Food contact materials: authorised substances

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EU authorises use of multiple substances in food contact materials

Commission Regulation (EU) 2026/245 of 2 February 2026 amending Annex I to Regulation (EU) No 10/2011 as regards the authorisation or the conditions of use of several substances

Regulation (EU) 2025/2240 of 5 November 2025 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

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

Update

The European Union (EU) has authorised the use of the following substances that may be used intentionally in the manufacture of food contact materials (FCM):

- phosphorous acid, triphenyl ester, polymer with 1,4-cyclohexanedimethanol and polypropylene glycol, C10–16 alkyl esters
- calcium tert-butylphosphonate
- amines, di-C14-C20-alkyl, oxidised, from hydrogenated vegetable oil
- wax, rice bran, oxidised
- wax, rice bran, oxidised, calcium salt
- 2,2′-oxydiethylamine.

The EU has replaced the name of the substance “amines, bis(hydrogenated tallow alkyl) oxidised” by “amines, di-C14-C20-alkyl, oxidised, from hydrogenated tallow”.

What is the EU doing?

Newly authorised substances

The EU has authorised the use of the following substances that may be used intentionally in the manufacture of FCM:

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- phosphorous acid, triphenyl ester, polymer with 1,4-cyclohexanedimethanol and polypropylene glycol, C10–16 alkyl esters
- calcium tert-butylphosphonate
- amines, di-C14-C20-alkyl, oxidised, from hydrogenated vegetable oil
- wax, rice bran, oxidised
- wax, rice bran, oxidised, calcium salt
- 2,2′-oxydiethylamine.

The EU has also amended the name of the substance "amines, bis(hydrogenated tallow alkyl) oxidised" to "amines, di-C14-C20-alkyl, oxidised, from hydrogenated tallow".

The conditions of use for each substance can be found in the Annex to Regulation 2026/245.

Wood flour and fibres (untreated) and salicylic acid

In July 2023, Regulation 2023/1442 revoked the authorisation (with effect from 1 August 2023) of the use of the following substances in the manufacture of plastic materials designed to come into contact with food (substances and their associated number in the EU authorised FCM list):

- wood flour and fibres, untreated (96)
- salicylic acid (121).

Regulation 2023/1442 allowed such materials placed on the market before 1 February 2025 to remain on the market until stocks are exhausted. It also allowed these materials to be placed on the market *after* that date, provided that an authorisation application was submitted to an EU Member State before 1 August 2024, and that the European Food Safety Authority (EFSA) validated that application before 1 February 2025. (Applicants could be manufacturers of FCM or of inputs such as wood fibre, for example.)

Regulation 2025/2240 extended these transitional measures: plastic materials and articles manufactured with the two substances (salicylic acid, or untreated wood flour and fibres) could continue to be placed on the market until **31 January 2026**, provided that an application for authorisation was submitted before 1 August 2024, and that use of the substance is limited to the conditions described in the application.

Plastic materials manufactured using these substances can be put on the market *after* 31 January 2026 provided that EFSA has validated the application.

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Why?

Since the last amendment to Regulation 10/2011, EFSA has published further scientific opinions on new substances that may be used in FCM, and on the use of substances already authorised (EFSA 2024a, 2024b, 2024c, 2024d, 2024e).

Regarding wood flour and fibres, EFSA (2019) considered that an evaluation was needed for specific wood species on a case-by-case basis. Applications were invited for authorisations related to wood flour/fibres and salicylic acid (EFSA 2019, 2020). However, EFSA considered that none of the applications received was accompanied by information that is necessary for risk assessment. As applicants found it difficult to submit the required data by the required date, and there are no immediate safety concerns from the use of untreated wood flour and fibres in plastic materials, the EU has now extended the date by which EFSA must validate the applications.

A technical report (EFSA 2023) describes the principles applied to safety assessments for the use of mixtures of natural origin (e.g. containing components from wood) in the manufacture of FCM, and may be used by applicants.

Timeline

The new substances authorised in Regulation 2026/245 can be used from **23 February 2026**.

