Commission Implementing Regulation (EU) 2020/1435 of 9 October 2020 on the duties placed on registrants to update their registrations under Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1435

of 9 October 2020

on the duties placed on registrants to update their registrations under Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC[(1)], and in particular Article 132 thereof,

Whereas:

(1) The Council Conclusions of 26 June 2019‘Towards a Sustainable Chemicals Policy Strategy of the Union’ reiterated the importance of concrete actions to ensure the compliance and improve the quality of registration dossiers; and in particular the need for an effective mechanism for their updating.

(2) Article 22(1) of Regulation (EC) No 1907/2006 places a responsibility on registrants (whether individual registrants or the lead registrant and other members of a joint submission) to update their registrations without undue delay with relevant new information and submit them to the European Chemicals Agency (‘the Agency’). Information counts as ‘new’ if the registrant has become aware of it or may reasonably be expected to have become aware of it since the last update or, in the absence of any updates, since initial registration, whether or not the information actually existed before then. The responsibility to update their registrations requires registrants to monitor and track all relevant information in order to ensure their registrations remain up-to-date at all times. In the case of joint submissions, the responsibility to update the registration is, for information that was jointly submitted, the responsibility of all the registrants in accordance with Article 11 of Regulation (EC) No 1907/2006 and is covered by the data-sharing and cost-sharing provisions laid down in Commission Implementing Regulation (EU) 2016/9[(2)].

Changes to legislation: *Commission Implementing Regulation (EU) 2020/1435 is up to date with all changes known to be in force on or before 18 August 2021. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(3) The latest general report published by the Commission in accordance with Article 117(4) of Regulation (EC) No 1907/2006 indicated a need to improve compliance with the obligation placed on registrants in Article 22(1) of that Regulation. Compliance with that obligation is important to ensure that registration dossiers reflect the current situation at all times, so that the Agency and Member States can evaluate dossiers and substances in an efficient manner and advice on safe use is based on up-to-date and reliable data. Therefore, in order to facilitate compliance with and enforcement of Article 22(1) of Regulation (EC) No 1907/2006 and improve efficiency in giving effect to the provisions of that Regulation, it is appropriate to specify deadlines by which that obligation is to be complied with.

(4) In order to facilitate compliance with, and enforcement of, the provisions on information requirements in Article 10 and 12 of Regulation (EC) No 1907/2006, and consequently also of the general and ongoing obligation to register in Articles 6 and 7 of that Regulation, the deadlines that apply to the update of registration dossiers after an amendment of the Annexes to that Regulation should be clarified.

(5) The deadlines specified by this Regulation should be as short as possible, taking into account what, based on past practice, is reasonably attainable by registrants. On that basis, a deadline of three months should be specified for updates of a more administrative nature and if updates include the generation of data to fulfil the requirements of Annex VII or VIII to Regulation (EC) No 1907/2006 following receipt of the study report. Deadlines of six, nine or 12 months should be specified for more complex updates, such as those requiring the generation of data based on a testing proposal or changes to the chemical safety report or the guidance on safe use. In cases where a member of a joint submission cannot make a particular update until the lead registrant has first updated the registration, that member should be given nine months for the update of a chemical safety report and three months for any other update from the date when the Agency confirmed that the registration as updated by the lead registrant is complete. In cases where an update is required as a consequence of an amendment to the Annexes to Regulation (EC) No 1907/2006, the deadline should be its date of applicability except where another deadline is provided in such an amendment.

(6) The deadlines specified by this Regulation should operate as upper limits. In other words, registrants should be required to provide updates as swiftly as possible and in any event by no later than the relevant specified deadline. Exceeding the deadline would automatically lead to the conclusion that an undue delay had occurred in updating the registration. However, for the purposes of point (c) of Article 22(1) of Regulation (EC) No 1907/2006, no deadline should be specified for the update triggered by a change to a lower tonnage band, given that such a change in tonnage may be of a temporary nature and the update would not have any negative consequence for the protection of human health and the environment.

