

Key messages on intermediates

Ninth Stakeholders' Day

21 May 2014

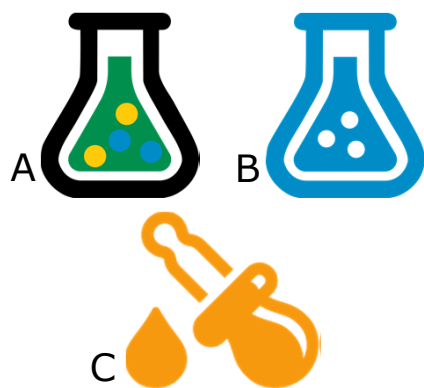
Augusto Di Bastiano
European Chemicals Agency



What is an intermediate under REACH?



- A substance to be transformed into another substance
- It is used with that intention
- It does not exist anymore after the transformation (except as a residue)
- Other uses: solvent, processing aid, catalyst etc. are not intermediates even if chemical transformations occur



- A and B are used to manufacture C
- C is a “new” substance - different from A and B
- A and B are intermediates

What are the obligations for intermediates in REACH?

- Reduced registration requirements (if under strictly controlled conditions - SCCs)
- Exempted from authorisation
- Exempted from dossier and substance evaluation (on site isolated intermediates under SCCs)
- Exempted from restrictions (on site isolated intermediates)





Registration of intermediates: Conditions under Articles 17 and 18

CONDITION	RELEVANCE
Compliance with definition of intermediate – Article 3(15)	Derogations for intermediates are applicable <u>only</u> if this condition is met
Reduced information on substance properties. Application of strictly controlled conditions (SCCs)- Articles 17 and 18	Derogation from registration requirements apply if SCCs are fulfilled
For transported isolated intermediates: confirmation from downstream users (use as intermediate and SCCs) - Article 18	Requirements for intermediates apply in the whole supply chain.
<i>It is recommended to provide information on the conditions as an attachment in section 13 of the IUCLID dossier</i>	



Registration of intermediates: conditions under Article 10

CONDITION	RELEVANCE
Compliance with definition of intermediate – Article 3(15)	Derogations for intermediates are applicable <u>only</u> if this condition is met
Information on substance properties (requirements based on tonnage) and uses	Relevant to all REACH processes
Conditions of safe use to be demonstrated for the whole life cycle of all uses*	

* requirements based on hazards and tonnage

Why intermediates are important

Registration requirements are reduced as safe use is guaranteed by strictly controlled conditions.

Quantities used as intermediate are relevant for:

- Dossier and substance evaluation
- Prioritisation of substances for Annex XIV (authorisation)
- Applications for authorisation



Sources of information are registration dossiers

Correct decisions require correct information

Verification of intermediate conditions (ECHA)

- Information may be in the dossier
- ECHA may request information from registrants and downstream users under Article 36 of REACH on:
 - Use as an intermediate
 - Strictly controlled conditions (SCCs)
- If conditions are not met:
 - Compliance check and/or
 - Possibly enforcement actions by Member State national enforcement authorities

Industry is strongly encouraged to give complete and good quality information to make sure that they meet the conditions for intermediates

ECHA support

- Updated Guidance on Intermediates published in December 2010
- Dossier Quality Assistant to help registrants detect potential inconsistencies in their registration dossiers (including registrations according to Article 17 or 18) is available
- Practical Guide on registration of intermediates (coming soon)

Industry is strongly encouraged to review, on their own initiative, their intermediate registrations to make sure that they are in line with Article 3(15) and Article 17 and 18 requirements

... Take home messages

- *Intermediate use in the whole supply chain must be clear for registration under Articles 17 and 18 as well as for registration under Article 10*
- *Reduced registration requirements (Articles 17 and 18) demand less data on substance properties, but same information on the use - use itself and conditions of use*
- *Good quality dossiers will reduce the possibility*
 - that additional information has to be provided to ECHA through Article 36 letters and/or corrective actions are taken
 - that authorities will not take the tonnage used as an intermediate into account when screening and subjecting substances for further regulatory actions

Thank you

augusto.dibastiano@echa.europa.eu

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