EUROPEAN
COMMISSION

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COMMISSION REGULATION (EU) …/…

of XXX

amending Annex I to Regulation (EU) No 10/2011 as regards a migration limit for the substance styrene

(Text with EEA relevance)

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amending Annex I to Regulation (EU) No 10/2011 as regards a migration limit for the substance styrene

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THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC[1], and in particular Article 5(1), second subparagraph, points (a) and (e) thereof,

Whereas:

(1) Commission Regulation (EU) No 10/2011[2] lays down specific rules as regards plastic materials and articles intended to come into contact with food. In particular, Annex I to that Regulation establishes a Union list of authorised substances that may be intentionally used in the manufacture of plastic materials and articles intended to come into contact with food.

(2) The substance 'styrene' (FCM No 193) is authorised to be used as a monomer or starting substance without a specific migration limit ('SML') or other specific restrictions. That authorisation is based on an opinion of the Scientific Committee for Food ('SCF') of 5 March 1982[3]. The SCF placed styrene in list 4B[4], which includes substances for which a Tolerable Daily Intake ('TDI') could not be established, but which could be safely used if the levels of monomer residues in plastic materials and articles intended to come into contact with food ('FCM') are reduced as much as possible.

(3) In 2018, the International Agency for Research on Cancer ('IARC') evaluated both styrene and its primary metabolite styrene 7,8-oxide and classified them in 2020 as 'probably carcinogenic to humans'[5]. In view of that evaluation, the Commission

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1 OJ L 338, 13.11.2004, p. 4, ELI: http://data.europa.eu/eli/reg/2004/1935/oj.

2 Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1 ELI: http://data.europa.eu/eli/reg/2011/10/oj.

3 Scientific Committee for Food. Styrene monomer (Opinion expressed on 5 March 1982). Thirteenth Series (1982). (Cat. N° EUR 7982 -DA-DE-EN-FR-IT-NL)

4 Scientific Committee for Food. Report on the Compilation of the evaluations of the Scientific Committee for Food on certain monomers and additives used in the manufacture of plastics materials intended to come into contact with foodstuffs expressed until 21st March 1997. Forty-second Series (2000). (No Catalogue: GT-29-98-001-EN-C, ISBN 92-828-5886-3).

5 Kogevinas M., Gwinn W., Kriebeld D. et al. Carcinogenicity of quinoline, styrene, and styrene-7,8-oxide. The Lancet Oncology, 2018, 728-729. Carcinogenicity of quinoline, styrene, and styrene-7,8-oxide - The Lancet Oncology. IARC Monographs on the evaluation of carcinogenic risks to humans.

mandated the European Food Safety Authority ('the Authority') on 5 December 2018 to evaluate whether the authorisation of styrene as provided for in Regulation (EU) No 10/2011, would still be in accordance with the requirements of Regulation (EC) No 1935/2004. In case the Authority would determine that that authorisation would not be in accordance with Regulation (EC) No 1935/2004, it was also requested to specify under what conditions the substance could be safely used, provided that this could be determined using the data from IARC.

(4) The Authority adopted a scientific opinion on 9 September 2020[6] concluding that the IARC conclusions cannot be directly applied to the evaluation of risks for consumers from the oral exposure to styrene. However, the Authority could not exclude a concern for genotoxicity associated with oral exposure to styrene. In order to fully assess the potential genotoxicity of styrene and conclude on its safety when used in plastic FCMs, the Authority considered that a systematic review of genotoxicity and additional data would be required. The Authority also concluded that styrene migration from FCMs into the majority of foods would be below 0,01 mg/kg, but could be as high as 0,23 mg/kg in some fatty foods, and that the use of styrene in plastic FCMs, without a migration limit could give rise to health risks.

(5) To address the remaining uncertainty on genotoxicity, the Commission provided the Authority with a new mandate on 4 May 2023, requesting it to evaluate whether styrene is genotoxic following oral exposure and whether the use of styrene, if authorised in accordance with Article 5 of Regulation (EU) No 10/2011 and subject to an SML of 0,04 mg/kg food, based on the WHO guideline value for drinking water[7], would be in accordance with Article 3 of Regulation (EC) No 1935/2004.

(6) The Authority adopted an opinion on 8 May 2025[8], concluding that there was no evidence that styrene is genotoxic following oral exposure and that its use would not be of safety concern if its migration remains below 0,05 mg/kg food and the European Reference Laboratory[9] showed in a proficiency test that the participating National Reference Laboratories and Official Control Laboratories would be capable to verify compliance with a SML set at that level. Therefore, it is appropriate to set an SML of 0,05 mg/kg food for the use of styrene in the manufacture of plastic FCM.

