complex defence products, especially due to:

High number of component articles /suppliers (e.g. jet fighter)	Complex, multi-tier and global supply chains	No aligned reporting standard across all sectors and companies	Lack of info for legacy systems and imports (e.g. due to US/ITAR)	Different interpretations about the level of reporting

- The efforts required to comply are considered by industry as an excessive burden with regard to the added value to safe use of those articles, especially by importers.
- With judgment 10 September 2015 in case C-106/14 the CJEU has ruled that the calculation of the 0.1% threshold in complex articles for the application of 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"*.
  - Industry fears that the situation will further deterioriate as a result of the judgment.
  - ECHA is currently aligning its guidance for substances in articles with the judgment.
  - Different views persist about the level of reporting, especially whether it should normally include the component article where the reportable SVHC is located (view of most MoDs)

Findings of the Impact Assessment
Categories of Findings



Findings of the Impact Assessment
Consequential / Other Findings

- **High or hidden costs** of REACH (shorter maintenance intervals, recertification, price increases from R&D, etc.)
- **Limited HSE benefits** of REACH so far in the defence sector (existing strict procedures, highly skilled personnel, low volumes of SVHC, etc.).
- **Potential loss of competitiveness**
- **Significantly higher future impacts** are anticipated [registration in 2018, Art. 33 compliance, further additions to Annex XIV, Cr(VI) decisions, etc.].
- **Industry relocation risks** to avoid REACH constraints for SVHC in production / manufacturing of articles.

Consequential/Other Findings
High or Hidden Costs of REACH

Costs of REACH may be significant both for the defence industry and MoDs as customer (hence, the tax payer)

DIRECT REACH COMPLIANCE COST

- Article 33 and authorisation applications were often considered as disproportionately high by industry, comparing to the benefit
- Human resource cost increased both with industry and MoDs

INDIRECT COSTS

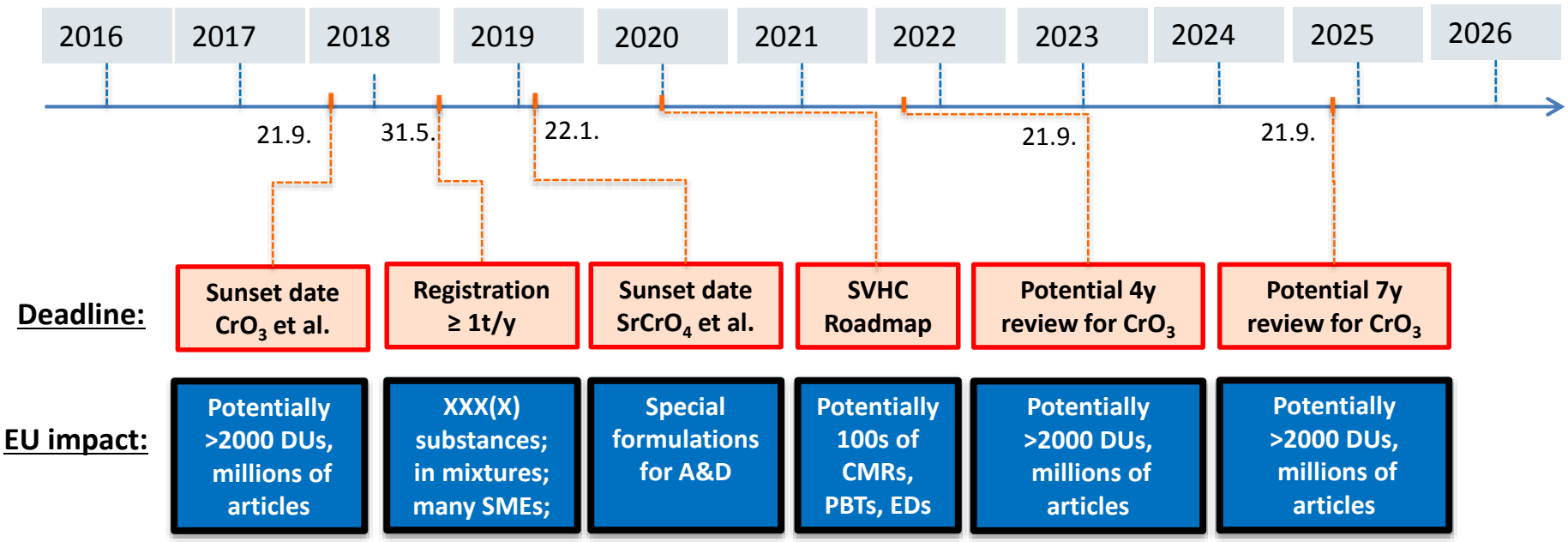
- SVHC substitution R&D and requalification tasks represent the largest cost.
  - 45.5% of MoDs report increased R&D costs
- Further costs expected to manage the consequences of substitution, e.g. shorter maintenance intervals due to worse substitutes.
- Transfer of upstream costs through product price.
  - Some examples reported
  - Main impact (= increase) expected in the future

