



EUROPEAN COMMISSION
ENVIRONMENT DIRECTORATE-GENERAL
Circular Economy and Green Growth
Sustainable Chemicals

DIRECTORATE-GENERAL INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES
Consumer, Environmental and Health Technologies
REACH
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Room: 1D

Centre Albert Borschette

Concerns: Implementing Regulation on duty to update dossiers - Status update

Agenda Point: 5.1

Action Requested: For discussion

Written comments on this document should be sent by 30 August 2019 to
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Background:

- (1) Article 132 of Regulation (EC) No 1907/2006 (REACH) requires that the measures necessary to put the provisions of that Regulation efficiently into effect shall be adopted in accordance with the procedure referred to in Article 133(3) therein.
- (2) Following expiry of the final registration deadline for the transitional phase-in regime on 1 June 2018, it has become a priority that registration dossiers are fully compliant with the applicable standard information requirements.
- (3) The Commission reports in accordance with Article 117(4) of REACH on the experience acquired with the operation of REACH show the need to improve the effective update of registration dossiers in order to maintain or achieve full compliance.
- (4) In order to allow the European Chemical Agency ('the Agency') and Member States to efficiently evaluate registration dossiers and substances, registrants need to ensure that the dossiers are coherent and compliant at any time, enabling them to ensure that advice on safe use is based on up-to-date and reliable data.
- (5) Article 22 of REACH describes the further duties of registrants once they completed their registration pertaining to updates of their registration. These updates should be undertaken 'without undue delay' in the cases provided in Article 22(1)(a)-(i) or as requested by the Agency from the registrant in accordance with Article 22(2).
- (6) Taking into account the practical experience the Agency has acquired since REACH is in force, Article 22(1) should be put efficiently into effect. Therefore, this Implementing Regulation specifies timeframes for the updates in accordance with the individual cases listed in Article 22(1)(a)-(i). Those timeframes should be understood as upper limits, i.e. registrants should provide the update as swiftly as possible and exceeding the timeframe would lead to the conclusion that an undue delay in updating exists.
- (7) This Implementing Regulation will neither affect the updates of registrations requested by the Agency in accordance with Article 22(2) of REACH nor the specific timeframes already foreseen in REACH for other regulatory processes.
- (8) In order for the system of dossier updates to operate effectively, registrants should put in place appropriate mechanisms to ensure that the need for a dossier update, and corresponding update of the Chemical Safety Assessment (CSA)/Chemical Safety Report (CSR) if relevant, is promptly identified. The relevant triggers should be part of internal management processes and practices of the registrants. The Agency should describe the triggers in guidance documents.
- (9) In line with the objectives of the Article 1(3) of REACH and underpinned by its recitals 16 to 19, the registrants have the responsibility to manage the risks of a substance. Registrants are therefore expected to actively and periodically - e.g. at least once per year - review if the conditions for dossier updates according to Article 22(1) are met. Article 36 of REACH requires registrants to assemble and keep any related information.

- (10) For the update of dossiers, which are part of a joint submission, registrants should fulfil their registration and data-sharing obligations in a fair, transparent and non-discriminatory way as specified in Title III of REACH, as well as in Implementing Regulation (EU) 2016/9.
- (11) All updated registration dossiers are subject to a completeness check conducted by the Agency in accordance with the first two subparagraphs of Article 20(2) of REACH. For updates involving a change of tonnage band in accordance with Articles 12(2) and 22(1)(c), the entire Article 20(2) applies. Based on the third and fourth subparagraph of Articles 20(2), the third subparagraph of Article 21(1) and Article 22(3), the Agency should reject the update to the higher tonnage band, in case of an incomplete registration, but only after having given the registrant the opportunity to provide the complete data within a reasonable timeframe.
- (12) The obligation to ensure through effective, proportionate and dissuasive measures that a registrant updates his registration in line with his REACH obligations is an enforcement duty of the Member States.

Draft provisions prior to Interservice Consultation for input:

Article 1

Specifying the meaning of "without undue delay" in Article 22(1) of Regulation (EC) No 1907/2006

1. This Implementing Regulation specifies the meaning of “without undue delay”, as referred to in Article 22(1) of Regulation (EC) No 1907/2006. For this purpose, the appropriate timeframes, within which a registrant shall update his registration with new relevant information in the specific cases of Article 22(1)(a)-(i) of Regulation (EC) No 1907/2006 and submit such information to the Agency, are detailed in Articles 3 to 11 of this Implementing Regulation. These timeframes are upper time limits and apply without prejudice to the timeframes specified for updates in accordance with Article 22(2) of Regulation (EC) No 1907/2006.
2. Where an update under Article 22(1)(a)-(i) triggers the need to also update the Chemical Safety Assessment and the Chemical Safety Report, only one combined update shall be submitted, addressing all different aspects to ensure complete and compliant content in the registration dossier. The timeframe for submitting that combined update shall be 6 months.

Article 2

Tracking the changes specified in Article 22(1) of Regulation (EC) No 1907/2006

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 itemised in Article 22(1) of Regulation (EC) No 1907/2006 have occurred.

Article 3

Changes in a registrant's status or in his identity

Any change in accordance with Article 22(1)(a) of Regulation (EC) No 1907/2006 shall be updated within 1 month of that change taking effect legally.

