

EU REACH Authorisation

Challenges for the Defence Industry and Potential Solutions

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Study Commissioned by European Defence Agency

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

End
2016

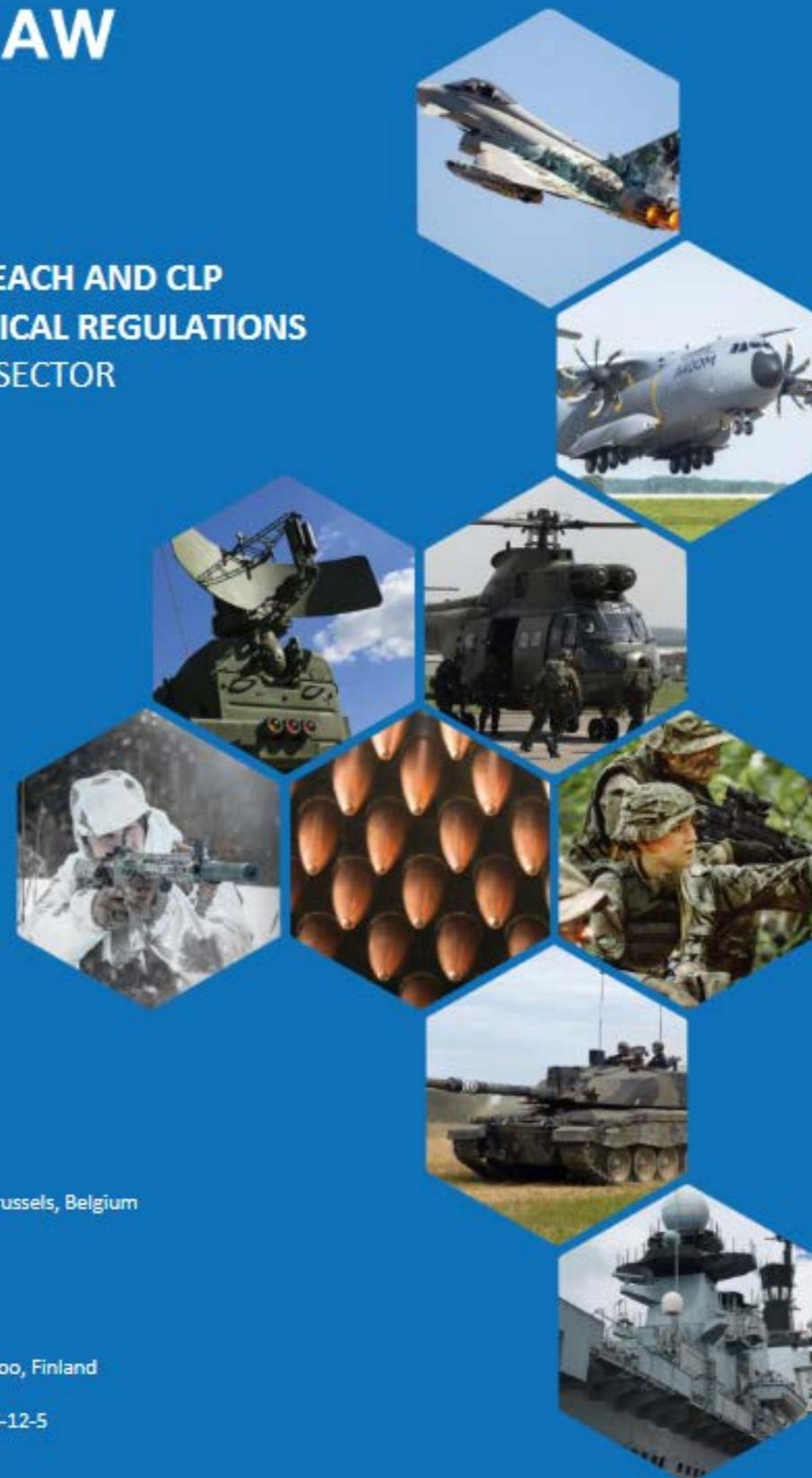
- Study finalised

Oct
2017

- EDA REACH Roadmap 2018 – 2020

REACHLAW

STUDY ON
THE IMPACT OF REACH AND CLP
EUROPEAN CHEMICAL REGULATIONS
ON THE DEFENCE SECTOR
FINAL REPORT
16 DECEMBER 2016



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EXECUTIVE SUMMARY

BACKGROUND AND OBJECTIVES

The REACH² and CLP³ 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, POP⁴) also have an impact on European defence capabilities.

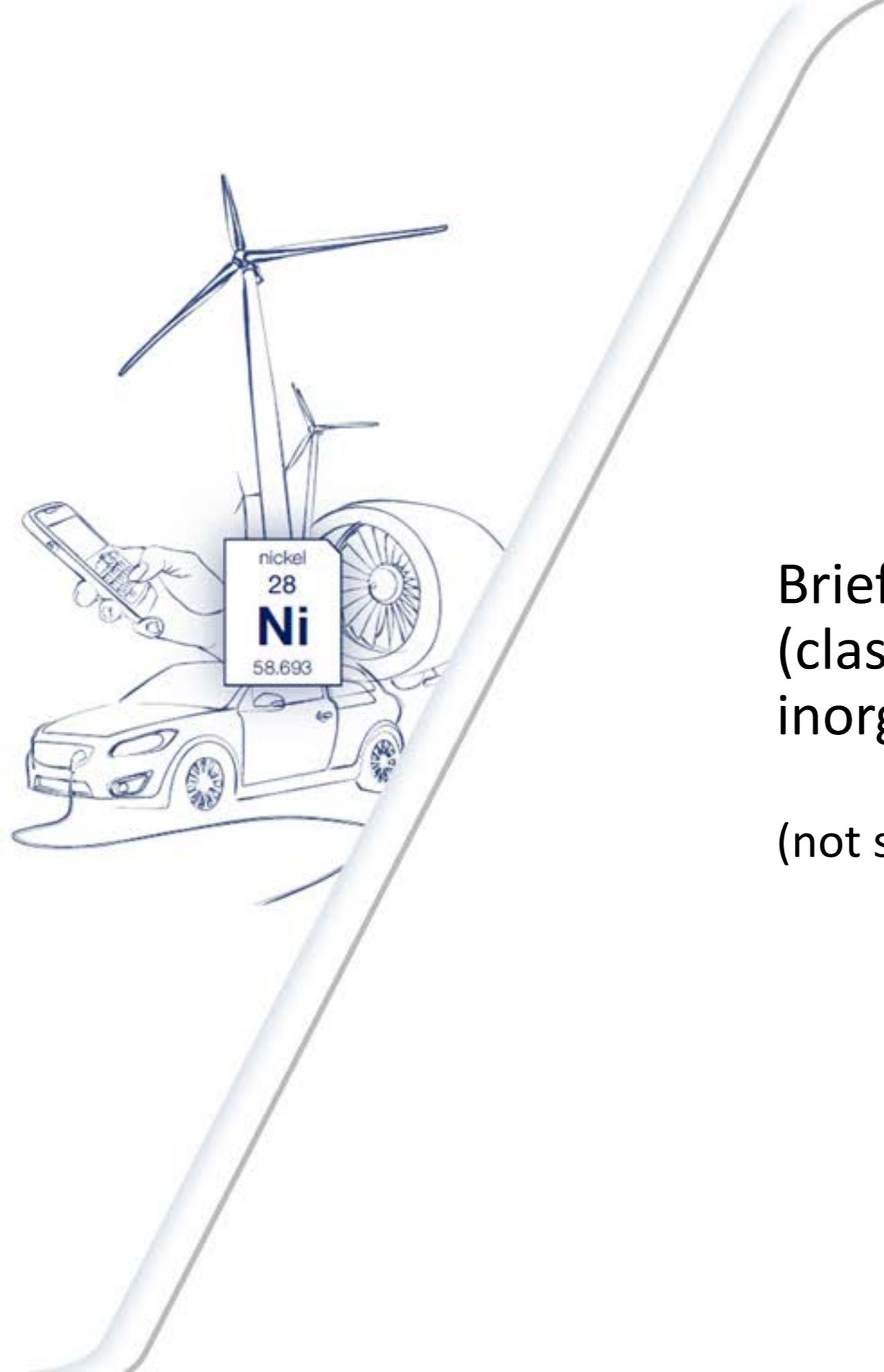
Among the aforementioned chemical Regulations, REACH, and the associated CLP Regulation, may have the greatest impact on defence capabilities, primarily due to the extended lifecycle of military equipment. A REACH Regulation review is planned by the European Commission (EC) to take place in 2017, to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

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.

