

# Discussion on definition of intermediates & status

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## **Definition of intermediate: REACH Art 3(15)**

(...) a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (...)

- Implies that the substance itself does not exist anymore after the chemical processing (because it is transformed into another substance)
- The risk of exposure to humans and the environment is limited to the chemical processing (that is normally performed in specific industrial settings)

# Type and Status of Intermediates

3 categories

- Non Isolated (outside scope of REACH)
- On-site isolated intermediates (Art 17)
- Transported isolated intermediates (Art 18)
  
- Even if substance fits definition, to have the legal status of intermediate under REACH, with associated reduced information requirements, Article 17/18 requirements need to be satisfied

## Intermediates under REACH

- 1 Reduced registration requirements (Art 17 and 18 of REACH)
  - limited information on properties
  - brief general description of use
  - only information on RMM
- 2 Exemption from authorisation (Art 2.8 of REACH)
- 3 Exemption from restriction (OSI Art 68.1 of REACH)
- 4 Exemption from dossier evaluation and substance evaluation (OSI Art 49 of REACH)
- 5 Potential exemption from evaluation for TII (they are not mentioned in Art 41).
- 6 Reduced fee requirements

*Points 1, 4, 5 and 6 apply if intermediates are manufactured and used under Strictly Controlled Conditions (Art 17 and 18 of REACH)*

## **Power of enforcement: ECHA and MS**

- ECHA can review dossiers on intermediates
- ECHA can request additional information from registrants if the level of information provided is not adequate (Art. 36)
- ECHA can notify MS about non-compliant dossiers
- Member States Enforcement Authorities are entitled to verify compliance to requirements

# The Art 36 letter: addressing status

## *Requested information*

- a description of the relevant chemical reactions taking place when the intermediate is used to manufacture another substance;
- a description of the technical role in the process for which of the intermediate is used in the manufacturing process of the other substance. The description shall include the following justifications:
  - why the substances cannot be manufactured without the intermediate
  - why the presence of any reaction product from the intermediate is essential to the composition of the manufactured substance
- the chemical identity of the substance manufactured from the intermediate;
- whether the substance manufactured from the intermediate is:
  - a substance on its own; or
  - a substance in a mixture.
- whether the substance manufactured from the intermediate is subject to registration requirements under the REACH Regulation and, if not, the reason why.

## The template: addressing status

### ECHA

- Information requested addressed?
- Clear evidence that the requirements are not met?
- Need for clarification onsite?

### Enforcement Authorities

- What can be checked onsite?
  - Process descriptions (substance used to manufacture another)
  - Substance information (including manufactured substance)
  - SCCs
- What can be fed back to ECHA?
  - Check that information is available at the site
  - Inform the registrant to update dossier with required information



## Some examples of non-intermediates

From Guidance on Intermediates Appendix 4

- Substances used as catalysts
- Substances used as processing agents (e.g. Dispersing agents, viscosity modifiers, lubricants, antistatic agents etc)
- Substances used as curing agents
- Substances used as surface treating agents
- Substances used as desiccant

## Example 1 – issue with intermediate status

Substance: A – transported isolated intermediate  
Manufacture/Use: formulation/blending, polymer production, scavenger use  
Info available: Description of uses unclear, including info about the DU uses  
“this information is not available to us as a manufacturer”

### **Status**

Art 36 Response: By email: “information available at their office”  
DU confirmation: blank template letter sent to DUs attached  
“List of DUs and confirmation letters available at their office”

Conclusion: Need for clarification onsite

- Authority to check whether information on uses and DU letters are available onsite.
- Authority to instruct company to update IUCLID dossier with information

## Example 2 – issue with intermediate status

Substance: B – transported isolated intermediate  
Manufacture/Use: Description of uses unclear, PROCs and ERCs don't match  
Info available: Limited information in dossier, use as intermediate unclear, information on SCCs not in sufficient detail

### ***Status***

Art 36 Response: Registration updated to full registration with no intermediate use

Conclusion: Verification of intermediate status terminated

## Example 3 – issue with intermediate status

Substance: C – transported isolated intermediate  
Manufacture/Use: formulation/packing, use as laboratory agent  
Info available: Use as intermediate unclear,  
Information on SCCs not in sufficient detail

### ***Status***

Art 36 Response: Update of the dossier with sufficient information on uses,  
Some uses were removed from the dossier and detailed  
information provided on the SCCs

DU confirmation: Blank template letter sent to DUs attached  
“List of DUs and confirmation letters available at their office”

Conclusion: Intermediate definition ok, however need for clarification onsite  
- Authority to check whether SCCs are in place and DU letters are available onsite.  
- Authority to instruct company to update IUCLID dossier with information with DU information

**Thank You.**  
**Questions?**

