

# Food contact materials: authorised substances

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EU extends transitional rules regarding plastic food packaging materials that contain salicylic acid and untreated wood flour or fibres

Commission Regulation (EU) <u>2023/1442</u> 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

Regulation (EU) <u>2025/2240</u> 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

### **Update**

In July 2023, the European Union (EU) revoked the authorisation of the use of untreated wood flour and fibres, and salicylic acid, in the manufacture of plastic materials intended to come into contact with food. It also amended the conditions under which certain substances may be used in plastic food contact materials (FCM). For safety reasons, untreated wood flour and fibres, and salicylic acid, will no longer be authorised – with some transitional exceptions.

However, the EU did permit the continued sale of these materials provided businesses submitted an application to an EU Member State authority for validation by the European Food Safety Authority (EFSA). Following complications with providing EFSA with the necessary data to validate applications, those applicants are being allowed additional time to complete their applications, and can continue to place these plastic materials on the EU market until 31 January 2026.

# What is the EU doing?

In July 2023, Regulation <u>2023/1442</u> 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 EFSA validated that application before 1 February 2025. (Applicants could be manufacturers of FCM or of inputs such as wood fibre, for example.)

The new Regulation (2025/2240) extends these transitional measures: plastic materials and articles manufactured with the two substances (salicylic acid, or untreated wood flour and fibres) may 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.

Under Regulation <u>2023/1442</u>, new conditions of use were also established for:

- phthalic acid, dibutyl ester (157)
- phthalic acid, benzyl butyl ester (159)
- phthalic acid, bis(2-ethylhexyl) ester (283)
- phthalic acid, diesters with primary, saturated C8-C10 branched alcohols (728)
- triethanolamine (793)
- perchloric acid, salts (perchlorate) (822)
- diethyl[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenyl]methyl]phosphonate (1007)
- phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10-16 alkyl ester (1076)
- benzene-1,2,4-tricarboxylate (1078)
- triethanolamine-perchlorate (1080)
- N-bis(2-hydroxyethyl)stearylamine partially esterified with saturated C16/C18 fatty acids (1081)
- phosphoric acid, mixed esters with 2-hydroxyethyl methacrylate (1082)
- benzophenone-3,3',4,4'-tetracarboxylic dianhydride (BTDA) (1083).

The new conditions of use for the above substances are set out in the Annex to Regulation 2023/1442.

# 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.





Regarding wood flour and fibres, <u>EFSA (2019)</u> considered that an evaluation was needed for specific wood species on a case-by-case basis.

The Regulation therefore invited specific applications for authorisation related to wood flour or fibres, and to salicylic acid, before April 2024 (EFSA 2019, 2020). EFSA could initially assess the validity of applications for the authorisation to use salicylic acid or untreated wood flour or fibres until 1 February 2025. However, EFSA considered that none of the applications received was accompanied by information that is necessary for risk assessment. As there are no immediate safety concerns from the use of untreated wood flour and fibres in plastic materials, and there were difficulties for applicants in submitting the required data and completing their application in time, the EU has now extended the date by which EFSA has to validate the applications received. An EFSA technical report (EFSA 2023) describes principles applicable to the safety assessment 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 Regulation revoking the use of untreated wood flour and fibres, and salicylic acid, in plastic FCM applies from 1 August 2023.

The transition period allows plastic materials containing salicylic acid or untreated wood flour or fibres to 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 considers that an application is 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 in order 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.





### **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 <u>10/2011</u> 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 <u>2023/2006</u> 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

Regulation (EC) No <u>1935/2004</u> of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food

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) <u>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</u>. EFSA Journal, 17(11): 5902.

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): 6124.

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 Supporting Publications.

European Commission (2013) <u>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).</u>

European Commission (2014) <u>Union Guidelines on Regulation (EU) No 10/2011 on plastic</u> materials and articles intended to come into contact with food.

European Commission (2015) Food contact materials.

### **Sources**

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

Commission Regulation (EU) <u>2025/2240</u> as regards the transitional measures for plastic materials and articles manufactured with salicylic acid or untreated wood flour or fibres

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