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COMMISSION

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COMMISSION REGULATION (EU) .../...

of **XXX**

amending Regulation (EU) 2023/1442 as regards the transitional measures for plastic materials and articles manufactured with salicylic acid or untreated wood flour or fibres

(Text with EEA relevance)

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amending Regulation (EU) 2023/1442 as regards the transitional measures for plastic materials and articles manufactured with salicylic acid or untreated wood flour or fibres

(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 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/EEC¹, and in particular Article 5(1), second subparagraph, point (a), thereof,

Whereas:

- (1) Commission Regulation (EU) No 10/2011² lays down specific rules as regards plastic materials and articles intended to come into contact with foods. In particular, Annex I to that Regulation establishes a Union list of substances that may be used in the manufacture of plastic food contact materials and articles.
- (2) Commission Regulation (EU) 2023/1442³ revoked the authorisations for the substances ‘wood flour and fibers, untreated’ (FCM No 96) and ‘salicylic acid’ (FCM No 121) as of 1 August 2023. A transitional measure was provided to allow that plastic materials and articles complying with Regulation (EU) No 10/2011 as applicable before the entry into force of this Regulation which were first placed on the market before 1 February 2025 may remain on the market until the exhaustion of stocks. Furthermore, a transitional measure was also provided to allow the placing on the market of plastic materials and articles manufactured with those substances also after 1 February 2025, provided that certain conditions are met. Those conditions include the requirement that an application for authorisation was submitted before 1 August 2024, and that the European Food Safety Authority (‘the Authority’) considered the application valid before 1 February 2025.
- (3) The only application submitted for the authorisation of ‘salicylic acid’ was declared valid by the Authority before 1 February 2025, however, with respect to ‘untreated wood flour or fibers’ from a specific wood species, none of the applicants was able to

¹ 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 (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 Commission Regulation (EU) 2023/1442 of 11 July 2023 amending Annex I to Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, as regards changes to substance authorisations and addition of new substances (OJ L 177, 12.7.2023, p. 45, ELI: <http://data.europa.eu/eli/reg/2023/1442/oj>).

submit the information that the Authority considers necessary for its risk assessment in accordance with its administrative guidance for the preparation of applications on substances to be used in plastic food contact materials⁴.

- (4) After the entry into force of Regulation (EU) 2023/1442, the Authority published a technical report⁵ that broadly describes principles that could be applicable to the safety assessment of the use of mixtures of natural origin, such as wood. The timing and nature of the report caused uncertainty regarding the information that the Authority considers necessary for its assessment of ‘untreated wood flour and fibers’. In addition, the report specified that in certain situations analytical tests may be required which, due to their duration, were difficult to complete in time to allow the Authority to consider the applications valid by 1 February 2025, as required by Article 2(3) of Regulation (EU) 2023/1442.
- (5) In the light of the difficulties to submit the information in time that the Authority considers necessary for its risk assessment and given the absence of immediate safety concerns resulting from the use of the ‘untreated wood flour and fibers’ in plastic materials and articles as described in the applications, it is appropriate to amend the date by which the Authority must have considered the application valid for the transitional period to apply, so that applicants have a reasonable, although limited, time to complete their application and that, as intended by Article 2(3) of Regulation (EU) 2023/1442, plastic materials and articles manufactured with ‘untreated wood flour or fibers’ for which an application has been submitted pursuant that provision may continue to be first placed on the market until a decision is taken on their application.
- (6) It is also appropriate to clarify that plastic materials and articles benefiting from the transitional period may continue to be first placed on the market and remain on the market until the applicant withdraws its application or a decision on that application is taken.
- (7) Regulation (EU) 2023/1442 should therefore be amended accordingly.
- (8) Since the transitional measure amended by this Regulation allows for the first placing on the market of plastic materials and articles manufactured with ‘salicylic acid’ or ‘untreated wood flour or fibers’ after 1 February 2025, this Regulation should apply as of that date in order to ensure the smooth transition sought by that transitional measure.
- (9) 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

Article 2 of Regulation (EU) 2023/1442 is amended as follows:

- (1) paragraph 3 is replaced by the following:

⁴ Administrative guidance for the preparation of applications on substances to be used in plastic food contact materials (<https://doi.org/10.2903/sp.efsa.2021.EN-6514>).

⁵ Principles that could be applicable to the safety assessment of the use of mixtures of natural origin to manufacture food contact materials, EFSA supporting publication, 3 November 2023, <https://www.efsa.europa.eu/en/supporting/pub/en-8409>.

‘3. Plastic materials and articles manufactured with the substance salicylic acid or untreated wood flour or fibers from a specific wood species may continue to be first placed on the market between 1 February 2025 and 31 January 2026 provided that the following conditions are fulfilled:

- (a) an application for the authorisation of the substance has been submitted to the competent authority in accordance with Article 9 of Regulation (EC) No 1935/2004 before 1 August 2024;
- (b) the use of the substance to manufacture the plastic material and article, and the use of thereof, is limited to the intended conditions of use described in the application;
- (c) the information provided to the Authority in accordance with Article 9(1), point (b), of Regulation (EC) No 1935/2004 includes a statement that the application is an application in accordance with this paragraph.

Plastic materials and articles, which meet the conditions of the first subparagraph, may continue to be first placed on the market also after 1 February 2026 provided that the Authority has considered the application referred to in point (a) of the first subparagraph valid by that date.’

- (2) paragraph 4 is replaced by the following:

‘4. Plastic materials and articles may be first placed on the market in accordance with paragraph 3 and remain on the market until the applicant withdraws its application or until the Commission adopts a decision granting or refusing the authorisation for the use of salicylic acid or the untreated wood flour or fibers from a specific wood species pursuant to Article 11(1) of Regulation (EC) No 1935/2004.’

Article 2

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 1 February 2025.

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