EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

amending Implementing Regulation (EU) No 307/2012 as regards transparency and confidentiality requirements for the EU risk assessment of substances under scrutiny

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION IMPLEMENTING REGULATION (EU) …/...

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amending Implementing Regulation (EU) No 307/2012 as regards transparency and confidentiality requirements for the EU risk assessment of substances under scrutiny

(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 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods[1], and in particular Article 8(6) thereof,

Whereas:

(1) Regulation (EC) No 1925/2006 harmonises the national rules in Member States on the addition of vitamins and minerals and of certain other substances to foods.

(2) Commission Implementing Regulation (EU) No 307/2012[2] lays down, in particular, implementing rules for the application of the procedure referred to in Article 8(4) and (5) of Regulation (EC) No 1925/2006 concerning the safety assessment by the European Food Safety Authority ('the Authority') of the substances under scrutiny listed in Part C of Annex III thereto.

(3) Regulation (EU) 2019/1381 of the European Parliament and the Council[3] amended Regulation (EC) No 178/2002 of the European Parliament and of the Council[4]. Those amendments are aimed at strengthening the transparency and the sustainability of the EU risk assessment in all areas of the food chain where the Authority delivers a scientific risk assessment.

(4) The amendments to Regulation (EC) No 178/2002 introduced new provisions concerning, amongst others, general pre-submission advice by the staff of the Authority at the request of a potential applicant and the obligation to notify studies commissioned or carried out by business operators to support an application and the consequences in case of non-compliance with that obligation. The amendments also

1 Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 11 April 2012 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 102, 12.4.2012, p. 2).

2 Commission Implementing Regulation (EU) No 307/2012 of 11 April 2012 establishing implementing rules for the application of Article 8 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods (OJ L 102, 12.4.2012, p. 2).

3 Regulation (EU)_2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and the sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (OJ L 231, 6.9.2019, p. 1).

4 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 2.2.2002, p. 1).

introduced provisions on the public disclosure, by the Authority, of all scientific data, studies and other information supporting applications, with the exception of duly justified confidential information, early on in the risk assessment process, followed up by a consultation of third parties.

(5) Although Regulation (EU) 2019/1381 does not contain any provisions concerning the risk assessment of substances or ingredients, which had been listed to Annex III to Regulation (EC) No 1925/2006, its provisions are of direct relevance to that procedure, as outlined in Article 8(4) and (5) of Regulation (EC) No 1925/2006. These provisions concern the pre-submission phase, as regards pre-submission advice and the notification of commissioned studies, as well as the risk assessment phase, as regards transparency and confidentiality requirements and public consultations. They govern mainly application-based processes initiated by food business operators.

(6) Regulation (EC) No 1925/2006 gives an important role in demonstrating the safety of a particular substance under scrutiny listed in Part C of Annex III thereto not only to food business operators, but also to other interested parties, such as industry organisations or consumer organisations. Therefore, the evaluation of a substance under scrutiny does not require the submission of an application by a designated applicant, but all interested business operators and other interested parties may submit data and information to that end.

(7) It is necessary to ensure that the procedure for the safety assessment of the substance under scrutiny listed in Part C of Annex III to Regulation (EC) No 1925/2006 is governed by provisions comparable to those in Regulation (EU) 2019/1381 both for the pre-submission and the risk assessment phases.

(8) In view of the above, Regulation (EU) No 307/2012 should be aligned with the amendments to Regulation (EC) No 178/2002 introduced by Regulation (EU) 2019/1381, in particular as regards (i) the possibility, provided for in Article 32a, to request pre-submission advice from the staff of the Authority, whenever the Authority is required or requested to provide an opinion; (ii) the obligation, set out in Article 32b, to notify relevant studies to the Authority; (iii) the obligation of the Authority to consult third parties set out in Article 32(c), (iv) the obligations as regards the form of the submissions set out in Article 39f, and (iv) the confidentiality rules provided for in Article 39.

(9) The provision by the Authority, upon request, of pre-submission advice on the rules applicable to, and the content required for the submission of the files demonstrating the safety of a substance under scrutiny, listed in Part C of Annex III to Regulation (EU) No 1925/2006, can improve the quality of the submissions, and thus provide support to the safety assessment. However, food business operators and any other interested parties may not be able to make full use of the pre-submission advice due to the deadline for the submission of their files. In the interest of the improved quality of the scientific assessment, food business operators and other interested parties should be able to request pre-submission advice for a potential submission from the day of the adoption of an opinion by the Authority under Article 8(2) of Regulation (EU) 1925/2006, which identifies the possibility of harmful effects on health associated with the intake of a substance, but scientific uncertainty persists.

(10) The studies required to prove the safety of a substance under scrutiny, listed in Part C to Annex III to Regulation (EU) 1925/2006, take in account a number of factors and therefore may vary significantly. Extending the period for food business operators or interested parties to submit files from 18 to 24 months from the date on which a

substance has been listed in Part C of Annex III to Regulation (EU) No 1925/2006 can facilitate the preparation and submission of files, and therefore provide support to the safety assessment.