Quantification (allocation to REACH) is difficult, especially for indirect costs

- Reporting was not homogeneous. Complexity of military procurement programmes.
- Further cost analysis would be required for better quantification of the impact. Future developments (registration 2018, evolution of SVHC Regulation, Article 33) have major relevance.

Consequential/Other Findings
Future Impacts

- The future impact of REACH – and hence the related cost – is expected by MoDs and defence industry to be significantly higher than the impact that has been realised so far. Particularly if REACH (and CLP) implementation continues as is.
- Example of major REACH challenges ahead (with a focus on chromates):



Consequential/Other Findings
Relocation Risks Are a Threat to Security of Supply

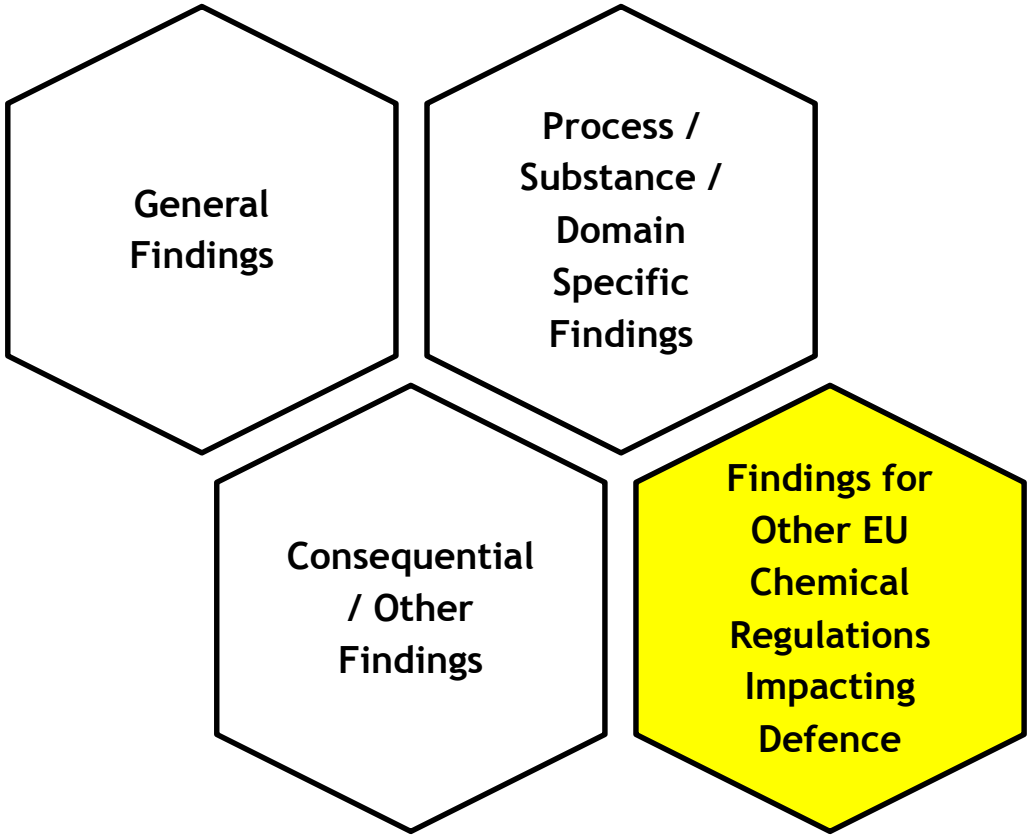
- **The possibility to relocate is limited in the defence sector, but...**
- REACH challenges the competitive position (level-playing field) of EU defence companies in export markets and causes industry to consider relocation to avoid the REACH constraints for SVHCs used in article production and manufacturing processes, especially 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, because supply chains outside the EU with imports are more difficult to control, manage and monitor (e.g. due to design and ITAR restrictions, if the production is moved to the US), and there are concerns, that some products may not meet the required specification or even be counterfeit.