Focus of Study
on REACH
(Review) and
hence
Authorisation
as major
impact



Brief reflections on CLP (classification and labelling) and inorganic substances

(not specifically addressed by the study)

Key findings

- The physical form of a metal is a key factor; massive and alloyed forms are usually less hazardous than powder forms
- There are mixed views on the adoption of additional criteria for metal alloys and special mixtures (such as plastic, glass etc.), although more Member State authorities are in favour of the adoption of new rules for metals classification than against
- The Transformation/Dissolution Protocol can be used to evaluate the aquatic toxicity of the metals and sparingly soluble metal compounds, however, further guidance is required for alloy testing
- JRC are developing a bio-elution test method which may be an alternative to *in vivo* testing; discussions are on-going concerning the potential applications (CLP Article 12) of the bio-elution test
- Further guidance is requested on the classification of metals and special mixtures

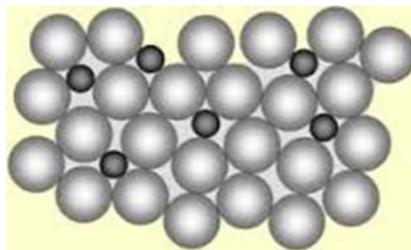
Update:
ECVAM,
not JRC, is
working
on this

Knowing which material presents a hazard is the starting point for targeted risk management

Accuracy is required. Authorities and industry need to cooperate for a further refinement

- Classification methodology in the EU for alloys such as stainless steel

Alloys



versus

Simple Mixtures

DEFINITION OF MIXTURE



Mixture
*a combination of two or more pure substances
in which each pure substance retains its
individual chemical properties*

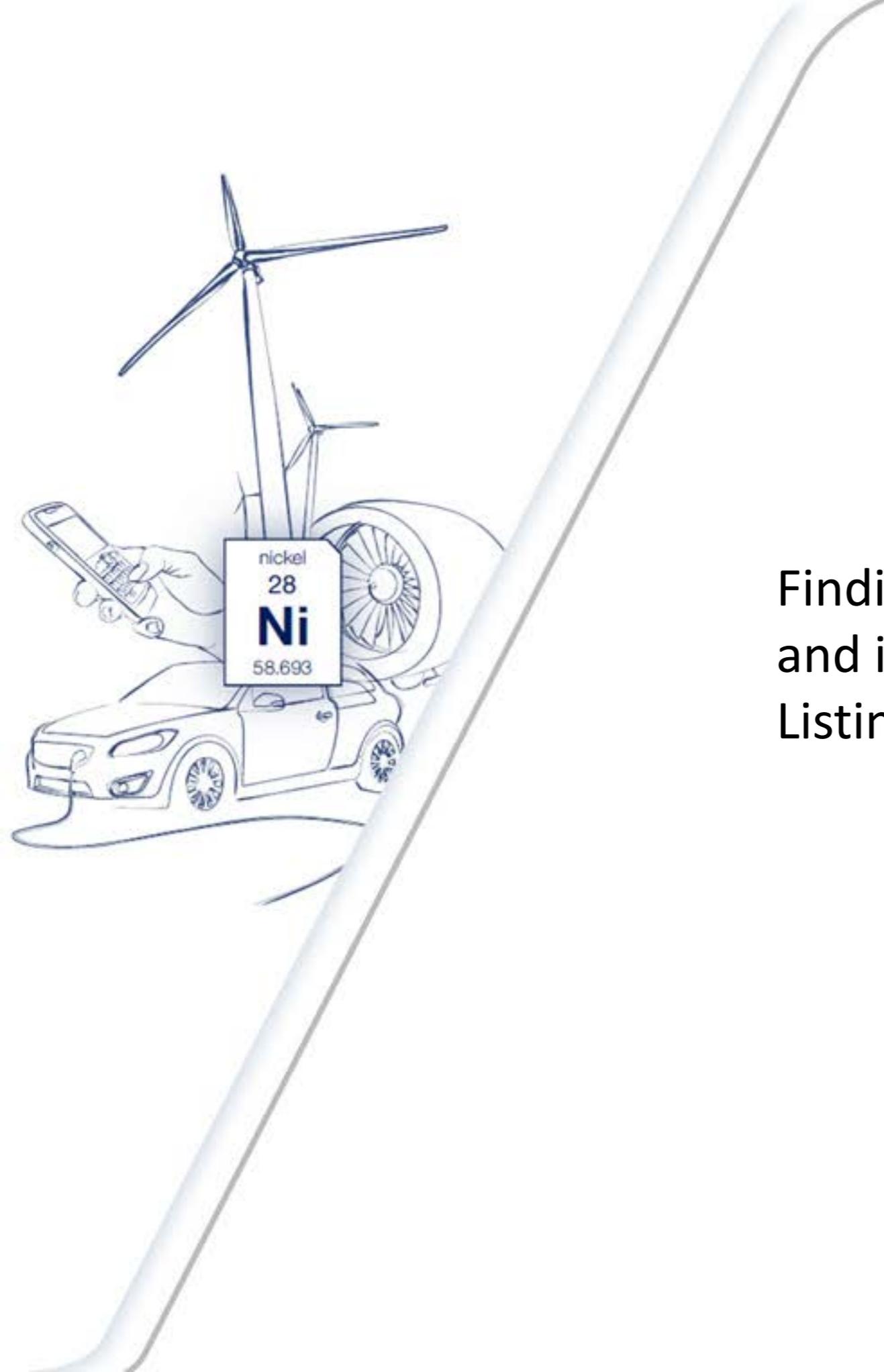
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- Alloys are more than simple mixtures: alloying **changes the intrinsic properties** of individual pure metal constituents (e.g. mechanical properties, corrosion resistance, ...)

