Common Substance Identity (SID) check PPP/CLH

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Need of Substance Identity (SID) check

- Undertaking a **SID check** at the early stage of the EFSA peer review process is considered an important aspect to ensure harmonization and consistency between the EFSA-ECHA naming convention, **even in cases where there is no parallel alignment of the two processes at the start of PC.**

- The aim is to avoid possible discrepancies in the naming between the same substances handled by the 2 agencies or requests for changes raised at a late stage of the process when amendments on naming consistently in all background documents would be difficult to undertake.

- To this end the ECHA **SID involvement in the PPP/CLH process** has been foreseen.

SID check includes the name used to identify the substance and the related identifiers (e.g. EC/CAS numbers)

Legal framework for aligned PPP/CLH

Commission Implementing Regulation (EU) No 2020/1740

- It is expected that in the near future, in the case of renewal of approval of active substances falling in the scope of **Commission Implementing Regulation (EU) No 2020/1740**, the issue of dis-alignment between the CLH and PPP process will not be an issue anymore as the **joint launch** of the PC will occur on a standard basis.
- To comply with the above Regulation, **at the latest at the time of submission of the draft renewal assessment report**, the RMS must submit a **proposal to ECHA** to obtain an opinion on a harmonised classification of the active substance at least for the hazard classes defined in Article 11(9) of Commission Implementing Regulation (EU) 2020/1740, or to confirm the existing classification, where applicable, or for re-classification of the active substance in accordance with the criteria of Regulation (EC) No 1272/2008.

Obligation for RMS:

Art 11(9): the **RMS should submit the CLH report to ECHA at the latest at the same time when submitting the RAR to EFSA**

Legally applicable timelines in the EFSA process

Renewals:

- max 3 months, in accordance with the provisions laid down in Art 12(1) of Regulation (EU) No 2020/1740:' *The Authority shall examine whether the draft renewal assessment report received from the rapporteur Member State contains all the relevant information in the agreed format and circulate it to the applicant and to the other Member States* ***at the latest three months*** *after its receipt.*'

NAS:

- max 30 days, in accordance with the provisions laid down in Art 12(1) of Regulation (EC) No 1107/2009: '*The Authority shall circulate the draft assessment report received from the rapporteur Member State to the applicant and the other Member States* ***at the latest 30 days*** *after its receipt. It shall ask the applicant to circulate an update of the dossier where applicable to the Member States, the Commission and the Authority*'.

EFSA is bound by strict legislative timelines allocated for the circulation of the assessment reports for commenting after receipt of the initial DAR/RAR

Alignment at the intake phase among EFSA and ECHA

RMS

Preparing CLH proposal to ECHA for parallel consultation

Drafting RAR and taking into accounts comments received in Public Consultation

Submission of RAR

EFSA/ECHA

Completeness check of RAR in EFSA

Accordance check of CLH report in ECHA

Uncertainty in the timelines for revisions of RAR/CLH by RMS?

Parallel consultation on CLH proposal with ECHA

Publication of RAR and starting public and targeted consultation

Collect comments from MS, applicant, EFSA and public

EFSA and ECHA are committed to ensure alignment in their processes

The aim would be also to align the SID check for substances during the completeness/accordance check phase.

SID Check

ECHA SID team will perform a **systematic SID check** for all **upcoming PPP substances**, even in the case where no alignment is foreseen, at an early stage, before the start of the process.

This will require additional resources to be put in place at the beginning of the process but it is expected to provide benefits to facilitate the alignment and avoid possible divergencies at a later stage.

The SID check will be undertaken on a **standard basis**, for all upcoming PPP substances, including those having **an ISO common name.**

Priority will be given depending on when the substances are expected to enter the peer review process

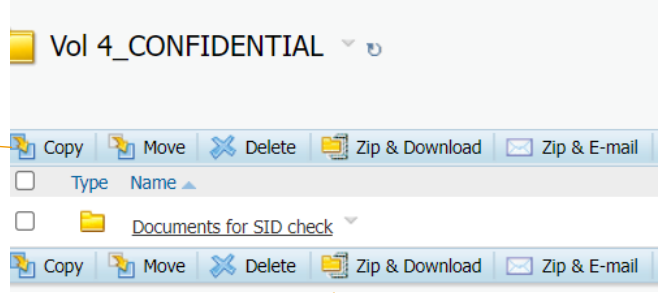
- **The planning of the upcoming DAR/RARs is available on EFSA DMS accessible to MSs/ECHA:**

