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## **IE comments on document CA/55/2019 on an Implementing regulation on the duty to update dossiers**

We thank the Commission for document CA/55/2019 on an Implementing Regulation on the duty to update dossiers, which was discussed at the recent CARACAL 30 meeting on July 1<sup>st</sup>. During that meeting, we made some interventions. We note that this paper is also on the agenda of the REACH Committee meeting which will be held on July 9<sup>th</sup> and 10<sup>th</sup> and we have noted that in the recent rev 1 version of the paper, some of the issues we raised during the CARACAL discussions have been addressed. Therefore, we will not fully repeat the points we made during the CARACAL meeting here.

We have some remaining points for your consideration ahead of the interservice consultation, as follows:

- Article 2 of the draft Implementing Regulation states *“In line with the obligation to assemble and keep information in accordance with Article 36 of Regulation (EC) No 1907/2006, registrants shall have monitoring and tracking systems in place that enable them to identify if any of the cases itemized in Article 22(1) of Regulation (EC) No 1907-2006 have occurred”*. This appears to go beyond the current requirement in Article 36 of REACH, in that it requires registrants to have a “monitoring and tracking system” in place whereas Article 36 requires registrants to “assemble and keep available all information” needed to carry out his duties. This may require further consideration.

Background point 8 also mentions that the relevant triggers should be described by ECHA in guidance documents. It is unclear what additional information would be provided in guidance documents, other than what is already specified in Article 22(1) of REACH.

- Article 5(1) and Article 5(3) state: *“As of the moment that the registrant becomes aware...”*  
It may be difficult to determine “as of the moment”, which may lead to difficulties from an enforcement point of view. While we appreciate that Article 12(2) of REACH is generally saying the same thing, we would suggest that the wording is amended to align it with Article 12(2): *“As soon as the registrant becomes aware...”*
- Article 5(4) addresses updates related to cessation of manufacture or import, where the volume in the registration dossier is set to zero and the registration status is “inactive”. Article 5(5) addresses restart of manufacture or import, where the volume in the registration dossier is increased and the registration is re-activated.

We note that “cease of manufacture or import” is also possible by a registrant upon receipt of a draft evaluation decision in accordance with Article 50(3) of REACH. In such scenarios, the registration is no longer valid (it is revoked rather than inactivated) and thus it is not possible to “restart” manufacture or import without the submission of a new registration dossier.



While we appreciate that the provisions outlined in Articles 5(4) and 5(5) of the draft Implementing Regulation relate only to Article 22(1)(c) of REACH, as the term “cease of manufacture or import” is used in the context of both Article 22(1) and Article 50(3) of REACH, consideration could be given to clarifying that the provision outlined in Article 5 of the draft Implementing Regulation does not apply to cease of manufacture or import as outlined in Article 50(3) of REACH. This would avoid any misinterpretation by industry.

**Health and Safety Authority.**

**9<sup>th</sup> July 2019**