# Feedback and Alignment on UVCBs dossier

# Outline

1. **Roadmap**
   - Actions road map & timeline, including feedback from ECHA's (ECHA meeting on January 22 and site visit on February 14)
2. **UVCB dossiers alignment**:
   - How we are working to ensure UVCB dossiers alignment
3. **Data access:**
   - Issues related to data access and experience on LoAs
4. **Registration submission specific issue**
5. **Aob**

# 1. Roadmap

- Responds to a specific ECHA request on January 22
- Identifies relevant aspects that need to be reflected in the dossiers:
  - Improve understanding
  - Rules not clear
- Highlights actions and timeline foreseen
- Reminds ECHA where their advice is needed
- Differentiates between short term, mid term and long terms actions

→ Useful checklist for us to keep track on actions & ensure alignements in the dossiers

# 1. Road map: short term (1)

How to ensure consistency within UVCBs dossiers?

| Topic | Objective | Action |
|---|---|---|
| Generic | Improve **understandability** of the overall approach | Include introduction explaining overall approach & highlight metals specificities |
| SID | Improve **communication/common understanding** on UVCBs processes and variability | Organise plant visit |
| | Check EINECs entries selected; **clarify scope** of UVCB dossiers and how variability is handled | Ensure unambiguous scope of the dossier & matching EINECS entries/substances registered. |

# 1. Road map: site visit (1)

- Site visit suggested to ECHA in December
- ECHA's constraints: site visit in Finland
- In January: agreement on site visit at Boliden on February 14:
  - ECHA SID Unit, Boliden and Outotec expert, Katia Lacasse and Hugo Waeterschoot
  - Boliden, smelter, electrolysis plant, Outotec

# 1. Road map: site visit (2)

- Cu flow sheet was presented and discussed as example of Flow sheet

- Outcomes of site visit:
  - Good, open and constructive discussion
  - Understanding of variability and what determines it
  - Understanding industry wants to make a solid but pragmatic case
  - Positive feedback also from ECHA's Scientific Advisor

# 1. Road map: site visit (3)

Remaining issues:

- Grouping of processes in SID & scope of EINECs
- ECHA SID has expertise on e.g. electrolysis
- Increased understanding from ECHA, does not go without better explanations in the dossier!!

# 1. Road map: short term (2)

| Topic | Objective | Action |
|---|---|---|
| Classification | Improve **understanding** by improve **documentation** on classification methodology to ensure **robustness** | Include introduction to explain overall approach with respect to classification & constituents summary table reporting speciation/ concentration used |
| | Improve **transparency** of MeClas outcomes | Include brief description of MeClas & justifications/validation for MeClas |

# 1. Road map: short term (3)

| Topic | Objective | Action |
|---|---|---|
| Hazard Assessment | Improve **understanding** of main principles & **explain** methodology: constituents based approach; worst speciation assumption if unknown | Include introduction to explain overall approach, how U&V of UVCB are addressed, include constituent summary table information |
| | Improve **transparency** on:<br>- DNELs/PNECs selection<br>- Traceability for future updates | Improve DNELs/PNECs table, include considerations on physical forms, hazard conclusions and timeline to include DNELs/PNECs |
| | Clarify data sharing rules for DNELs/PNECs available on dissemination website | ECHA to provide feedback on how such data could be used for registration |

# 1. Road map: short term (4)

| Topic | Objective | Action |
|---|---|---|
| Exposure Assessment | Improve **understanding** of main principles & **explain** methodology (use of monitoring data) | Explain the **scope** of the exposure assessment, data collection and **precautionary** nature of exposure assessment |
| | Report details on monitoring data analysis/ use | Explain use of TDP, biomonitoring data, monitoring data collection and analysis |

| Topic | Objective | Action |
|---|---|---|
| Risk Characterisation | Demonstrate robustness, scientifically based UVCB assessment | Report RCRs types based on data availability and demonstrate RCRs reliability/based on robust assumptions & report expected timeline for updates |

# 1. Road map: short term (5)

| Topic | Objective | Action |
|---|---|---|
| Uncertainty analysis | Include uncertainty analysis and **demonstrate robustness** of methodology | Demonstrate that variability of composition is reduced when doing exposure assessment |

| Topic | Objective | Action |
|---|---|---|
| Combined toxicity | Improve dossiers with **information** on **combined toxicity** as soon as it becomes available | Include **up-to-date scientific considerations** on combined toxicity, **state of the art** on scientific approaches (Tier 0 combined tox) and expected timeline |