- **Upcoming RARs:** https://dms.efsa.europa.eu/otcs/cs.exe?func=ll&objaction=overview&objid=11099466 (see columns N-O-P-Q-R concerning SID)

- **Upcoming DARs:** https://dms.efsa.europa.eu/otcs/cs.exe?func=ll&objaction=overview&objid=11099374 (see columns M-N-O concerning SID)

SID check and EFSA DMS

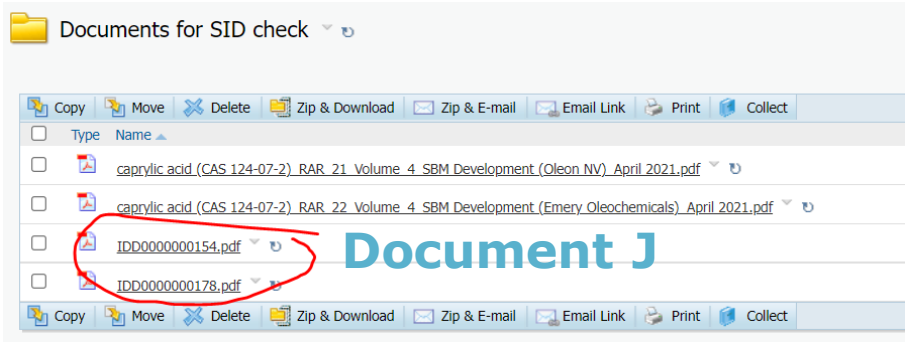
The documents for SID check are shared via the DMS external **'Assessment report'** folder: **01 Member States/ Vol 4 confidential/ 'Documents for SID check'.** The SID feedback can be uploaded to the same folder.



Document J (with the confidential core data containing the raw data on composition of the substance and manufacturing process) extracted from the applicants' dossier for the expected upcoming substances (AIR and NAS) are uploaded standardly in the same folder (completed for the substances expected for 2022).

For the upcoming substances with **IUCLID** dossiers, there will be no longer need to extract the Doc J from the dossiers; ECHA colleagues can check the relevant information directly in the IUCLID dossiers.

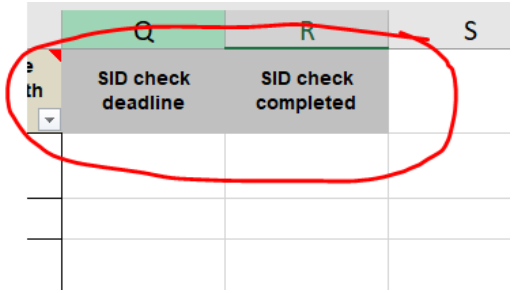
EFSA shares the DAR/RAR Vol 4 standardly at the moment it is received by EFSA, in the same dedicated DMS folder. The same dedicated folder for SID check is also **accessible to MSs.**



Potential need for clarifications to the RMS or proposed amendments will be included in the **SID feedback** when appropriate. The RMSs will be asked to consider eventual **SID comments** during the **CC check**.

Keeping timelines

- Potential verification by EFSA of the **SID feedback**, might be needed before changes on the naming and revisions of the RAR will be requested from the RMS during the CC.
- To keep on the status of substances under SID check and related **timelines** two columns to the expected **RAR excel sheet** (https://dms.efsa.europa.eu/otcs/cs.exe/link/11099466) were added. Same with **DAR excel sheet**.



- **To be filled in for all cases (CLH report and PPP RAR/DAR in parallel or not).**
- **The feedback on the SID check will be provided to the DS/RMS with the accordance check/completeness check outcome.**

Coordination FDP/PREV SC/Phys-chem colleagues

Conclusion

- In the case of renewal of approval of active substances falling in the scope of **Commission Implementing Regulation (EU) No 2020/1740**, a **joint launch of the PC** will occur on a standard basis. To comply with the above Regulation, at the latest at the time of submission of the draft renewal assessment report, the RMS must submit a proposal to ECHA to obtain an opinion on a harmonised classification of the active substance in accordance with the criteria of Regulation (EC) No 1272/2008.
- The aim would be to align the naming of the substance in the scope of Regulation 2020/1740 during the completeness/accordance check phase in the scope of **joint PCs in EFSA/ECHA**.
- Further **improvement of timelines in CC/ACC** is explored between ECHA and EFSA.

Inter-agencies collaboration

to improve the **consistency of assessments** common to both PPP and CLH also in view of One Substance One Assessment (OSOA)

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