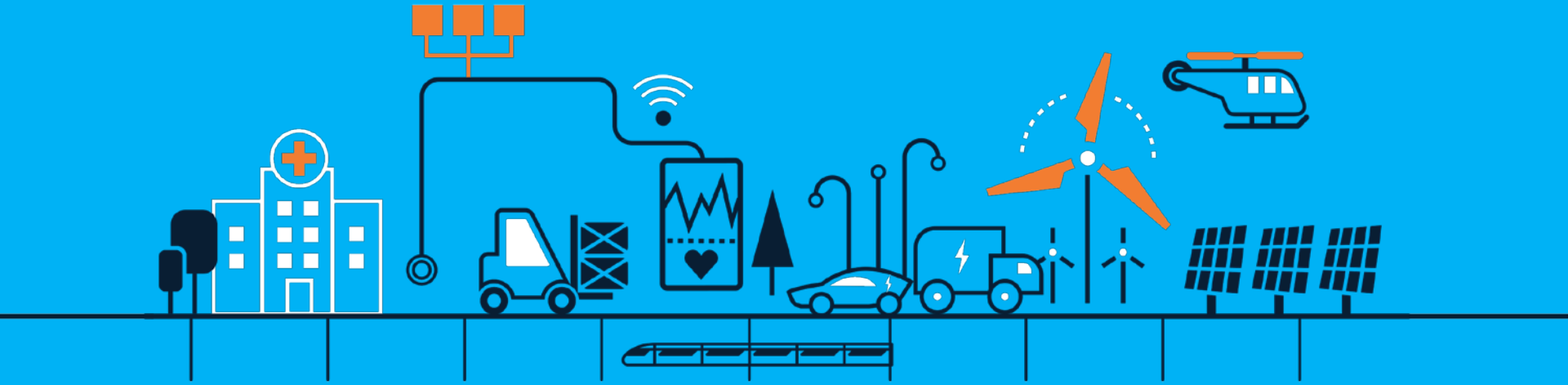
Use of Article 58(2) of REACH - exemptions for risks covered by other legislation



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Disclaimer

Agenda

- What conditions must be met before a REACH Article 58(2) exemption from authorisation can be considered?
- Overview of available case law and legislative history
- Challenges for future successful Article 58(2) exemption applications

REACH Authorisation-Objectives

- The authorisation procedure under the REACH regulation aims to assure that the **risks** from Substances of Very High Concern (SVHCs) are **properly controlled** and that these substances are **progressively replaced by appropriate alternatives** while **ensuring the good functioning of the EU internal market**.
- However REACH foresees circumstances when a use of an SVHC may be exempted from authorisation ……..how might this be applied?

REACH Article 58(2)

- "uses or categories of uses may be exempted from the authorisation requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled"
- "In the establishment of such exemptions account shall be taken, in particular of the proportionality of risk to human health & the environment related to the nature of the substance….."

REACH Article 58(2)-Who grants the exemption?

- The decision to grant an exemption from the authorisation requirement under Article 58(2) is taken by the **Commission**, taking into consideration ECHA's recommendation.
- It should be noted that any Art. 58(2) request is assessed **case-by-case**.
- Obtaining an **exemption is a possibility**, not an entitlement, and Commission **requires support from Member States**

REACH Article 58(2)- What does ECHA consider when making its recommendation to Commission ?

Whether:

- **There is existing EU legislation (i.e. Regulations and Directives adopted by the EU institutions) addressing the use (or categories of use) that is proposed to be exempted.** *Special attention has to be paid to the definition of use in the legislation in question compared to the REACH definition of use set out in Article 3(24) of REACH.*
- **The existing EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV.** *Generally, the legislation in question should specifically refer to the substance to be included in Annex XIV*
- **The existing EU legislation imposes minimum requirements for the control of risks of the use. The piece(s) of legislation has to define the measures to be implemented by the actors and to be enforced by authorities in a way that ensures the same minimum level of control of risks throughout the EU and that this level can be regarded as proper. This can include EU legislation that allows EU Member States to impose more stringent requirements than the specific minimum requirements set out in the EU legislation in question.** *Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation*
- *In its opinion on the 7th draft recommendation on priority substances for inclusion in REACH Annex XIV ECHA added an additional requirement by interpreting "proper control" to mean that the "**existing legislation must provide a binding substitution regime with a timeline and review period** in a similar manner to REACH authorisation"*