Plastic materials containing salicylic acid or untreated wood flour or fibres could be sold in the EU until **31 January 2026** if an application for the use of those substances was submitted to an EU Member State competent authority before 1 August 2024.

If, by 31 January 2026, EFSA considered that an application was valid, the plastic materials can be sold on the EU market even after this date. These plastic materials can remain on the EU market unless the applicant withdraws their application or the European Commission refuses the authorisation.

What are the major implications for exporting countries?

Operators will need to ensure that packaged products comply with the requirements set out in the Regulation to continue exporting to the EU market.

In particular, exporters need to ensure that food does not contain harmful substances that exceed the migration limits set out in the Regulation. This requires transparent communication with packaging suppliers. Where listed substances are used, monitoring may be required to ensure migration limits are not exceeded.

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Recommended Actions

Suppliers of packaged food to the EU market should inform packaging suppliers about the prohibition on the use in plastic materials of untreated wood flour and fibres, and of salicylic acid. They should also be aware of upcoming changes in the SML concerning substances listed in Regulation 10/2011, Annex I.

Background

Commission Regulation 10/2011 specifies which substances may be used in plastic FCM, and establishes specific migration limits (SML) that limit their presence in food. It also requires that materials and articles comply with specified quality and safety standards, and that they are labelled appropriately. The Regulation applies to all plastic materials and articles intended to come into contact with food, including packaging, containers, and utensils.

For substances with no SML or other restrictions in Annex I, a generic SML of 60 mg/kg will apply.

Regulation 10/2011 includes several annexes:

- List of authorised substances for plastic FCM (Annex I)
- Restrictions on the use of certain substances in plastic FCM (II)
- Food simulants (III)
- Declarations of compliance (IV)
- Compliance testing (V)
- Correlation table (VI).

Regulation 2023/2006 sets out general rules on good manufacturing practice related to quality assurance systems, quality control systems, and documentation. It also sets out specific rules on printing inks and quality assurance systems for plastic recycling processes.

Resources

ECHA (2017) Opinion on an Annex XV dossier proposing restrictions on four phthalates (DEHP, BBP, DBP, DIBP). Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC), European Chemicals Agency.

EFSA (2019) Update of the risk assessment of 'wood flour and fibres, untreated' (FCM No 96) for use in food contact materials, and criteria for future applications of materials from plant origin as additives for plastic food contact materials. EFSA Journal, 17(11): e05902.

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EFSA (2020) Review and priority setting for substances that are listed without a specific migration limit in Table 1 of Annex 1 of Regulation 10/2011 on plastic materials and articles intended to come into contact with food. EFSA Journal, 18(6): e06124.

EFSA (2023) Principles that could be applicable to the safety assessment of the use of mixtures of natural origin to manufacture food contact materials. Technical Report. EFSA Journal, 20(11): 8409E.

EFSA (2024a) Safety assessment of the substance 'phosphorous acid, triphenyl ester, polymer with 1,4-cyclohexanedimethanol and polypropylene glycol, C10–16 alkyl esters', for use in food contact materials. EFSA Journal, 22(4): e8694.

EFSA (2024b) Safety assessment of the substance calcium *tert*-butylphosphonate for use in food contact materials. EFSA Journal, 22(4): e8705.

EFSA (2024c) Safety assessment of the substance amines, di-C14-C20-alkyl, oxidised, from hydrogenated vegetable oil, for use in food contact materials. EFSA Journal, 22(5): e8769.

EFSA (2024d) Safety assessment of the substances 'wax, rice bran, oxidised' and 'wax, rice bran, oxidised, calcium salt' for use in food contact materials. EFSA Journal, 22(8): e8960.

EFSA (2024e) Safety assessment of the substance 2,2′-oxydiethylamine for use in plastic food contact materials. EFSA Journal, 22(12): e9105.

European Commission (2013) Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain [updated 2016].

European Commission (2014) Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food [updated 2016].

European Commission (2015) Food contact materials.

Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food

Sources

Regulation (EU) 2023/1442 on plastic materials and articles intended to come into contact with food, as regards changes to substance authorisations and addition of new substances

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