Metal ion release (not content) determines hazard posed by an alloy

A practical example why this is important

- EU authorities are proposing a contentious classification of Co metal. It includes the classification as Carc 1B for all routes of exposure (inhalation, oral, dermal) with low concentration limit triggering classification (0.01%) → if classification is based on content rather than release, this may trigger inappropriate concerns
- Bio-elution testing has been done for stainless steel alloys and cobalt, to identify the release of cobalt and predict the toxicity of the alloys
 - The bioelution-based approach is a better predictor of the toxicity of stainless steel than just classifying on the basis of the concentration of cobalt in the alloy
- This will ensure that stainless steel can continue to be used safely without any concern or possible stigmatization
- Bio-elution will provide different results for different alloys – some alloys have shown to have higher releases than others, thereby leading to different and more appropriate classification



Findings of the EDA study on REACH and in particular on Candidate Listing and Authorisation

Introduction to some major regulatory challenges identified by the study

Pool of substances fulfilling criteria of Art. 57 REACH: CMRs, PBTs, vPvBs, substances of ELoC (equivalent level of concern)

Substances selected from the pool as relevant SVHCs
(Substances of Very High Concern)
→ Substances on the Candidate List

Duty to communicate
(supplier to recipient of article)

Covers any article containing substance on Candidate List in concentration above 0.1% w/w (“article” does not cover only the complex article (e.g. plane), but each single component (screw, ...))

Substances on Candidate List may be subjected to Authorisation

- Authorisation = Prohibition to use, unless user has obtained authorisation for use
- Obtaining authorisation: Highly bureaucratic and costly
- Considerable pressure to substitute

Examples of substances, where the defence sector was already impacted: Cr(VI) compounds, Phthalates, sulfochromate yellow, lead chromate)