REACH Article 58(2)- Case Law

- To date only one exemption under REACH article 58(2) has been granted

- Use of phthalates in the immediate packaging of medicinal products (Regulation 143/2011) on the basis that “medicinal products are covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC and that **this legislation provides for a framework to properly control risks of such immediate packaging materials by imposing requirements on the quality, stability, and safety of the immediate packaging materials**.

- Q: Did this exemption meet **all of the criteria** currently being applied by ECHA?

REACH Article 58(2)- Case Law

- Most prominent judgement on application of REACH Article 58(2) comes from "**VECCO**" (2017) on use of chromium trioxide where the European Court confirmed a previous ruling of the General Court (T-360/13)
- Applicants brought an **action in an annulment** by claiming that the Commission had breached Article 58(2) on not exempting the use of the substance as an active catalyst from authorisation requirements on basis that **existing legislation properly controlled the risks**
- General Court ruled that it is necessary to examine :

➢ Whether there is **existing specific community legislation** imposing minimum standards relating to protection of human health or the environment for the use of the substance

➢ Whether on the basis of that specific Community legislation the **risk is properly controlled**

➢ Lastly and only if the two cumulative conditions are met, the Commission **MAY** grant exemption, enjoying a margin of discretion

REACH Article 58(2)-Case Law

Existing Specific Community Legislation in place

- **Community legislation** is understood as "*a rule of law adopted by a European entity intended to produce binding effects*". (e.g. a Directive but not national measures, voluntary practices or Commission communications)
- Legislation is **specific** when the substance is referred to as such by the legislation (not when a category of substances such as carcinogens or mutagens)
- Finally Article 58(2) refers to concept of **minimum requirements**. The GC clarified that a general framework of duties imposed on actors cannot be considered "minimum requirements" but ruled that requiring occupational exposure limits does constitute minimum requirements on basis they offer protection of human health whilst allowing MS to adopt stricter requirements if necessary

Following assessment of all pieces of legislation referred to by the applicant the GC ruled that the criteria for specific existing community legislation were not met and as such Commission did not have discretion to grant an exemption

REACH Article 58(2)-Case Law

Proper Control of Risk

- Courts silent on this aspect
- Reasonable interpretation would be that ONLY risk **stemming from hazards justifying subjecting a substance to authorisation** (eg CMR) and its use (with potential for exposure) is the one to be considered.
- Courts do not provide much guidance on what represents "**proper control**" and whether this can be applied to "threshold" and "non-threshold" substances
- However in VECCO case (for a non-threshold substance) neither European or GC ruled that Article 58(2) could not apply
- If adequate control = proper control then Section 6.4 of Annex 1 to REACH provides a benchmark for defining **proper control** as where "**exposure levels do not exceed the appropriate DNEL**"
- By contrast for **non-threshold substances it** is not possible to establish a DNEL but Section 6.5 provides describes conditions which should be established that ensure that the "**likelihood of effects are avoided**"
- **Following that interpretation it could argue that conditions of "proper control" could be met if existing specific community legislation imposes enforceable/binding minimum requirements for substance use or when it "ensures likelihood of effects are avoided" (for non-threshold)**

REACH Article 58(2)-Case Law

What margins of discretion does Commission have in deciding on an Article 58(2) exemption?