# 1. Road map: other tasks at medium term

| Topic | Objective | Action |
|---|---|---|
| Hazard Assessment | Clarify DNELs/PNECs data selection to ensure **transparency** on **follow up** when data will be available | If DNELs/PNECs are currently not available: improve robustness of the approach/justification to limit qualitative assessment |
| Exposure assessment | **Improve** monitoring data report & demonstrate alignment with R14 Guid. Doc. | Improve explanation link between exposure data and constituents concentration |
| Uncertainty | **Improve** uncertainty analysis | Ensure report on conservatism applied and assess uncertainty specifically addressing UVCBs aspects |
| Validation | Work on **validation** of the approach and **enhance** credibility/robustness | Improve uncertainty analysis and include outcomes in dossiers |
| Combined toxicity | **Improve** dossier with information on comb tox as soon as available | Develop a tiered approach paper for environmental comb tox to consistently updated dossier |

# 1. Road map: other actions at long term

| Topic | Objective | Action |
|---|---|---|
| Classification | **Improve robustness** and **acceptance** of MeClas | Publish MeClas tool in peer-reviewed literature |
| Exposure assessment | **Improve robustness** and **acceptance** of MEASE | Implement recommendations from the ETAM project. Publish MEASE scientific documentation |
| Validation | **Improve validation** approach/ methodology to **enhance** credibility/robustness | Reflect on how to check assumptions |
| Combined toxicity | **Research on combined tox** to improve combined toxicity knowledge for updates/ validation of methodology | E.g. literature review |

# 2. UVCB dossiers alignment (1)

Short-term actions to create an EM checklist:

- EM could:
  - Provide support to consortia/consultants preparing UVCBs dossiers
  - Draft generic sections where relevant to be included
  - Keep track on further communication with ECHA:
    - how disseminated information can possibly be used
    - Check industry IUCLID proposal

# 2. UVCB dossiers alignment (2)

- Consortia/consultants could:
  - Continue with dossiers preparation
  - Have good summary of what ‘must be’ in the UVCBs CSR

- Issues o f importance:
  - Consistency within all consultants to finalise dossiers
  - Combined toxicity paragraph is needed to include it as generic item

# 3. Data access

- MMD is used as starting point for several metals
- LoA exercise is run in parallel to the use of MMD data:
  - Free data sharing agreement→ for most of the MMD substances
  - Free data sharing agreement→ for some of the non-MMD substances

- What are the issues consortia are currently experiencing?

# 4. Registration submission: specific issue

A specific case was raised in case of intermediates submission:

- LR confirms SCCs and provided ECHA with Appendix 3 data
- Co-registrants acknowledged ECHA on Article 10 upgrade

Can LR submits Art 10 dossier on behalf of the joint submission, claiming his SCCs status (i.e. lighter dossier needed)?

- Yes *(a LR can act as LR even in case he ceases manufacture!*)

- Reference Guidance: Data submission Manual, Part 05 - How to complete a technical dossier for registrations, February 2013

# 4. Registration submission: specific issue (LR)

- During the Dossier creation procedure, registrants are required to provide admistrative information
- Step 6 of the "Dossier creation wizard”: provide information in the so called "IUCLID 5 Dossier header”
- “IUCLID 5 Dossier header” allows ECHA to determine the type of dossier; is used to ensure that the dossier can be accepted for further processing;  it has also impact on the registration fee.

# 4. Registration submission: specific issue (co-registrants)

- During the Dossier creation procedure, registrants are required to provide admistrative information

