

Registration of intermediates: tips for duty holders

Eighth Stakeholders' Day

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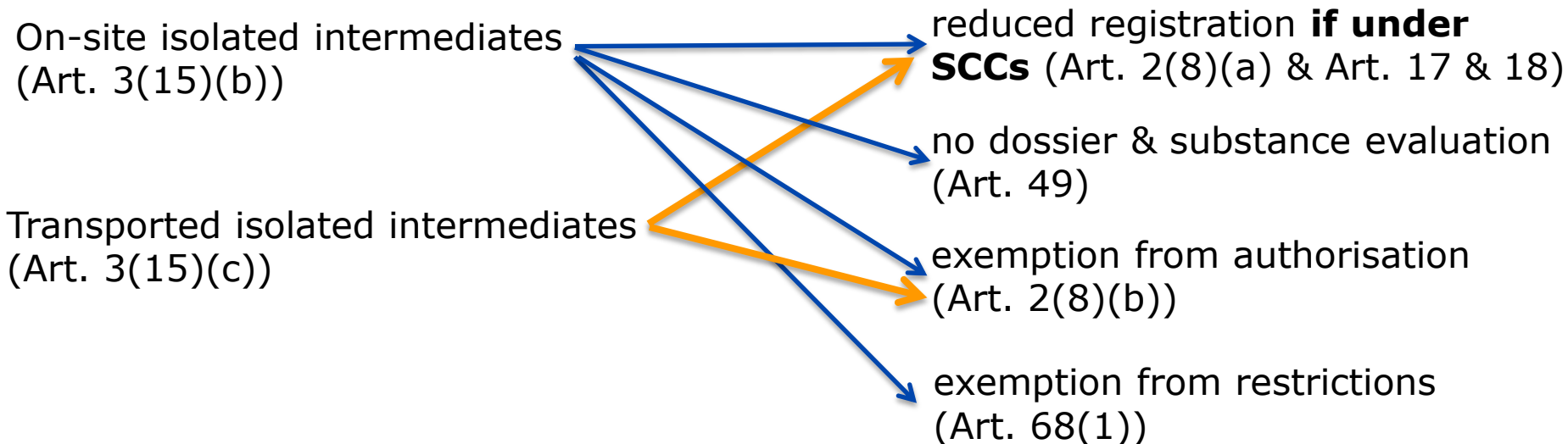
Outline

- Reasons to follow intermediate registrations
- ECHA's activities on intermediate registrations
- Advice for industry
- Conclusions

Definitions – intermediate and SCCs

- Definition in 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*
 - Non-isolated
 - On-site isolated
 - Transported isolated
- Strictly controlled conditions - SCCs (Art. 17(3) & 18(4)):
 - *Rigorously contained by technical means during whole lifecycle*
 - *Procedural and control technologies that minimise emission and any resulting exposure*
 - ...

For reasons of workability and because of their special nature – special requirements for registration/authorisation/restrictions



Before submitting reduced registration, the registrant has to assemble information confirming that the substance is used as an intermediate and is used under SCCs

Intermediates – ECHA activities

Interpretation of intermediate definition and/or SCCs should be strict



- To ensure protection of humans and environment because in reduced registration information on hazards and risk assessment are missing
- To ensure the useful effect of registration/authorisation/restriction processes



Therefore, ECHA is & will



Use Art. 36 to verify intermediate status of registrations

Perform IT supported mass screening

Art. 36 to verify intermediate status of registrations

- Requested information:
 - to clarify the use of the substance and conditions applied during all life-cycle stages of the substance
 - to check that before registration, the registrant was *certain* about downstream use and conditions of use of the substance
- Currently, priority is given to substances in Annex XIV and in the Candidate List

ECHA is entitled to ask DUs for confirmations to be provided in the dossier

Allows the supply chain of intermediates to be followed

IT supported mass screening

- Approx. 5 500 intermediates dossiers were screened
- 2 388 dossiers: based on information provided on uses, intermediate use and/or SCCs are incompatible with the conditions required → communications sent via REACH-IT → 1 844 dossiers updated + 107 dossiers intended to be updated
- If the incompatibility remains → ECHA considers initiating legally binding actions and will inform NEAs

Tools to support industry

- Updated Guidance on Intermediates published in December 2010
 - Explanation of definition of intermediate (with some examples) provided
 - SCCs are explained and examples are provided
 - a proposed template for reporting of Risk Management Measures (RMMs) is made available
- Dossier Quality Assistant to help registrants detect potential inconsistencies in their registration dossiers (including registrations according to Article 17 or 18) is available
- ECHA exploring further needs and best ways to support industry in preparation of intermediate registration dossiers

Industry is strongly encouraged to review, on their own initiative, their intermediate registrations to ensure that they are in line with Art. 3(15) and Art. 17 & 18 requirements

Tips from intermediate status verification (1)

- Dossier status (annual quantity) has to reflect real situation, i.e. if no production/import, tonnage of registration has to be put at 0
- Use
 - Consider technical function of the substance in a process – *“intermediate is used in manufacturing of another substance where it is itself transformed into that other substance”* (Guidance on Intermediates) -> e.g. processing aids are not intermediates
 - Production of waste is not main intention of manufacturing process

Tips from intermediate status verification (2)

- Conditions of use
 - Explanation of RMMs shall be attached in section 13 of IUCLID dossier – especially steps where breakage of the containment system is expected (e.g. (un)loading, cleaning, maintenance, sampling) have to be addressed
 - Phys-chem. properties can be taken into account designing SCCs, but 'risk' based approach is unacceptable, i.e. comparison of exposure levels with (no)effect concentrations or national/international limits is unacceptable
 - Continuous releases from the process are not expected (unacceptable), but monitoring may be used to demonstrate the level of fugitive emissions
 - Use of PPE as a means to ensure rigorous containment/SCCs during normal operating conditions (except for accidents, incidents, maintenance, cleaning) is not accepted

Conclusions

- Registrants to act proactively by assessing correspondence of their intermediate registrations with updated Guidance on Intermediates and if relevant update registration:
 - for reduced registration – to provide attachment with RMMs in IUCLID section 13
 - if substance is not used as an intermediate and/or is not used under SCCs, the registration should include the information specified in Art. 10
- Registrants have to be certain that their DUs use the substance as an intermediate and use it under SCCs
- ECHA will further verify status of intermediate registrations and will further support industry on related issues

Thank you