Article 4

Changes in the composition of the substance

Any change in accordance with Article 22(1)(b) of Regulation (EC) No 1907/2006 shall be updated within 6 months from start of manufacturing or import with the changed substance composition.

Article 5

Changes in the annual or total quantities manufactured or imported resulting in a change of tonnage band, including cessation of manufacture or import

1. As of the moment that the registrant becomes aware that the next tonnage threshold is reached, the registrant shall immediately submit an inquiry to the Agency in accordance with Article 12(2) of Regulation (EC) No 1907/2006.
2. In accordance with Article 22(1)(c) of that Regulation, based on the communication of the Agency in response to the inquiry, the registrant shall update his registration with relevant information and submit it to the Agency:
 - within 6 months in case of submission of testing proposals or additional existing data; submission of member dossiers within the tonnage band of the joint submission; submission of additional tonnage information for intermediate use under strictly controlled conditions;
 - within 6 months after receiving the final test report from the laboratory in case new data is generated for an update to Annex VII or Annex VIII.
3. As of the moment that the registrant becomes aware that a lower tonnage threshold is reached, the registrant shall submit an update to the Agency within 1 month.
4. If manufacture or import ceased, the registrant shall submit an update to the Agency within 1 month from the time he last manufactured or imported.
5. If manufacture or import restarts, the registrant shall submit an update to the Agency before restarting.

Article 6

New identified uses and new uses advised against

In accordance with Articles 22(1)(d) and 37(3) of Regulation (EC) No 1907/2006, updates pertaining to new uses, uses that are no longer relevant, or uses advised against shall be made within 1 month from receiving all relevant information on them, with a view to preparing an exposure scenario or category of use in the related chemical safety assessment and chemical safety report.

Article 7

New knowledge of the risks of the substance to human health and/or the environment

1. In accordance with Article 22(1)(e) of Regulation (EC) No 1907/2006 new knowledge means any information becoming available to the registrant since the last update, or, in the absence of updates, since the initial registration. Such new knowledge shall be understood as originating from inter alia:
 - Reports of risks of the substance published in peer-reviewed literature (including inter alia new hazard information for human health or environmental safety and new exposure information (e.g. monitoring, epidemiology));
 - Hazard or risk assessments of the substance conducted by competent authorities or scientific institutes (including e.g. reports and opinions identifying a substance as PBT or vPvB substance);
 - Information on the substance, its uses and corresponding risk management measures, generated and communicated within the supply chain.

2. In order to put Article 22(1)(e) of Regulation (EC) No 1907/2006 efficiently into effect, the registrant shall be obliged to periodically review relevant information sources.

3. Updates related to such new knowledge, including changes to the classification and labelling if applicable, shall be done within 6 months from the registrant having such knowledge. This timeframe does not apply to the occasions triggering a safety data sheet update in accordance with Article 31(9)(a) - (c) of Regulation (EC) No 1907/2006.

Article 8

Changes in the classification and labelling of the registered substance

In accordance with Article 22(1)(f) of Regulation (EC) No 1907/2006, once a change in the classification and labelling of the registered substance occurs (due to inter alia changed self-classification, harmonised classification or changes to the CLP Regulation), the changed classification shall be updated within 1 month from when it is applied.

Article 9

Updates or amendments of the chemical safety report

In accordance with Article 22(1)(g) of Regulation (EC) No 1907/2006, information pertaining to changes of the chemical safety report shall be updated within 6 months from the moment a need for changing the chemical safety report is identified, including when an application for authorisation (Article 62(4) of Regulation (EC) No 1907/2006) has been submitted by the registrant.

Article 10

Testing proposals prior to conducting a test listed in Annex IX or Annex X

In accordance with Article 22(1)(h) of Regulation (EC) No 1907/2006, if a registrant or a consortium of joint registrants identifies the need to perform a test listed in Annex IX or X, he shall develop a testing proposal and update his registration accordingly within 6 months.

Article 11

Changes in the access granted to information in the registration

In accordance with Article 22(1)(i) of Regulation (EC) No 1907/2006, new confidentiality requests shall be added at the same time as the new information is added in the registration. In cases where granted confidentiality is no longer treated as such by the registrant, the registrant shall submit an update to the Agency within 1 month.

Article 12

Updates of joint submissions and data-sharing

1. In case of joint submissions, the data sharing obligations under both Regulation (EC) No 1907/2006 and Implementing Regulation (EU) 2016/9 shall also apply to dossier updates, including on costs related to a review of potential new information as per Article 22(1)(e) of Regulation (EC) No 1907/2006.
2. The update timeframes referred to in Articles 3 to 11 of this Implementing Regulation shall be applied to both the lead registrant and each of the members of the joint submission. For cases where an update from a member of a joint submission requires a prior update from the lead registrant, the member registrant has 1 month to submit the update, counted from the date the updated lead submission was deemed complete.

Article 13

Completeness checks of registration updates concerning a change of tonnage band

1. Where, in accordance with Article 22(1)(c) of Regulation (EC) No 1907/2006, an update of a registration dossier concerning increased quantities and a change of tonnage band has been submitted and found incomplete as result of a completeness check, the Agency has the power to reject that update in accordance with Article 20(2), the third subparagraph of Article 21(1) and Article 22(3) of Regulation (EC) No 1907/2006.
2. As a consequence of the rejected update the registrant may neither import nor manufacture the increased quantities.
3. The Agency shall reject an update only after having given the registrant the opportunity to provide the missing information within a reasonable deadline.