



EUROPEAN
COMMISSION

Brussels, **XXX**
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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**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) .../...

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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/EC¹, and in particular Article 132 thereof,

Whereas:

- (1) 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) 2016/9².
- (2) 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

¹ OJ L 396, 30.12.2006, p. 1.

² Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data-sharing in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 3, 6.1.2016, p. 41–45.

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.

- (3) 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 after the reception of the study report. Deadlines of six, nine or twelve 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.
- (4) 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.
- (5) The deadlines specified by 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 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, nor the deadlines for updates as a result of amendments to any of the Annexes to that Regulation.
- (6) 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.
- (7) 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.

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 Council³, 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.

Article 7

Updates or amendments of the chemical safety report or the guidance on safe use

In a case falling within point (g) of Article 22(1) of Regulation (EC) No 1907/2006, the registration shall be updated and submitted to the Agency by no later than 12 months from the date when the need to update or amend the chemical safety report or the guidance on safe use referred to in Section 5 of Annex VI to that Regulation was identified.

Article 8

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

1. In a case falling within point (h) of Article 22(1) of Regulation (EC) No 1907/2006, the registration shall be updated to include the testing proposal and submitted to the Agency by no later than 6 months from the date when the registrant identifies the need to perform one or more of the tests listed in Annex IX or X to that Regulation.

2. The deadline specified in paragraph 1 of this Article shall not apply in the case of a testing proposal developed as part of a testing strategy addressing a group of substances. Instead, in that situation the relevant registrations shall be updated and submitted to the Agency by no later than 12 months from the date when the registrant or registrants identify the need to perform one or more of the tests listed in Annex IX or X to that Regulation.

³ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

Article 9

Changes in the access granted to information in the registration

In the case of a change falling within point (i) 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 the change occurred.

Article 10

Updates involving further testing

The deadlines specified in Articles 1, 2, 4, 5 and 6 of this Regulation shall not apply if any circumstance falling within point (a), (b), (d), (e) or (f) of Article 22(1) of Regulation (EC) No 1907/2006 triggers the need to generate data to satisfy the information requirements laid down in Annex VII or VIII to Regulation (EC) No 1907/2006.

In this case, the update to the registration as a result of that circumstance and the update to the registration as a result of satisfying the data requirements of Annex VII or VIII shall be submitted to the Agency together by no later than 3 months from the date when the final test reports needed for the update have been received.

In such a circumstance:

- (a) the contract negotiation with a testing laboratory shall be initiated for the relevant tests by no later than 3 months from the date when the need to conduct further tests is identified;
- (b) the need to conduct further tests referred to in point a) shall be identified within the relevant deadline specified in Article 1, 2, 4, 5 or 6 of this Regulation.

Article 11

Other combined updates

1. In a case covered by Article 10 of this Regulation or falling within points (a) to (f) or (i) of Article 22(1) of Regulation (EC) No 1907/2006 that also triggers the need to update or amend the chemical safety report or the guidance on safe use in accordance with point (g) of Article 22(1) of that Regulation, the update to the registration as a result of that circumstance and the update to the registration as a result of updating or amending the chemical safety report shall be submitted to the Agency together by no later than 12 months from the date when the final test reports needed for the update have been received.

2. Without prejudice to paragraph 1 of this Article, an update of a registration that is the result of a circumstance falling within more than one of the points (a) to (i) of Article 22(1) of Regulation (EC) No 1907/2006 shall be submitted to the Agency together by no later than the longest deadline specified in Articles 1 to 10 of this Regulation, counting from the date when the first need to update the registration was identified.

Article 12

Updates of joint submissions

1. By way of derogation from the preceding Articles of this Regulation, where an update by a member of a joint submission pursuant to Article 22(1) of Regulation (EC) No 1907/2006 is

dependent on the lead registrant making a prior update to the registration, that member shall update his registration and submit it to the Agency by:

- (a) no later than 3 months, in a case requiring an update as a result of a circumstance falling within points (a) to (f), or (i) of Article 22(1) of Regulation (EC) No 1907/2006;
- (b) no later than 9 months, in a case requiring an update or amendment of the chemical safety report or the guidance on safe use, in accordance with point (g) of Article 22(1) of Regulation (EC) No 1907/2006;
- (c) no later than 9 months, in case a circumstance falling within points (a) to (f) or (i) of Article 22(1) of Regulation (EC) No 1907/2006 that also triggers the need to update or amend an existing chemical safety report or the guidance on safe use, in accordance with point (g) of Article 22(1) of that Regulation. In that situation, the update to the registration as a result of that circumstance and the update to the registration as a result of updating or amending the chemical safety report or the guidance on safe use shall be submitted to the Agency together.

2. The deadlines specified in paragraph 1 of this Article shall apply from the date when the Agency informs the lead registrant, in accordance with Article 22(3) of Regulation (EC) No 1907/2006, and the other members of the joint submission that the registration dossier as updated by the lead registrant is complete.

3. Where an update by a member of a joint submission pursuant to Article 22(1) of Regulation (EC) No 1907/2006 is not dependent on the lead registrant making a prior update to the registration, the deadlines specified in Articles 1 to 11 of this Regulation shall apply.

Article 13

Entry into force

This Regulation shall enter into force on the sixtieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
Ursula von der Leyen
The President