



Simplification of the authorisation procedure and potential exemption from the authorisation requirement under Article 58(2) REACH

Workshop on managing risks related to chemicals: REACH and OSH Legislation
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Overview

- Is there a need for simplification of the REACH authorisation procedure with regard to occupational risks?
- Is there scope for simplification of the REACH authorisation with regard to OSH aspects?
- Going beyond simplification: are there cases where the existence of OSH legislation justifies an exemption from authorisation based on Article 58(2) REACH?

Feedback from industry concerning authorisation

- Complex and costly procedure
- Lack of legal certainty with negative consequences on long-term investments
- Authorisation does not apply to substances present in imported articles
- Sometimes disproportionate (required even for 1 kg/year).
- Socio-economic aspects only taken into account at the very end of the process (authorisation application)

Commission proposals to improve the authorisation process

- **Objectives**

- Increase predictability
- Reduce workload for applicants and for the Committees
- Find solutions for cases where authorisation procedure appears to be disproportionate compared to the expected benefits

- **Further improvements for the authorisation process**

- For all cases: clarify what is the appropriate level of information required for an authorisation dossier
- For specific cases: simplified requirements to be defined (implementing regulation)
 - Simplified CSR, SEA and Analysis of alternatives
 - Simplified procedure for ECHA committees
 - Significant reduction of application costs



Scope for simplification of authorisation with regard to OSH aspects

- 1) Are there elements in applications for authorisation which overlap with what employers are already doing under OSH legislation?
- 2) If so, can those elements be replaced by what employers are already doing under OSH legislation?
- 3) How?

REACH authorisation vis-à-vis OSH requirements

REACH authorisation:

- ✓ **Control of risks:**
 - Adequate control (CSR)
OR
 - Socio-economic benefits
> risks (CSR, SEA)
- ✓ **Effort towards substitution (AoA, SEA):**
 - for determining length of review period
 - no authorisation if there are suitable alternatives (SEA route)

OSH (CAD, CMD):

- ✓ **Prevention and protection against risks from exposure to chemical agents in the workplace → hierarchy of measures:**
 - 1) Substitution
 - 2) Collective protection measures
 - 3) Individual protection measures

[+ regular measurements of chemical agents which may pose a risk]
[+ any applicable OEL]
(documented by employer)

Some food for thought

- If there is an IOEL for a substance, should the IOEL be considered as the reference DNEL? Or the national OEL? Or the most stringent of the two?
 - Should the above apply only in cases where there are no other routes of exposure than the inhalation route?
 - Could the above apply on the basis of a SCOEL recommendation? (no amendment of CAD yet)
- If there is a BOEL for a substance, can compliance with that BOEL be considered as equivalent to demonstration that the socio-economic benefits > occupational risks?
 - Should the above apply only in cases where there are no other routes of exposure than the inhalation route?
- If no Union OEL exists, should compliance with national OELs be considered as equivalent to demonstration that the socio-economic benefits > occupational risks?
 - Should the above apply only with regard to the applicant's own uses, and not to uses downstream?



Beyond simplification: scope for application of Art. 58(2) REACH on the basis of OSH legislation

Conditions for applying Article 58(2) REACH:

- 1) On the basis of existing Union legislation
- 2) Legislation must impose minimum requirements relating to the protection of human health or the environment for the use of the substance
- 3) Risk must be properly controlled as a result

In which cases does OSH legislation fulfil the condition of ensuring the proper control of the risk?



Article 58(2) REACH and OSH: where we are

- No support so far from MS where no Union OEL exists (but Court case T-360/13 pending)
- No support where IOEL exists:
 - MS may exceed the IOEL
 - Dermal exposure not reflected
- Not yet addressed: cases where a BOEL exists

One further thought

Is there scope for a restriction under REACH with regard to industrial uses if the concept of prevention of / protection from risks under OSH is recognised as equivalent to proper control of risks under REACH?



THANK YOU