- 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 out of EU (e.g. to their home country) could be higher for non-EU companies. On the other hand, EU companies with operations outside EU may also have this option for non-strategic components.

Findings summary — 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 ("explo-sive 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

Findings of the Impact Assessment
Categories of Findings



Findings of the Impact Assessment

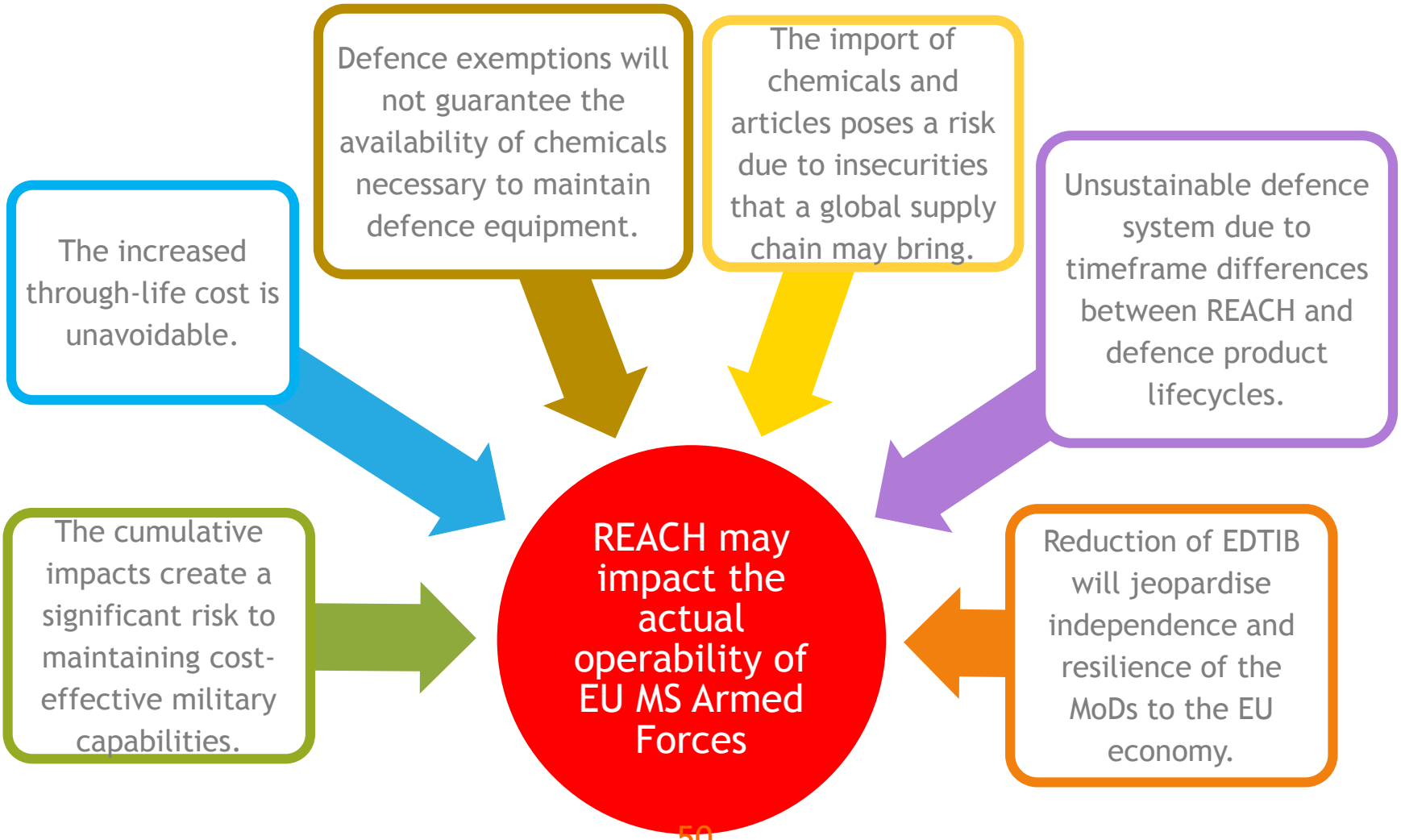
Findings for Other EU Chemical Regulations Impacting Defence