(11) The obligation to notify relevant studies set out in Article 32b of Regulation (EC) No 178/2002 should apply also to food business operators or interested parties who intend to submit for evaluation the file as defined in Article 2 of Regulation (EU) No 307/2012. A further adaptation to the procedure of Article 32b of Regulation (EC) No 178/200 is however, required. The procedural consequences provided for by Article 32b of Regulation (EC) No 178/2002 in case of non-compliance with its provisions result in delays in the assessment of the file. However, given the imperative time limit of 4 years prescribed by Article 8(5) of Regulation (EU) 1925/2006 delays in the evaluation could mean that the prescribed time limit would not be respected. Therefore, those procedural consequences are not appropriate in the context of the evaluation procedure for substances placed in Part C of Annex III to Regulation (EU) No 1925/2006 and should not be provided for. In order to allow the Commission to take a decision concerning a substance under scrutiny listed in Part C of Annex III to Regulation (EU) No 1925/2006 within the required deadline, only files submitted within 24 months from the date on which a substance has been listed in that Annex should be taken into consideration.

(12) Regulation (EU) 2019/1381 shall apply from 27 March 2021. Therefore, in order to ensure legal certainty and clarity with regard to transparency requirements for procedure under Article 8(4) of Regulation (EC) No 1925/2006 and to allow for uniform implementation of the transparency and confidentiality requirements for the EU risk assessment for all concerned sectors, it is necessary that this Regulation enters into force on the third day following that of its publication. For the reasons of legal certainty this Regulation should apply to the files submitted to the Authority from that date onwards.

(13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) No 307/2012

Regulation (EU) No 307/2012 is amended as follows:

(1) Article 5 is replaced by the following:

'Article 5

Substance listed in Part C of Annex III to Regulation (EC) No 1925/2006

1. Until the adoption of standard data formats pursuant to Article 39f of Regulation (EC) No 178/2002, the Authority shall only consider valid a file, presented in an electronic format, which allows downloading, printing and searching of documents.

After the adoption of standard data formats, the file shall be presented in accordance with those standard data formats to be considered valid.

Where the Authority considers a file not valid, it shall inform the food business operator or interested party that has submitted the file and the Commission of the reasons why it considers that file not valid.

2. The Authority shall only take into consideration, for the purposes of the decision referred to in Article 8(5) of Regulation (EC) No 1925/2006, files submitted within 24 months from the entry into force of a decision listing a substance in Part C of Annex III to that Regulation, pursuant to Article 8(2) thereof.';

(2) the following Articles are inserted:

'Article 5a
Pre-submission advice

At the request of a food business operator or any other interested party, the staff of the Authority shall provide advice on the rules applicable to, and the content required for, the submission of a file containing the scientific data aiming to demonstrate the safety of a substance listed in Part C of Annex III to Regulation (EC) No 1925/2006.

Food business operators and other interested parties may request pre-submission advice for a potential submission from the day of the adoption of an opinion by the Authority under Article 8(2) of Regulation (EU) 1925/2006, which identifies the possibility of harmful effects on health associated with the intake of a substance.

Such pre-submission advice shall be provided in accordance with Article 32a of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*.

Article 5b
Notification of studies

1. Food business operators and other interested parties shall notify to the Authority, without delay, the title, the scope, and the starting and planned completion dates of any study commissioned or carried out by them to demonstrate the safety of a substance listed in Part C of Annex III to Regulation (EC) No 1925/2006, as well as the laboratory or testing facility located in the Union carrying out that study.

2. Laboratories and other testing facilities located in the Union shall also, without delay, notify the Authority of the title and the scope of any study commissioned by food business operators and other interested parties, carried out by such laboratories or other testing facilities to demonstrate the safety of a substance listed in Part C of Annex III to Regulation (EC) No 1925/2006, its starting and planned completion dates, as well as the name of the food business operator or interested party who has commissioned that study.

3. Studies notified in accordance with this article shall be included by the Authority in the database referred to in Article 32b(1) of Regulation (EC) No 178/2002.

Article 5c

Transparency

Where the Authority is to deliver an opinion on a substance under scrutiny listed in Part C of Annex III to Regulation (EC) No 1925/2006, on the basis of a valid file, it shall:

(a) make public the data submitted in that file in accordance with Article 38(1)(c) of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*.

(b) consult stakeholders and the public, pursuant to Article 32c(2) of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*, on the basis of the non-confidential version of the data submitted in accordance with this Regulation.

Article 5d

Confidentiality

Upon the submission of a file, the food business operator or other interested party may request the treatment as confidential of certain parts of the information or data submitted.

Such a confidentiality request shall be accompanied by a verifiable justification that demonstrates that the disclosure of such information or data significantly harms the interests of the requestor, within the meaning of Article 39(2) and (3) of Regulation (EC) 178/2002, which shall apply *mutatis mutandis*.'

Article 2

Entry into force and application

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

It shall apply to the files submitted to the Authority from that date.

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN