EUROPEAN
COMMISSION

Brussels, XXX
SANTE/11650/2020 CIS
(POOL/E2/2020/11650/11650-EN CIS.docx)
[…](2020) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

amending Regulation (EU) No 257/2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives

(Text with EEA relevance)

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(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 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives[1], and in particular Article 32 thereof,

After consulting the European Food Safety Authority,

Whereas:

(1) Commission Regulation (EU) No 257/2010[2] sets up a programme for the re-evaluation by the European Food Safety Authority ('EFSA') of the safety of food additives that were already permitted in the Union before 20 January 2009.

(2) 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] and Regulation (EC) No 1331/2008 of the European Parliament and of the Council[5]. Those amendments are aimed at strengthening the transparency and the sustainability of the EU risk assessment in all areas of the food chain where EFSA delivers a scientific risk assessment.

(3) The amendments to Regulation (EC) 178/2002 introduced new provisions concerning, amongst other issues: general pre-submission advice by the staff of EFSA at the request of a potential applicant and the obligation to notify studies commissioned or carried out by business operators to support an application or notification and the consequences in case of non-compliance with that obligation. It also introduced provisions on the public disclosure, by EFSA, of all scientific data, studies and other

1 OJ L 354, 31.12.2008, p. 16.

2 Commission Regulation (EU) No 257/2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives (OJ L 80, 26.3.2010, p.19),

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).

5 Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1).

information supporting applications, with the exception of confidential information, early on in the risk assessment process, followed up by a consultation of third parties. The amendments also set out specific procedural requirements for the submission of confidentiality requests and the assessment thereof by EFSA in relation to the information submitted by an applicant, where the Commission requests the opinion of EFSA.

(4) Regulation (EU) 2019/1381 also amended Regulation (EC) No 1331/2008 to include provisions ensuring consistency with the adaptations of Regulation (EC) No 178/2002 and taking into account sectoral specificities with respect to confidential information.

(5) Regulation (EU) 2019/1381 does not contain provisions concerning the procedure for re-evaluation of food additives set out by Regulation (EU) No 257/2010. Indeed, while Regulation (EU) 2019/1381 sets out rules concerning applications and notifications, Regulation (EU) No 257/2010 gives an important role not only to business operators interested in the continuity of the approval of a food additives but also to other interested parties such as industry or consumer organisations. Therefore, the re-evaluation of a food additive does not require the submission of an application by a designated applicant and all interested business operators and other interested parties may submit data and information to that end.

(6) It nevertheless appears appropriate to provide for levels of transparency and confidentiality in the context of this procedure that are comparable to those applicable in the context of the procedure for updating the Union list of approved food additives, while taking into account of the specificities of the re-evaluation procedure. In particular, it is appropriate to provide that certain rules applicable to the procedure for updating of the Union list of approved food additives also apply in the framework of the re-evaluation procedure but concern all interested business operators and other interested parties. This is the case of the possibility, provided for in Article 32a of Regulation (EC) No 178/2002, to request from the staff of EFSA a pre-submission advice whenever EFSA will be required or requested to provide an opinion, the obligation set out in Article 32b of the same Regulation to notify to EFSA relevant studies, the obligations as regards the form of the submissions set out in Article 39f of Regulation (EC) No 178/2002 and the confidentiality rules provided for in Article 39 of Regulation (EC) No 178/2002 and in Article 12 of Regulation (EC) No 1331/2008.

(7) As regards the obligation to notify relevant studies, some adaptations to the re-evaluation of the procedure are, however, required. On the one hand, the procedural consequences provided for by Article 32b of the Regulation (EC) No 178/2002 in case of non-compliance with its provisions result in delays in the assessment of the re-submitted applications. However, delays in the re-evaluation of already approved food additives mean that they may remain on the market longer than they would otherwise. It is therefore appropriate that, when providing for the obligation to notify studies relevant for the re-evaluation, specific procedural consequences are set out in order to avoid unnecessary delays in the procedure. On the other hand, given that EFSA is responsible for managing the database of studies provided in Article 32b of Regulation (EC) No 178/2002, it is appropriate that it verifies whether the obligation to notify studies has been complied with and, depending on whether it is required or requested to deliver and opinion or not, it takes a decision in this regard itself or informs the Commission of its views.

(8) Furthermore, while Article 38(1) of Regulation (EC) No 178/2002 already provides for the publication of the information and data submitted for the re-evaluation of food

additives by EFSA, in order to increase the transparency and the effectiveness of the re-evaluation procedure, it is appropriate to provide for a consultation of third parties, along the consultation provided for Article 32c of Regulation (EC) No 178/2002, in order to identify whether other relevant scientific data or studies are available on the food additive being re-evaluated.

(9) The re-evaluation of food additives should allow EFSA to conclude on the safety of the concerned food additives, their uses, levels of use and specifications. Experience has shown that the data obtained from the call for data carried out by EFSA is not always sufficient to allow EFSA to confirm the safety of specific food additives, their uses, levels of use and specifications without however identifying major safety concerns either. Given that the aim of the re-evaluation programme is to ensure that the safety of food additives can be fully re-evaluated before a decision to maintain or remove them from the Union list is taken, it is appropriate to clarify that further steps, such as further calls for data, may be taken as a follow up to an opinion of EFSA in order to complete the re-evaluation of the concerned food additive. Such further steps should however not extend the re-evaluation procedure beyond what is appropriate to allow drawing conclusions on the safety of the concerned food additives, their uses, levels of use and specifications. Therefore, it is also appropriate to clarify that, where information is not submitted in reply to those steps or where the information submitted is insufficient, the Commission may close the re-evaluation procedure and take a risk management decision based on the existing EFSA opinion. Since those requests made as a follow up to the first opinion of EFSA are part of the re-evaluation procedure, the same rules should apply as regards the procedure and its transparency and confidentiality.

(10) The objectives of Regulation (EU) 2019/1381 could not be attained within the framework of the procedure of revaluation of food additives if the setting up by Regulation (EU) No 257/2010 of the revaluation programme was considered as the request for a scientific output, the date of which determines the applicable transparency and confidentiality rules. Therefore, in order to ensure the effectiveness of Regulation (EU) 2019/1381, this Regulation should apply from the date of application of that Regulation and to data and information submitted in relation to re-evaluation procedures effectively launched by EFSA after that date and to steps taken after that date as follow-up of EFSA opinions.

(11) 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 257/2010

Regulation (EU) No 257/2010 is amended as follows:

(1) in Article 4, point (c) is replaced by the following:

‘(c) examine the data submitted by the interested business operator(s) and/or any other interested party in accordance with Articles 5, 6 and 7 of this Regulation;’

(2) the following Articles are inserted:

'Article 7a

Follow-up of EFSA opinions

1. Where, on the basis of the information referred to in Article 4, EFSA cannot confirm the safety of a food additive, of its uses or levels of use or recommend changes to the specifications, the Commission may take or request EFSA to take further steps, including the organisation of calls for data, in order to complete the safety assessment.

2. Where the data and information requested in accordance with paragraph 1 has not been submitted or where it does not allow to confirm the safety of the food additive, of its uses or levels of use or specifications, the food additive may be removed from the Union list in accordance with the procedure referred to in Article 10(3) of Regulation (EC) No 1333/2008*.

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* OJ L 354, 31.12.2008, p.16.

Article 7b

Pre-submission advice

Where EFSA is required or requested to deliver an opinion in accordance with this Regulation, the staff of EFSA shall, at the request of interested business operator(s) or any other interested, party provide advice on the rules applicable to, and the content required for the submission of information pursuant to Articles 4 to 7a. Such advice shall be provided in accordance with Article 32a of Regulation (EC) No 178/2002**, which shall apply *mutatis mutandis*.

** OJ L 31, 1.2.2002, p. 1-24.

Article 7c

Notification of studies

1. Interested business operators and other interested parties shall, without delay, notify EFSA of the title and the scope of any study commissioned or carried out by them to support the re-evaluation of an approved food additive in accordance with Articles 4 to 7a of this Regulation, as well as the laboratory or testing facility carrying out that study, and its starting and planned completion dates.

   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 business operators and other interested parties, carried out by such laboratories or other testing facilities to support the re-evaluation of an

approved food additive in accordance with Articles 4 to 7a of this Regulation, its starting and planned completion dates, as well as the name of the business operators or interested parties who commissioned such a study.

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

2. Studies submitted that have not been previously notified in accordance with this article shall not be taken into account for the re-evaluation of the concerned food additive, unless the interested business operator or other interested party submitting it provides a valid justification for their non-notification.

3. Where studies that have previously been notified by an interested business operator or other interested party in accordance with this Article are not included in the data submitted pursuant to Articles 4 to 7a of this Regulation, none of the data submitted by that interested business operator or other interested party for the specific re-evaluation or follow-up procedure shall be taken into account, unless the interested business operator or other interested party provides a valid justification for their non-inclusion.

4. Where EFSA is required or requested to deliver an opinion in accordance with this Regulation, it shall verify whether the data submitted in accordance with the procedures laid down in Articles 4 to 7a of this Regulation fulfil the requirements set out in this Article. Where an opinion by EFSA is not required or requested in accordance with this Regulation, the Commission may consult EFSA on whether the studies submitted pursuant to Articles 4 to 7a of this Regulation fulfil the notification requirements set out above. EFSA shall provide the Commission with its views within 30 working days.

5. Where EFSA detects, during its assessment as part of the procedures laid down in Articles 4 to 7a, that studies notified by an interested business operator or other interested party in accordance with this Article are not included in the data submitted in full, all data submitted by the concerned interested business operator or other interested party for the specific re-evaluation or follow-up procedure shall not be taken into account unless a valid justification is provided for their non-inclusion.

Article 7d

Format of submissions

Prior to the adoption of standard data formats pursuant to Article 39f of Regulation (EC) No 178/2002, data submitted in accordance with this Regulation shall be submitted in an electronic format allowing for the downloading, printing and searching of documents. After the adoption of standard data formats pursuant to Article 39f of Regulation (EC) No 178/2002, data shall be submitted in accordance with those standard data formats.

Article 7e

Transparency

Where EFSA is required or requested to deliver an opinion in accordance with this Regulation, it shall consult stakeholders and the public on the basis of the non-confidential version of the data submitted pursuant to this Regulation, in accordance with Article 32c(2), of Regulation (EC) No 178/2002, which shall apply *mutatis mutandis*.'

(3) Article 8 is replaced by the following:

'Article 8

Confidentiality

Upon submission of data in accordance with this Regulation, the interested business operator or other interested party may submit a request to treat certain parts of the information or data as confidential. Such request shall be accompanied by verifiable justification. Such confidentiality requests shall be assessed in accordance with Article 12 of Regulation (EC) No 1331/2008, which shall apply *mutatis mutandis*.'

Article 2

Entry into force and application

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

It shall apply from 27 March 2021 and to data and information submitted to EFSA or the Commission in relation to re-evaluation procedures launched and follow-up steps taken 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