Inconsistent regulatory approach impacting defence: regrettable substitutions, different perceptions on how to handle defence ("exemptions", "exclusions", "disapplications").

- Defence related provisions analysed (in BPR, ODS, POP, F-GAS, RoHS) are in each case separately drafted as part of the legislative process and therefore there is no single provision that could be used as a template to harmonise them to generally safeguard the interests of defence. Nevertheless, a consistent approach is recommended.
- The problems arise mainly from multi-regulation situations where the cumulative regulatory impact is resulting in regrettable substitution
  - 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.
  - Cumulative regulatory impacts can have a negative effect on the operability of long service life systems such as navy ships
  - The regulator, supported by expert stakeholders, needs to take cumulative regulatory effects more into account to avoid regrettable substitution in the future

Findings of the Impact Assessment

General Conclusion of the Impact Analysis



1. INTRODUCTIONS: THE EDA AND ITS REACH FACILITATOR ROLE
2. STUDY BACKGROUND, OBJECTIVES & METHODOLOGY
3. FINDINGS OF THE IMPACT ASSESSMENT
4. RECOMMENDATIONS: OUTLINE
5. STUDY FOLLOW-UP
6. QUESTIONS & ANSWERS

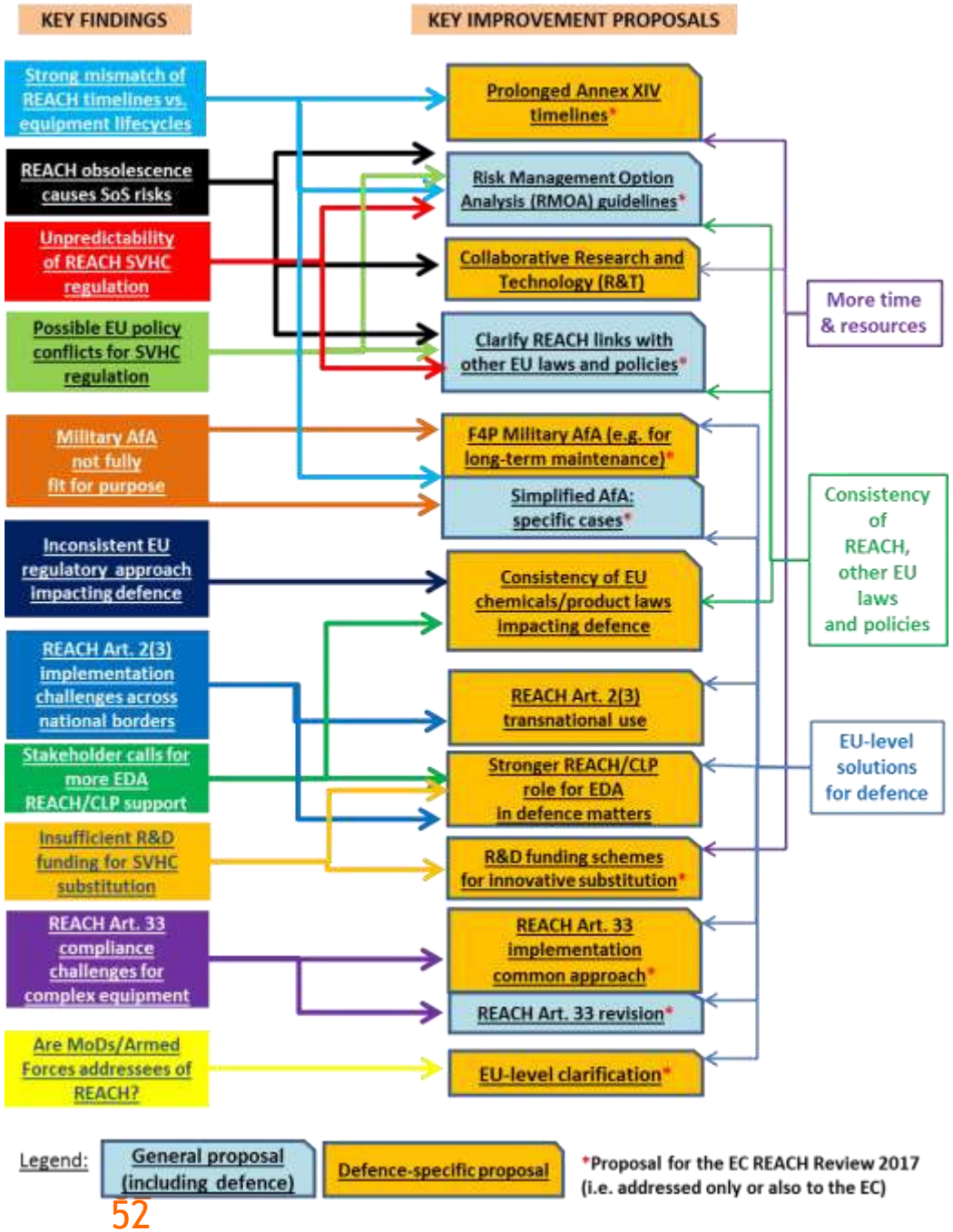
ANNEX: LIST OF STUDY RECOMMENDATIONS

Recommendations
Acting on Findings

In total, the impact assessment resulted in 21 findings and 26 improvement proposals, 14 thereof for the EC REACH Review 2017 and the remainder directed at defence sector stakeholders.

Categories of recommendations:

- MORE TIME AND RESOURCES FOR INNOVATIVE SUBSTITUTION OF SVHCS
- CONSISTENCY OF REACH, OTHER EU LAWS AND POLICIES
- EU-LEVEL SOLUTIONS FOR DEFENCE UNDER REACH
- ADDITIONAL IMPROVEMENT PROPOSALS FOR DIFFERENT ADDRESSEES (EC, ECHA and MSCAs - EU MoDs, EDA and defence industry - Authorities in charge of internal affairs)



Recommendations
Summary of Key Proposals

More time & resources

- **R&D funding schemes** for innovative substitution of SVHC (EC, MoDs).
- **Collaborative Research and Technology (R&T)** within EDA CapTechs for substitution of SVHC (EDA+MoDs).
- **Prolonged sunset dates** of SVHC for military-specific equipment (EC).