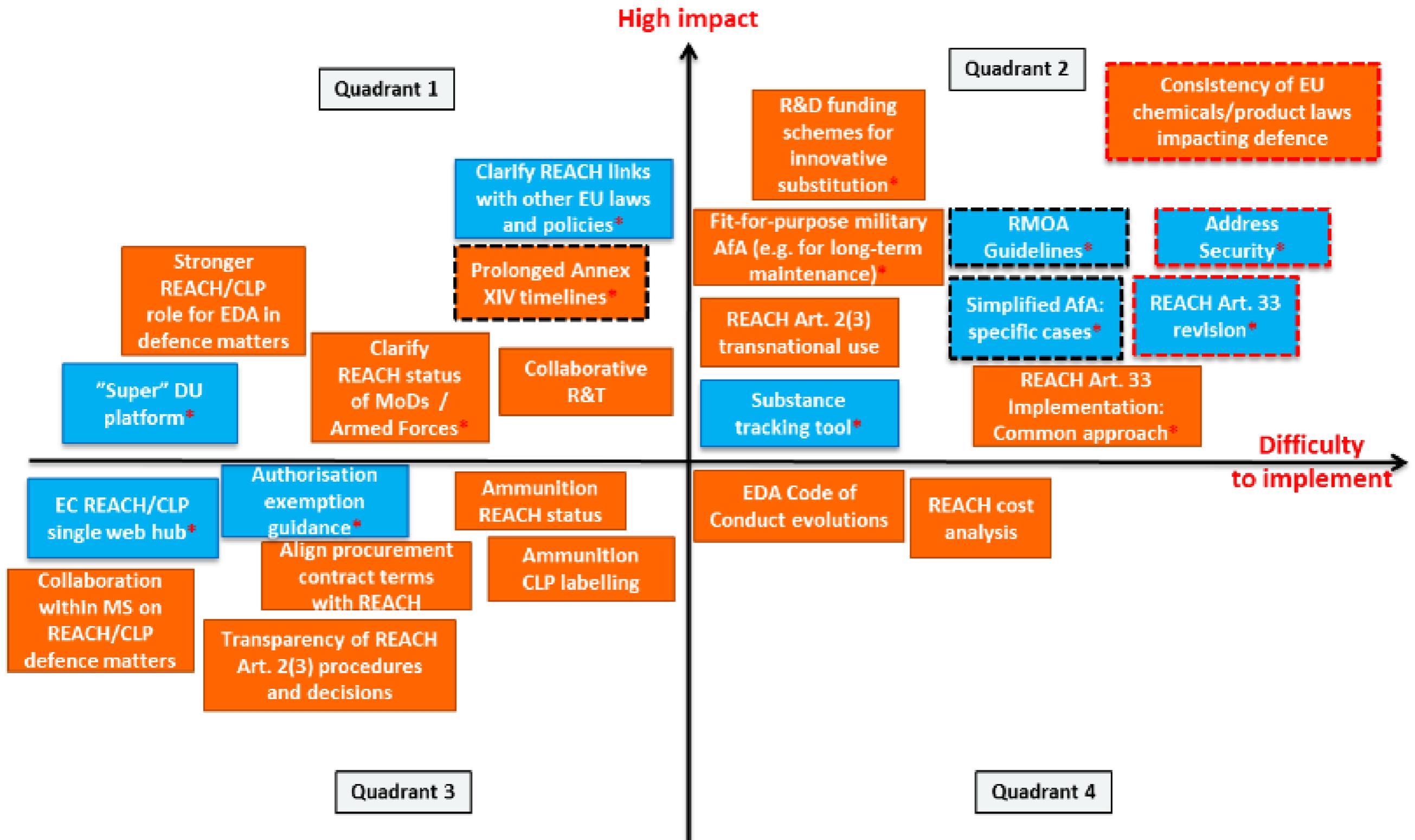
- Defence exemption limited in scope and not applied consistently in all EU Member States
- Many in the defence sector describe process as expensive, complex and unpredictable
 - Some describe a positive impact (improvement in RMM; better understanding of some materials in the supply chain)
- Clear socio-economic benefits of defence sector (average benefit to cost ratio: 1.77 million : 1 → Proportionality in applying the costly regime?)
- Difficulty in making the case for defence uses (often niche uses of the substance) in an upstream application

Findings regarding Substitution pressure from REACH

- “Substitutes are not necessarily less harmful and may offer less performance for a higher cost”
- 78.6% of respondents to survey: REACH → R&D activities on substitution.
Limitations:
 - Time-consuming, arduous and high chance of failure (in particular mentioned for inorganic substances)
 - 51%: R&D budget has not increased → less R&D in other areas
 - Improvement for HH and ENV achieved by substituting SVHC was in most cases not detectable
- Lack of company-level resources/funding as major obstacle to SVHC substitution
- REACH-induced obsolescence – 77.5% responded: “Yes, substances, mixtures or articles became unavailable for supply to me as a result of a REACH process → 69%: resulting process / product obsolescence

