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Updating a dossier due to new information: case study

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Warning to the reader: the information provided in this presentation is to not be regarded as legal advice.

1. Requirements for updating a dossier

2. Case study: new knowledge of the risks

3. Other cases

4. In conclusion



In which cases should a registrant update its dossier?

- ▶ Changes **specific to the registrant**: status, name, identity, quantities, identified use
- ▶ Change in the composition or in the C&L of the **substance**
- ▶ Change in the CSR or need to perform a **new test** (testing proposal)
- ▶ **New knowledge** of the risks of the substance to human health and/or the environment which leads to changes in the SDS or the CSR
- ▶ Change in the **access granted** to information in the registration
- ▶ Change in the **regulation** itself (new requirement) or due to Authorities' decisions (ECHA or EU Commission)

Update to dossiers: common parts vs registrant-specific part

- ▶ The update is to be submitted by the entity who submitted the registration initially i.e.
 - the registrant for dossier **individual** part (incl. the OR)
 - the Lead Registrant for dossier **common** parts



New study* on properties of a substance is made, which may impact the risks assessment described in the registration dossier.

Key steps to follow:

- ▶ Identify who owns this study and the IPR attached to the data
- ▶ Obtain access to the data (under NDA as required)
- ▶ Evaluate data and implications for the risk assessment, prepare robust study summary if conclusive (study is main entry for an end-point - “key study” in the Fleischer list- and Klimisch score 1 or 2)
- ▶ Obtain (the right to grant to registrants) “permission to refer” within the meaning of Art 10(a) of REACH
- ▶ Compensate data owner as required (cf rules outlined in Guidance on DCS)
- ▶ Inform other registrants (duty to share – Art. 30)
- ▶ Seek agreement on fair and transparent sharing of costs (Art. 29)
- ▶ Update relevant parts of the dossier
- ▶ Provide registrants with updated LoA
- ▶ LR to submit updated dossier

*involving tests on vertebrates



Example of a new study identified : SIEF process

- ▶ Owner requires compensation for granting access to the data
- ▶ CSR and IUCLID endpoint must be updated
- ▶ Assessment of impact on existing DNELs trigger need to revise Exposure Scenarios
- ▶ Dossier Common parts are updated
- ▶ Licence offered to SIEF members extended against fair share of costs incurred (see next slide)
- ▶ Communication is prepared to SIEF members about scope and content of the updated dossier
- ▶ LR committed (LR Agreement) to update the joint parts of the registration (full set of data submitted)
- ▶ Registrants should update their part of the dossier as required and potentially their SDS as well (based on changes made to the CSR)



Calculation of the dossier update cost (illustrative only):

| Activity/task | Cost, K€ |
|--|-----------|
| ▶ Access to data: compensation to owner | 50 |
| ▶ Update of CSR & IUCLID: 3 man-days + overhead | 4 |
| ▶ Assessment work & ES update: 5 man-days + overhead | 6.5 |
| ▶ Compile updated dossier: 2 man-days + overhead | 3.5 |
| Total cost to be shared | 64 |

- ▶ 12 registrations made + LR will need the updated dossier
- ▶ Update cost per registrant: $64/13 = 5 \text{ K€}$ (rounded) per registrant (= per legal entity)
- ▶ Initial dossier cost was 10K€. Cost of LoA for new registrants: 15K€



Annex 1 revision - published December 2010

(after 1st registration deadline)

- ▶ Required review of the CSA and documentation in Chemical Safety Report
- ▶ Need to assess if new ESs are required
- ▶ Need to include CLP classification in IUCLID Section 2 & CSR
- ▶ Justifications for classification to be presented according to CLP (updated from references to DSD)
- ▶ Submitted dossiers need to be compliant by Nov 2012
- ▶ Evaluation of updates needed to dossiers prepared by CONCAWE (not substance-specific)
- ▶ Calculation of cost incurred for preparing the revised dossiers
- ▶ Fair share of this cost to be recovered from all registrants
- ▶ Updated dossier to be submitted by the Lead Registrant



ECHA Guidance - published August 2011

- ▶ Guidance on information requirements and chemical safety assessment Part B: Hazard Assessment
- ▶ Assess need to incorporate additional exposure scenarios in updates to registration dossiers
 - ▶ To minimize the number of dossier update iterations, target to complete the work at same time as requirement for submitting updated dossier for Annex 1 revision
 - ▶ Cost for updating dossiers is to be shared among all registrants whose dossiers are impacted
 - ▶ The cost should be shared in a fair, transparent and non-discriminatory manner while leveraging synergies of having to update dossiers for several reasons



- ▶ Common parts of the dossiers submitted may have to be updated (quasi) simultaneously for several reasons
- ▶ The update requirements may affect several dossiers to a similar extent (other example: IUCLID update to 5.4)
- ▶ A pragmatic approach is required to minimize work (and cost) for all parties involved:
 - The parties in charge of the technical work (contractors, consortium, experts)
 - The LR in charge of the Joint Submission
 - The SFF in charge of communicating with SIEF members/registrants about the updates & the requirements
 - The Consortium in charge of collecting the financial compensation for the updated dossiers
- ▶ In application of fairness and transparency principles, registrants should know what the updates cover, why they need to obtain them (Art 22) and what the additional costs represent.



Some issues which can arise:

No agreement on data compensation or cost sharing is found

- ▶ a justification of this shall be provided by the registrant in the updated dossier (cf Art 30.3)
- ▶ Registrants shall demonstrate having made every effort to reach an agreement

Registrants reluctant to obtain (pay for) the LoA to the updated dossier

- ▶ The previous registrant(s) shall have a claim on such registrants for a proportionate share of the cost incurred, which shall be enforceable in the national courts.
- ▶ Absence of LoA to the updated dossier should be picked by the local inspection authorities as a non-compliance case (to be seen what penalties would be incurred)

The SIEF process remains to be seen in practice





Thank you for your attention !