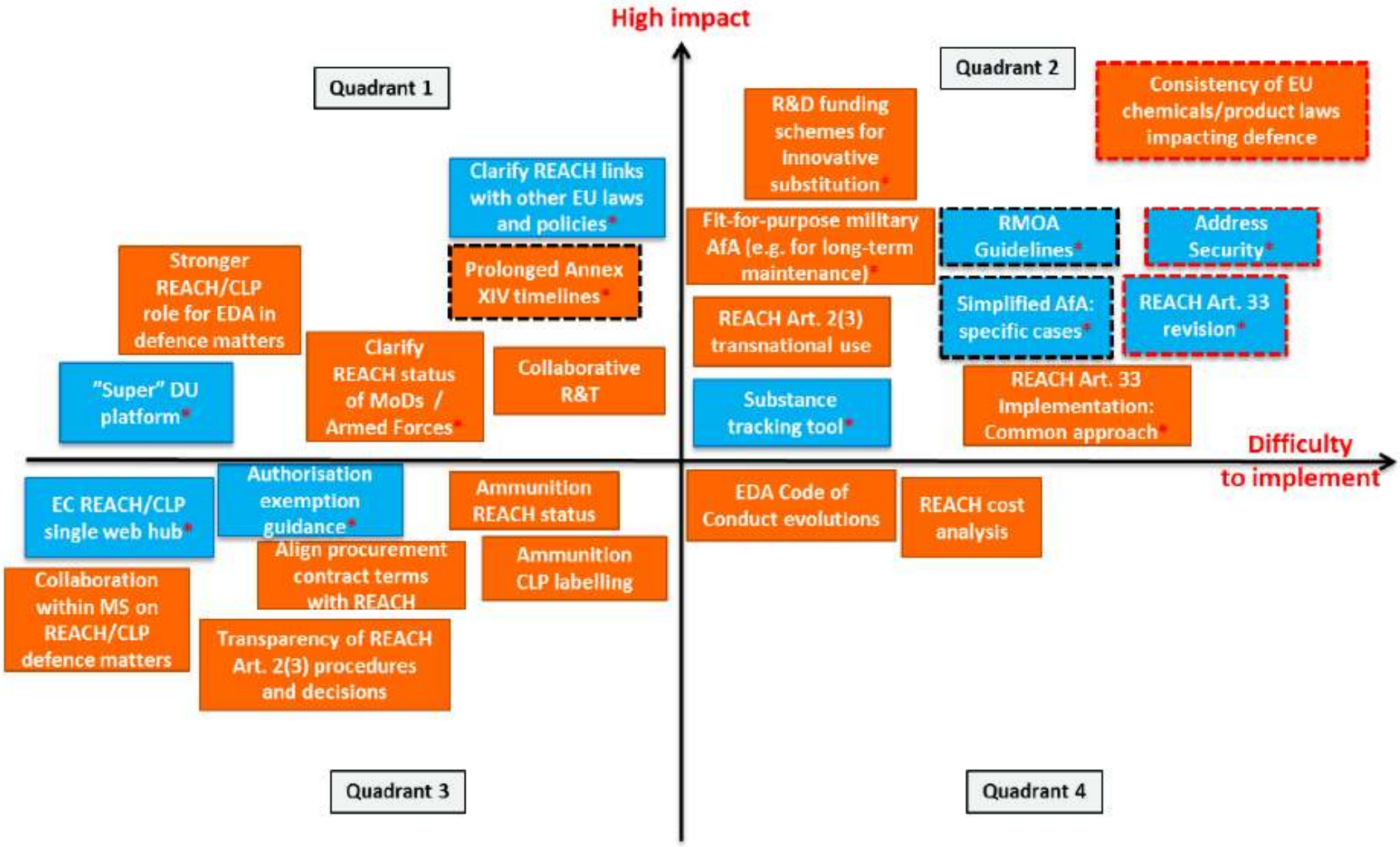
Consistency of REACH and Other EU laws & Policies

- Development and adoption of **EU-level guidelines for a Risk Management Option Analysis** (EC).
- **Consistency of EU chemicals/product laws** impacting defence (EDA+MoDs).
- **Clarification of REACH links** with other EU laws and policies (EC).

EU-level Solutions for Defence

- **Fit-for-purpose Application for Authorisation** (AfA) (EDA+MoDs+industry).
- **Simplified AfA** for specific cases (EC+ ECHA, MSCAs).
- **Practical implementation/ revision of communication requirements** of SVHC in defence complex articles (EC, EDA+MoDs, industry)
- Clarification of **addressee status of MoDs and AF** towards REACH (EC, EDA+MoDs).
- **Transnational use of defence exemptions** (EDA+MoDs).

Recommendations
Priority of Proposals



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Study Follow-Up

EDA Actions towards External REACH Stakeholders

towards EC

- **Forward the (full) study results** to DG GROW and DG ENV.
- Provide **input to EC public consultation** in relation to the **REACH Refit Evaluation**.
- Continue to **liaise / work together** with DG GROW and DG ENV.

towards ECHA

- **Forward the (full) study results** to ECHA.
- Continue to **closely liaise** with ECHA in order to support the implementation of proposed ECHA actions.

towards Defence industry

- **Distribute the (full) study results to** competent industry stakeholders (**ASD, NDIAs and contributing companies**).
- Continue to **closely liaise with defence industry** in view of examining future actions.

towards wider Dissemination

- **Publish** the (full) study report /results **in the EDA website**.

Thank you for your attention

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ANNEX: LIST OF STUDY RECOMMENDATIONS

Questions?

Please send your questions using the chat!
We will review them and come back in
a few minutes.

