

Status of intermediate dossiers and verification strategy

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Conditions set out by REACH for registration of intermediates

- Compliance with the definition of intermediate in Article 3(15) of REACH
 - As clarified in Appendix 4 of the Guidance on Intermediates
- Fulfilment of the strictly controlled conditions set out in Article 17 or 18 of REACH
 - As clarified in the Guidance on Intermediates
- In the case of transported isolated intermediates, confirmation that downstream users are implementing the strictly controlled conditions set out in Article 18 of REACH
 - As clarified in the Guidance on Intermediates

ECHA verification strategy: CCH

- ECHA decided not to use the compliance check process (CCH) to verify the status of intermediate
- CCH only allows ECHA to verify the compliance of the dossier with data requirements, however:
 - There is no requirement to submit detailed information on the synthesis of intermediate in the dossier
 - The requirement to submit strictly controlled conditions as part of the dossier is indirect and is limited to transported intermediates
 - There is no requirement to submit confirmation of downstream users in the dossier
- CCH would not allow to verify whether the registration meets the definition of intermediate and the actual conditions for a reduced data set

ECHA verification strategy: Article 36

- Verifying the validity of intermediate dossiers actually requires the confirmation of the conditions for the registration not the data required in the dossier
- Article 36 allows ECHA and Members states to request from any registrant « *all the information he requires to carry out its duties under this Regulation* »
- Before registering an intermediate, any registrant had to assemble information confirming:
 - that the use is intermediate
 - that strictly conditions were met
 - that downstream users are implementing them
- This information is exactly what ECHA asks in accordance with Article 36

Verification of intermediate use

- The purpose of the synthesis of the intermediate must be the manufacture of another substance
- To verify this, ECHA requests:
 - A description of the chemical reactions taking place in the manufacture another substance
 - a description of the technical role of the intermediate in the process
 - the chemical identity of the substance manufactured from the intermediate
 - whether that substance is a substance on its own or a substance in a mixture
 - whether the substance manufactured from the intermediate is subject to registration and, if not, the reason why
- ECHA also verifies that each registrant confirms his certainty that the substance is use by downstream users as an intermediate (e.g. copy of letters)

Verification of strictly controlled conditions

- The verification goes beyond the general considerations set out in Articles 17 and 18 of REACH
- The questions follow closely the specifications brought by the Guidance on intermediate
- The registrant of transported intermediates must also confirm that downstream users implement the strictly controlled conditions
- ECHA verifies:
 - Limitation of use sent by the registrant to downstream users
 - Confirmations received from each downstream user
- To facilitate the reply, also ECHA allows registrants to submit a model letter with a list of downstream users to which it was addressed

Summary of Art. 36 letter responses (3)

Scenario	
All conditions met	12
Clear breach of intermediates/SCCs	4
Information missing/unclear	11
Used only by DUs/Confirmations not received	4
Update to standard registration received	2
Other: Cease of manuf/import; Art 36 letter not read in REACH IT; Change of OR and country	7

Summary of Art. 36 letter responses (4)

Action	
Termination	19
MS on-site verification DE 5, BE 3, NL 2, UK 2, Poland 1, France 1, Cyprus 1 Manufacturer 9, importer 4, OR 2	15
CCH proposed by DEM/iDEM -- in addition MS on-site actions?	4
Other action	2

Need for MS on-site verification/enforcement

	Intermediate definition	SCCs	Information from DUs (intermediate definition/SCCs)
Proven to be ok in the registrant's response	9	7	2
Breach of Art. 36, enforcement by MSCA needed	5	2	11
Unclear information /on-site clarification needed	1	6	2

Forum Pilot project: reporting template

- Document 1: Clean version with no data
- Document 2: Sent to pilot project comments
- Document 3: document to be used for MSCA/enforcement communication
 - Improvements so far
 - Only the issues needing MSCA action reported
 - Some clarifications to the text based on ECHA internal review
 - To be further developed during the workshop

Forum Pilot project: comments/proposals on the reporting template

- Useful comments/suggestions from AT, FR, UK, NL
 - Template could be developed for enforcement purposes
 - If requested information not addressed: ECHA or enforcement action
 - Addressing DUs is important
 - Reference to legal requirement (but in many cases it is Art 36, wider than Art 17-18 or 3(15))
 - TII without DUs? There is transport between the registrant's sites
 - etc.