(7) In accordance with Articles 18(2) and 18(3) of Regulation (EU) No 10/2011, verification of compliance with the SML of FCM not yet in contact with food may be carried out either in food or food simulants set out in Annex III to that Regulation or by performing screening approaches in accordance with the rules set out in Chapter 2,

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Volume 121: Styrene, styrene-7,8-oxide, and quinolone (2019). IARC Publications Website - Styrene, Styrene-7,8-oxide, and Quinoline.

6 EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids) (2020). Assessment of the impact of the IARC Monograph Vol. 121 on the safety of the substance styrene (FCM No 193) for its use in plastic food contact materials. *EFSA Journal 2020;18(10):6247*. https://doi.org/10.2903/j.efsa.2020.6247.

7 In 2022, the World Health Organisation (WHO) derived a TDI for styrene in drinking water of 7,7 µg/kg body weight/day. Guidelines for drinking water quality, p. 465, 4th edition, World Health Organization 2022, based on a principal assessment from 2003. Guidelines for drinking-water quality: fourth edition incorporating the first and second addenda.

8 EFSA Panel on Food Contact Materials (2025). Re-assessment of the risks to public health related to the genotoxicity of styrene present in plastic food contact materials. *EFSA Journal 2025;23(6):9473*. https://doi.org/10.2903/j.efsa.2025.9473.

9 Determination of styrene in milk. FCM-23/02 Proficiency Test Report. Publications Office of the European Union, 2024, https://data.europa.eu/doi/10.2760/1868.

Section 2.2 of Annex V to the same Regulation. However, in its 2020 opinion on styrene, the Authority noted that testing the styrene migration from FCM into food using certain food simulants, under the conditions laid down in Regulation (EU) No 10/2011, may result in much higher migration levels of styrene than when using actual food, due to the impact of certain food simulants on the properties of styrene-based plastic materials. Therefore, if a material or article fails to comply with the SML in a verification carried out in food simulants or in a screening of compliance in accordance with Article 18(2) and (3) of Regulation (EU) No 10/2011, a conclusion of non-compliance should be confirmed by a testing in food. Considering that the migration of styrene into food tends to increase with a higher fat content in food, the food to be used for verification of compliance should be selected to represent the worst of the intended and foreseeable conditions of use regarding the migration of styrene into food. A note on the verification of compliance should be introduced to this end.

(8) Taking into account the conclusion by the Authority that, for the majority of the foods packed in plastics manufactured with styrene, migration levels of styrene would be below 0,01 mg/kg food[10], the transition to the use of the SML could be swift. However, it appears that testing the migration of styrene is currently not a common practice, and, therefore that operators require time to set up the systems for such testing. Therefore, in order to allow operators sufficient time to adapt to the changes provided for in this Regulation, and to ensure a high level of protection of human health, it is appropriate that plastic materials and articles complying with Regulation (EU) No 10/2011, as applicable before the date of the entry into force of this Regulation and any other relevant Union legislation, are allowed to be first placed on the market for a transitional period of 18 months. Furthermore, since the production of final plastic materials and articles typically involves the supply of products from intermediate manufacturing stages by other operators, operators placing on the market intermediate products and substances that do not yet comply with this Regulation should be required to inform the users of those products or substances that they cannot be used to manufacture plastic FCM to be placed on the market after the transition period ends.

(9) Regulation (EU) No 10/2011 should therefore be amended accordingly.

(10) 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 Annex I to Regulation (EU) No 10/2011

Annex I to Regulation (EU) No 10/2011 is amended in accordance with the Annex to this Regulation.

[10] EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids) (2020). Assessment of the impact of the IARC Monograph Vol. 121 on the safety of the substance styrene (FCM No 193) for its use in plastic food contact materials. *EFSA Journal 2020;18(10):6247*. https://doi.org/10.2903/j.efsa.2020.6247.

Article 2
Transitional measures

1. Plastic materials and articles complying with Regulation (EU) No 10/2011 as applicable before the entry into force of this Regulation, and any other relevant Union legislation, which were first placed on the market before *[insert date 18 months after the date of entry into force of this Regulation]* may continue to be placed on the market until the exhaustion of stocks.

2. In case a product from an intermediate stage of the manufacturing of plastic materials and articles or a substance intended for the manufacturing of such a product, material or article, which complies with Regulation (EU) No 10/2011 as applicable before the entry into force of this Regulation and which is first placed on the market after *[insert date 9 months after the date of entry into force of this Regulation]* does not comply with this Regulation, the declaration of compliance accompanying that product or substance shall indicate that it does not comply with this Regulation, and that it can only be used in the manufacture of plastic materials and articles to be first placed on the market before *[insert date 18 months after the date of entry into force of this Regulation]*.

Article 3
Entry into force

This Regulation shall enter into force on the twentieth 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
The President
Ursula VON DER LEYEN