REACH & CLP Impact on the Defence Sector
Further Information

- **Final study report (REACHLaw)**
  - https://www.eda.europa.eu/docs/default-source/documents/eda-reach-study-final-report-2016-december-16-p.pdf
- **Study fact sheet (EDA)**
  - https://www.eda.europa.eu/docs/default-source/eda-factsheets/2017-03-21-factsheet_reach
- **EDA REACH project webpage**
  - http://eda.europa.eu/what-we-do/activities/activities-search/reach
- **EDA REACH Portal:** National exemptions in the interest of defence
  - https://reach.eda.europa.eu

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ANNEX: LIST OF STUDY RECOMMENDATIONS

Defence specific proposal	General proposal (including defence)


Thank You
Shukria
Dhanyavadagalu
Vinaka
Maake
Asante
Köszönöm
Kiitos
감사합니다
Kam Sah Hammida
شكرا
Manana
Dankon
Matondo
Terima Kasih
Dank Je
Dankscheen
спасибо
Mauruuru
Biyan
Diolch i Chi
Taiku
Tack
Blagodaram
Ngiyabonga
Dziekuje
Chokrane
Grazie
Arigato
Juspaxar
Mochchakkeram
Gracias
Khap
Paldies
Tingki
நன்றி
Bedankt
Dakujem
धन्यवाद
cảm ơn bạn
Grazas
Gratias Tibi
Ua Tsaug Rau Koj
Mèsi
Kia Ora
Kop Khun
Obrigado
Děkuji
Nuwun
Nirringrazzjak
ありがとう
Suksama
Rahmat
Matur Nuwun
谢谢
хвала
Hvala
Welalin
Di Ou
Djiere Dieuf
Misaotra
Danke
Merci
Go Raibh Maith Agat
Eskerrik Asko
Salamat
ขอขอบคุณคุณ
Najis Tuke

More Time and Resources

“INNOVATE FIRST – REGULATE LATER”

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.

List of Recommendations
More Time & Resources

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

59% of industry respondents are not aware of any public funding, national or EU, covering REACH related R&D, but 91% support the idea of EU level funding for it.

The main thrust of this proposal Is to encourage medium/long term, low TRL, pro-active R&D leading to innovative substitution of SVHCs

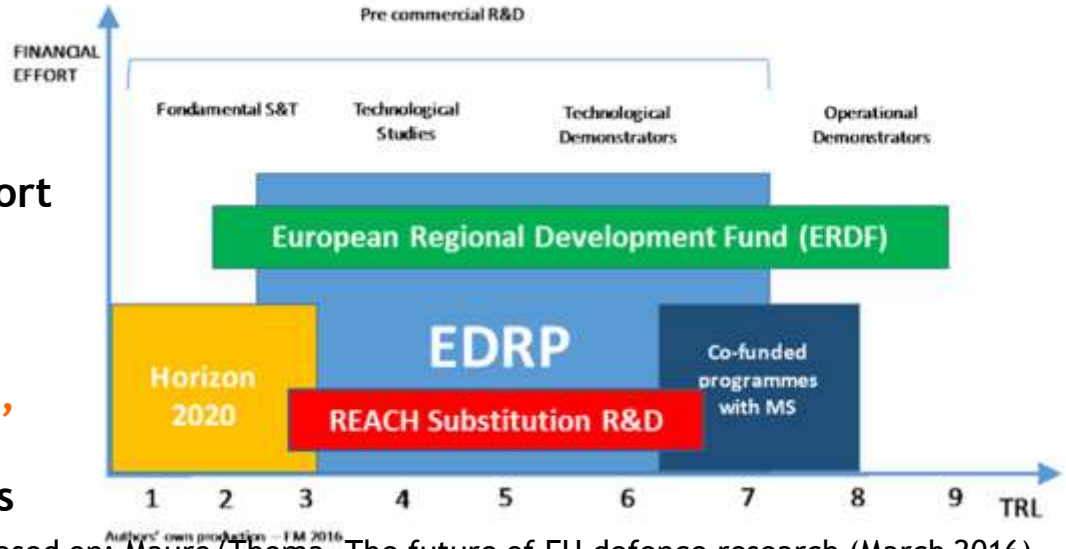

Diagram based on: Mauro/Thoma, The future of EU defence research (March 2016)

List of Recommendations
More Time & Resources

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.

The illustrative substance examples identified in the the study may generally 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 more detailed review by the EDA CapTechs would be required to identify the scope of further collaborative R&T with regard to REACH (i.e. substances and applications), in consultation with MoDs and defence industry.