NI observation: Substitution is not a panacea. Whether substitution pressure is appropriate needs to be decided case-by-case

Study recommendations



Legend:

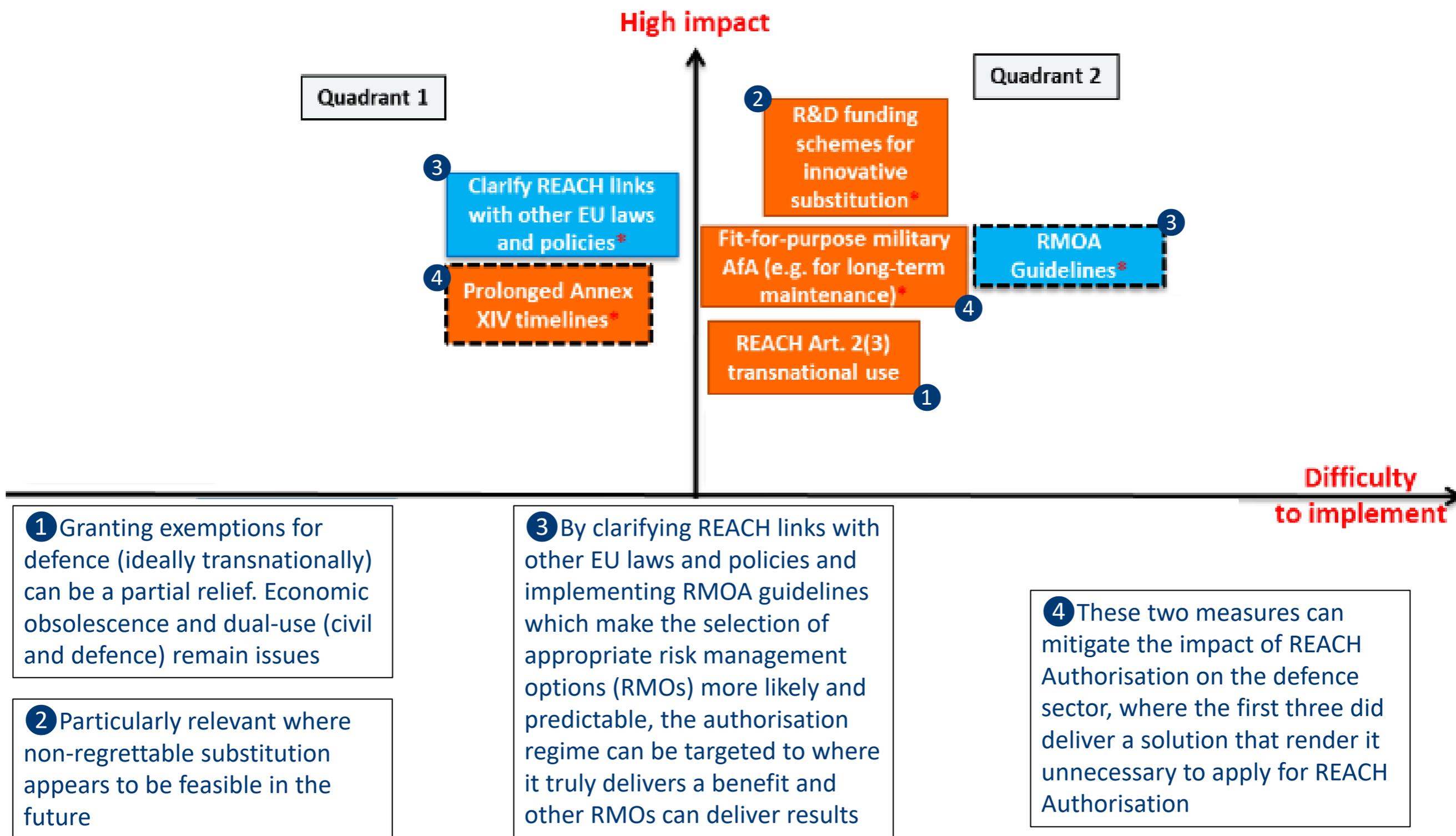
Defence specific proposal

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





Thank you for your attention

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