(7) The deadlines specified by this Regulation, with the exception of Article 13 of this Regulation, should apply only to the obligation in Article 22(1) of Regulation (EC) No 1907/2006, not to other updating obligations in that Regulation for which deadlines are specified elsewhere. It follows that the deadlines specified by this Regulation will not

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affect the deadlines for updates requested by the Agency in accordance with Article 22(2) of that Regulation, nor the specific deadlines laid down in Articles 31 and 32 and in Title V of that Regulation.

(8) In order to allow registrants sufficient time to adapt to introduction of the deadlines specified by this Regulation, this Regulation should not enter into force until the sixtieth day following that of its publication.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133(1) of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Changes in a registrant's status or in his identity

In the case of a change falling within point (a) of Article 22(1) of Regulation (EC) No 1907/2006, the registration shall be updated and submitted to the Agency by no later than 3 months from the date when that change takes effect.

Article 2

Changes in the composition of the substance

In the case of a change falling within point (b) of Article 22(1) of Regulation (EC) No 1907/2006, the registration shall be updated and submitted to the Agency by no later than 3 months from the date when manufacture or import begins with that change in substance composition.

Article 3

Changes in tonnage band

1 In the case of a change falling within point (c) of Article 22(1) of Regulation (EC) No 1907/2006 that results in a higher tonnage band, the registration shall be updated and submitted to the Agency by no later than 3 months from the following date:

a in a case where new data is generated for an update derived from the application of Annex VII or Annex VIII to Regulation (EC) No 1907/2006, the date when all the final test reports needed for the update have been received;

b in a case not falling within point (a), the date when the higher tonnage band is reached.

For cases referred to in point (a) of the first subparagraph, a contract negotiation with a testing laboratory shall be initiated for all the relevant tests by no later than 3 months from the date when the higher tonnage band is reached.

The deadlines specified in paragraph 1 of this Article apply without prejudice to the obligation of a registrant to inform immediately the Agency of the additional information he would require, as soon as the higher tonnage band is reached, in accordance with Article 12(2) of Regulation (EC) No 1907/2006.

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2 In the case of a change falling within point (c) of Article 22(1) of Regulation (EC) No 1907/2006 that involves cessation of manufacture or import, the registration shall be updated and submitted to the Agency by no later than 3 months from the date when manufacture or import ceased.

3 Paragraph 1 of this Article does not apply if the change occurs as a result of the registrant restarting manufacture or import in accordance with Article 50(2) of Regulation (EC) No 1907/2006. Instead, in that situation, the registration shall be updated and submitted to the Agency before manufacture or import is restarted.

Article 4

New identified uses and new uses advised against

In a case falling within point (d) of Article 22(1) of Regulation (EC) No 1907/2006, the registration shall be updated and submitted to the Agency by no later than 3 months from:

(a) in the case of a new identified use, the date when the registrant receives all the information needed to carry out the risk assessment for this new use;

(b) in the case of a new use advised against, the date when the information on the risks associated with that use is available to the registrant.

Article 5

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

In a case falling within point (e) of Article 22(1) of Regulation (EC) No 1907/2006, the registration shall be updated and submitted to the Agency by no later than 6 months from the date when the registrant becomes aware or may reasonably be expected to have become aware of the new knowledge in question.

Article 6

Changes in the classification and labelling of the registered substance

1 In the case of a change falling within point (f) of Article 22(1) of Regulation (EC) No 1907/2006 that is due to the addition, modification or deletion of a harmonised classification in Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(3)], the registration shall be updated and submitted to the Agency by no later than the date as of which that change is to apply.

2 In the case of a change falling within point (f) of Article 22(1) of Regulation (EC) No 1907/2006 that is due to an adaptation in the classification of a substance as a result of a new evaluation in accordance with Article 15 of Regulation (EC) No 1272/2008, the registration shall be updated and submitted to the Agency by no later than 6 months from the date when the decision to change the classification and labelling of the substance has been taken.