List of Recommendations
More Time & Resources

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)

- REACH does not define a minimum timeframe between Annex XIV inclusion and sunset date. Also, there may be more than one sunset date depending on the use.
- However, in practice 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)

Note: Extended use-specific sunset dates are now proposed by the EC for the first time for the use of certain substances in legacy spare parts and for repair

Consistency of REACH, Other EU Laws and Policies

BIG PICTURE

It is important to see REACH and Risk Management Option Analysis (RMOA) for substances of concern 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.

List of Recommendations
Consistency of REACH, Other EU Laws & Policies

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

- RMOA has become the usual standard approach to determine the most appropriate Risk Management Option (RMO) for the most hazardous substances, but there are no common rules today on how to do an RMOA.
- EU-level RMOA guidelines are seen as an important evolution of REACH and the EC SVHC Roadmap to 2020 for a number of significant reasons described in the study.
- The RMOA should also be a tool to ensure consistency with other EU laws/policies.
- The range of uses and industries impacted by the envisaged Risk Management Option as well as its expected impacts should determine the depth of the RMOA → enhanced assessment to conclude on candidate list for subsequent authorisation

List of Recommendations
Consistency of REACH, Other EU Laws & Policies

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)

RoHS Article 2(4)(a): disapplication for *"equipment which is necessary for the protection of the essential interests of the security of Member States […] "*

List of Recommendations
Consistency of REACH, Other EU Laws & 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

- **REACH vs. OSH legislation**
  - Definition of criteria under which EU OSH legislation can be sufficient, and REACH Authorisation may not be necessary, or an exemption under REACH Art. 58(2) viable
- **REACH vs. Critical Raw Materials (CRM) policy**
  - Examination of supply chain risks for defence-critical CRMs as a consequence of assumed REACH regulatory scenarios (such as REACH Authorisation)
- **REACH vs. Circular Economy**
  - How to consider Circular Economy principles (e.g. promotion of longevity and recycling/re-use) when applying REACH? (as some SVHCs support longevity/may not affect safe (re-)use)

EU Level Solutions for Defence under REACH

Defence does not operate in a "bubble"

The EU defence sector does not operate in a national bubble, with no exposure to external influences. It is highly reliant on cross-border activities. Therefore, REACH calls for EU-level solutions to ensure efficient implementation and a level-playing field for industry.

List of Recommendations
EU Level Solutions for Defence under REACH

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)

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)

List of Recommendations

EU Level Solutions for Defence under REACH

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

List of Recommendations
EU Level Solutions for Defence under REACH

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

- **Review objective**
  - Safe use advice
  - Anticipation of obsolescence?
  - End of life objectives?

- **Requirements**
  - Detection threshold instead of 0.1%?
  - How to show localisation for complex articles if required?

- **Return of experience** from both defence industry and MoDs would be useful

List of Recommendations
EU Level Solutions for Defence under REACH

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

[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")?*

List of Recommendations
EU Level Solutions for Defence under REACH

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**.*	

List of Recommendations
EU Level Solutions for Defence under REACH

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

Additional Improvement Proposals

Completing the Study Picture

The following improvement proposals for different addressees complete the study picture. They are not necessarily less important, but some of them - other than proposals to the EC and ECHA - address issues of a more limited scope.

List of Recommendations
Additional Proposals for EC, ECHA, MSCAs

"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

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)

List of Recommendations
Additional Proposals for EC, ECHA, MSCAs

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)

Authorisation exemption guidance*	Addressee
Guidance / practical guide on exemptions from authorisation	ECHA (with EC support)

List of Recommendations
Additional Proposals for EDA, MoDs and Industry

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)

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

List of Recommendations
Additional Proposals for EDA, MoDs and Industry

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)

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

List of Recommendations
Additional Proposals for EDA, MoDs and Industry

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

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*	

List of recommendations
Additional proposals for EDA, MoDs and Industry

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

List of Recommendations
Additional Proposals for EDA, MoDs and Industry

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

List of Recommendations
Additional Proposals: Emerging Security Issues

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

Contact details

REACHLAW
COMPLIANCE. SUSTAINED.

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