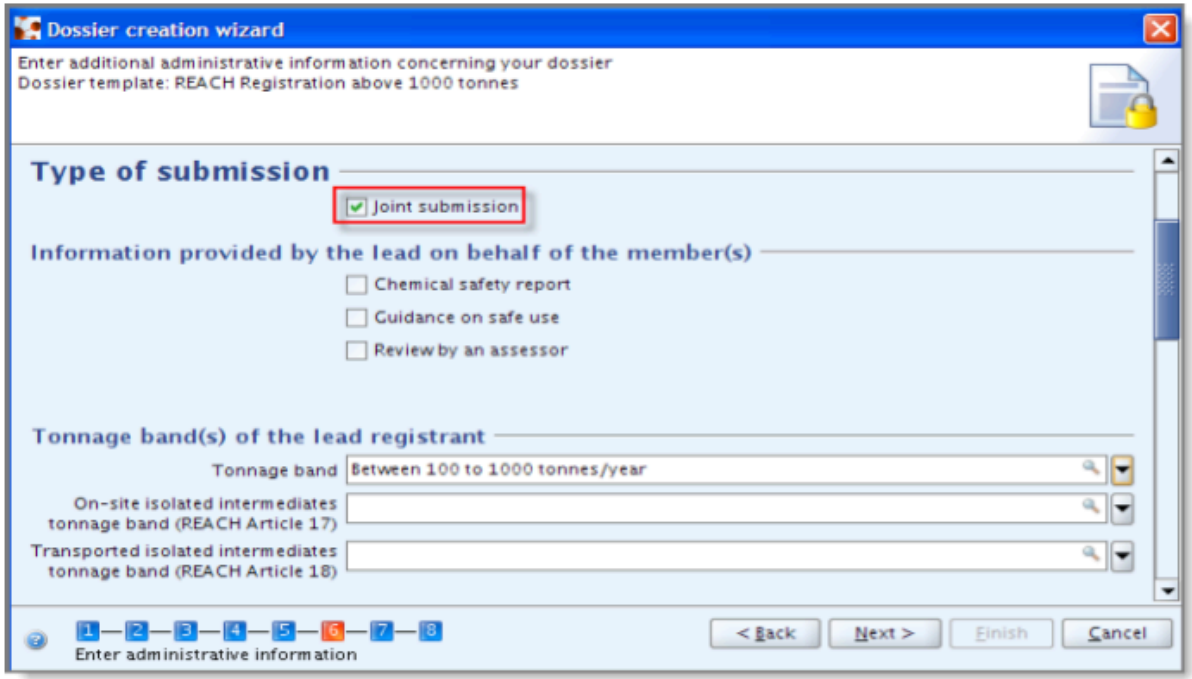
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# 4. How to complete Registration dossier: LR

- In box type of submission, ticks the “joint registration”
- In  tonnage band makes sure to indicate e.g. “Transported isolated Intermediate tonnage band (Article 18) as “above 1000tpa”

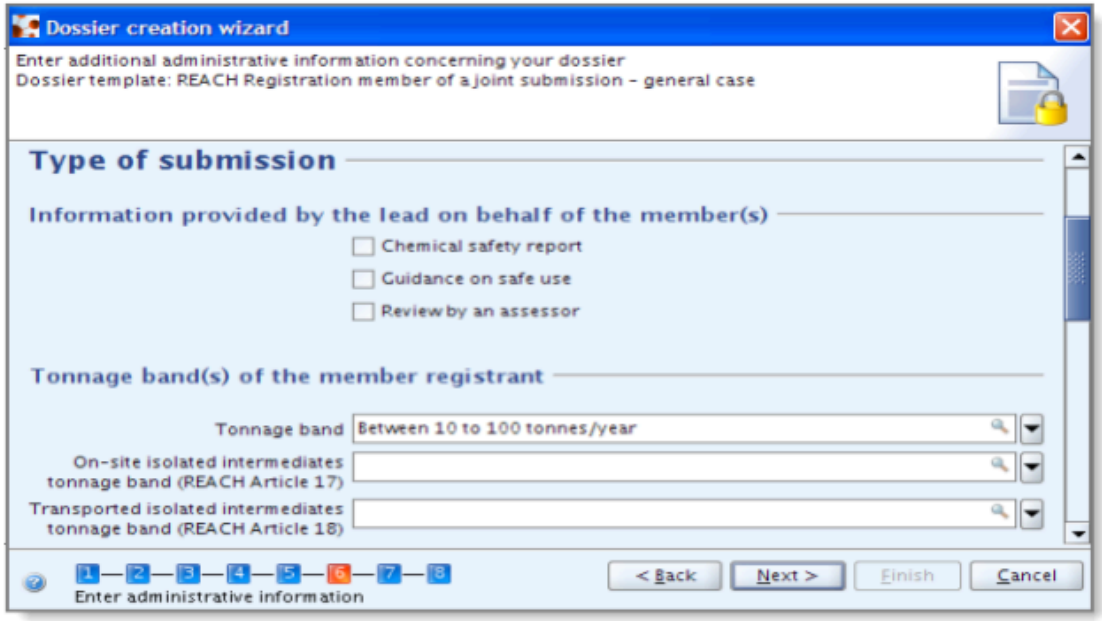
**Figure 64:  Joint submission (lead registrant)**



# 4. How to complete Registration dossier: members

- Members of joint submissions have previously selected one of the two member templates in dossier creation step 1:
  - "Member of a joint submission – general case" or
  - "Member of a joint submission – intermediates"
- In tonnage select "above 1000 tpa"

**Figure 65: Joint submission (member registrant)**



# 5. AoB

- ECHA is active in getting more information on the UVCBs submission:
  - How many dossiers are expected by end of April?
  - Does UVCB submission have an impact on SMEs?
  - MMD and access to other data