- Article 58(2) provides that, if cumulative criteria are met, "**uses or categories of uses may be exempted from authorisation requirements**"
- If **all conditions are not met** then **Commission does not have any discretion** and shall not grant
- The Commission should not replace the legislator, therefore Commission should establish **whether the legislator had intended to properly control risks** in question with existing substance specific legislation not whether it actually does so in practice
- Second sentence of Article 58(2) provides that *"in the establishment of such exemptions, account shall be taken, in particular, of the **proportionality** of risk…."*
- Therefore this could be interpreted that Commission holds a margin of discretion to decide that it is not proportionate to submit that use to authorisation and therefore grant an Article 58(2) exemption

Article 58(2) and Substitution Schemes

Does Article 58(2) require that the existing legislative regime in place pushes for substitution in a similar manner to the REACH authorisation requirements?

- Whilst objective of authorisation procedure is to progressively replace SVHCs with other appropriate substances or technologies where technologically or economically viable (Article 55) it cannot be inferred that **all** provisions of Title VII are to be interpreted in light of the substitution preference.

1. The GC in its VECCO ruling did not suggest in any way a push for substitution to be relevant for the assessment of Community legislation per Article 58(2)
2. The second sentence of **Article 55** specifically addresses the issue of substitution **at the stage of the application for authorisation**. However, **Article 58(2)** explicitly conditions an exemption of uses to **proper control of risk**, *nothing in this article provides for any kind of requirements regarding substitution*.
3. Fact that **Articles 57 and 58 do not include any reference to substitution** is notable given that REACH mentions the aim of substitution in all other instances (Recitals 12,70,72,73,74 & Articles 55 and 62)

Therefore conclusion must be that the **existence of a substitution regime in existing legislation should not be seen as a pre-requisite for granting Article 58 (2) exemption** but in relation to Commission assessment of proportionality could strengthen the case for such an exemption.

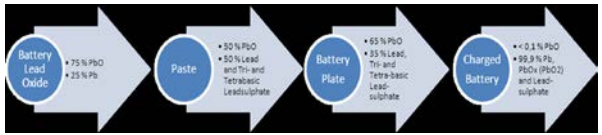
Case Study- 7th Priority List

Sealed Unit
<0.1% present

99%

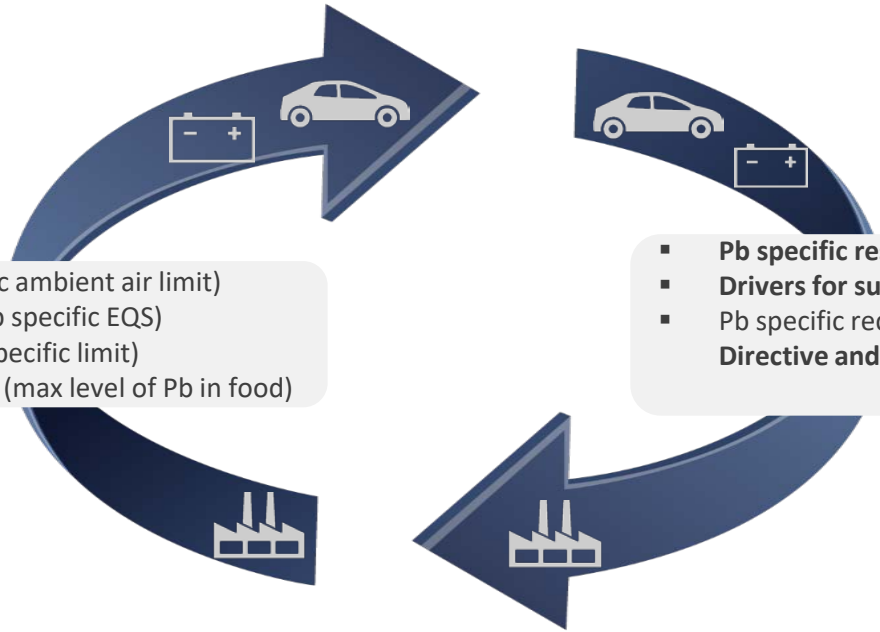
collection and recycling rate

- Lead Monoxide
- Lead Tetroxide
- Pentalead Tetraoxide Sulphate
- Tetralead Trioxide Sulphate



