

9 JULY 2019

[Eurometaux comments on  
CA/55/2019 Implementing Regulation on duty to update dossier](#)

Eurometaux has read with interest the document CA/55/2019 containing draft provisions for the **upcoming Implementing Regulation on duty to update dossier**. We thank the European Commission for the opportunity to comment on it prior to the launch of the interservice consultation.

Our general impression is that the proposed provisions do not take account of the reality of the joint submissions and the interconnection of the various elements of the registration dossier. The timeframes proposed in the current draft do not consider these aspects and should be increased in order to be implementable.

More specifically, we would like the European Commission to consider the revision of the proposal taking into account the following practicalities:

- Joint submissions are more common than individual submissions, so it is important to consider the time necessary to enable **decision-making within joint submissions** before updates can be actioned.
- The proposed timeframes are far too theoretical, and miss **the practical reality of submitting and maintaining joint REACH Dossiers**, as reference datasets containing the most recent and complete identification, classification and risk assessment of chemicals supplied to the EU market. Furthermore, it is important to note that these datasets constitute references beyond the EU-REACH scheme.
- The Implementing Regulation should take into account **the interconnection and interdependence between the individual items** that need to be updated and the overall dossier consistency. An update in an individual dossier's substance identity can affect the joint submission substance identification/scope, and such a change may need to be reflected in the classification and/or the risk assessment. Registration Dossiers are standalone datasets rather than a compilation of individual pieces of information. The timeframes proposed in the current draft do not consider the relationship there is between individual items and the overall risk assessment to be performed for a substance, and should be reviewed to enhance the 'compatibility' and 'interdependence' between each timeframe.
- CSA/CSR is a sort of overarching recap of the content of the IUCLID file. Changes made to the effects data or uses in the IUCLID file need to be reflected in the CSA/CSR. Updates to the CSA/CSR either take place immediately after or in parallel with updates to the IUCLID file. Changes to the CSA/CSR trigger a number of editorial adjustments as a minimum, and possibly a change in the conclusions that are subsequently communicated to the value chain, in the extended SDS. The timeframes proposed in the current draft do not consider the **alignment and consistency the IUCLID file and the CSA/CSR must have**, and should be reviewed to reflect the practical reality and role of the CSA/CSR.
- Dossier updates are typically managed as batches by companies or associations/consortia so that a number of update needs are identified and compiled into one actual update, at a frequency that varies depending on the amount and importance of the new information to be reported. The timeframes proposed in the current draft do not consider **the time-efficiency applied in the updates of joint submissions**, which will take place on a yearly basis rather than several times over the year.

Our detailed comments are available in the attached document "CA/55/2019\_Dossier-Updates-Eurometaux\_comments-Annex.pdf".

We feel also that a **guidance document** would be very useful to complement the Implementing Regulation.

**Contact persons at Eurometaux:**

Lorenzo Zullo ([zullo@eurometaux.be](mailto:zullo@eurometaux.be)), Violaine Verougstraete ([verougstraete@eurometaux.be](mailto:verougstraete@eurometaux.be))