>95% recycling efficiency for Pb

Case Study- 7th Priority List



GENERAL/MvE

- **Air Quality Directive** (Pb specific ambient air limit)
- **Water Framework Directive** (Pb specific EQS)
- **Drinking Water Directive** (Pb specific limit)
- **Food Contaminants Regulation** (max level of Pb in food)

WASTE

- **Pb specific restrictions in ELV Directive**
- **Drivers for substitution in Battery Directive**
- Pb specific requirements in **Waste Framework Directive and Waste Shipment Regulations**

MANUFACTURING

- **Binding European OEL** of 0.15mg/m3
- **Binding European biological exposure limit** of 70µg/dl blood
- Pb specific requirements in **Pregnant Workers Directives**
- **Industrial Emissions Directive BREF** (Pb AEL) and site specific Environmental permitting

Case Study- 7th Priority List
Are the Commission/ECHA Criteria met ?

- **Is there is existing specific EU legislation (i.e. Regulations and Directives adopted by the EU institutions) addressing the use (or categories of use) that is proposed to be exempted.**

A: Yes

- **Does the existing EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV.**

A: Yes… if existing legislation is functioning correctly

- **Does the existing EU legislation impose minimum requirements for the control of risks of the use.**

A: Yes certainly for industrial use… but depends upon what define as use

- *Does the "existing legislation must provide a* ***binding substitution regime with a timeline and review period*** **in a similar manner to REACH authorisation**"

A: Maybe… But again depends upon what you define as use?

Case Study- 7th Priority List
What did ECHA/MSC Say?

- **ECHA** notes that, **given the binding occupational exposure limit** set out for inorganic lead and its compounds and given the binding biological limit value set out for lead and its ionic compounds under Directive 98/24/EC, **minimum requirements relating to the protection of workers health appear to be imposed by EU legislation to properly control the risk for workers health** arising from the use of the lead substances recommended for inclusion in Annex XIV which are a source of the lead or its ion. Therefore, **for this particular life cycle stage** and target population (workers), the **requirements in relation to Art 58(2) REACH may be met.**

- ECHA notes that Article 58(2) requires that the risk be "properly controlled" on the basis of existing EU legislation, which must be assessed on a case-by-case basis **A demonstration of proper control could, for example, be strengthened or supported if EU legislation provides a binding substitution regime for a SVHC with timeline or review process**

- ECHA considers that **the uses with perhaps the strongest case for Art 58(2) exemption are those for which a legislative regime is already in place to push for substitution in a similar manner to the authorisation** requirement. It could be argued that such a regime applies to those uses of lead compounds which are exempted under the RoHS and ELV legislation (e.g. ~75 % of lead batteries).

- MSC is of the opinion that **there may be grounds for exemptions from authorisation for: - uses** of lead monoxide, lead tetroxide, pentalead tetraoxide sulphate and tetralead trioxide sulphate **that are regulated under the RoHS and ELV legislation**.

In conclusion, ECHA does not recommend any exemptions from the authorisation requirement on the basis of Article 58(1)(e) and Article 58(2) of the REACH Regulation (*Recommendation of the European Chemicals Agency of 10 November 2016 for the inclusion of substances in Annex XIV to REACH*)

SUMMARY-Challenges in Obtaining an Article 58(2) Exemption

- Still much **ambiguity in conditions required to meet the criteria** for an Article 58(2) exemption as not fully tested in General Court and limited existing case history

- Does demonstration of "existing specific Community legislation imposing minimum requirements relating to protection of human health & environment" apply to **all potential life cycle stages**?
- Can existing legislation be applied **holistically** or must a single piece of legislation be control the risk?
- What is "**proper control**" and how can this be demonstrated for non-threshold substances?
- Does the existing legislative framework need to drive **substitution** in similar manner as REACH authorisation?
- What **margin of discretion** does Commission have and how does **proportionality** play into this decision?
- Even if these questions are addressed and Commission uses its discretion to propose an exemption of a use from Authorisation this still needs approval of Member States through Comitology……

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The VECCO Case And Beyond, What Uses Can Be Exempted From Authorisation Under Article 58(2) Of The REACH Regulation.

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THANK YOU