

Food contact materials: authorised substances

Published by AGRINFO on 16 Feb 2023; Revised 08 Aug 2024

EU amends rules on substances in plastics coming into contact with food

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 EU has amended the conditions under which certain substances may be used in plastic materials intended to come into contact with food. For safety reasons, untreated wood flour and fibres, and salicylic acid, will no longer be authorised. For other substances, the permitted conditions of use are amended.

What is the EU doing?

The EU has reviewed the use of substances intentionally used in the manufacture of plastic materials designed to come into contact with food.

The following substances may no longer be used (listing substances and their associated number in the EU authorised food contact materials (FCM) list:

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

New conditions of use are 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 the Regulation.

Why?

Since the last amendment to Regulation (EU) No 10/2011, the European Food Safety Authority (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, [EFSA \(2019\)](#) considered that an evaluation was needed for specific wood species on a case-by-case basis.

The Regulation invited specific applications for authorisation related to wood flour or fibres, and to salicylic acid, before April 2024 ([EFSA 2019](#), [2020](#)).

Timeline

The Regulation applies from **1 August 2023**.

There will be a transition period to allow the sale of existing stocks: plastic materials containing these substances which were first placed on the market before 1 February 2025 may remain on the EU market until stocks are exhausted.

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 in excess of the migration limits set out in the Regulation. This requires transparent communication with packaging suppliers. Where listed substances are used, it may require monitoring 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 specific migration limit (SML) concerning substances listed in Regulation (EU) No [10/2011](#), Annex I.

Background

Commission Regulation (EU) No. [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 (EU) No 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

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

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): 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.

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](#).

European Commission (2015) [Food contact materials](#).

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

Visit the [AGRINFO website](#) to view the latest AGRINFO Update newsletters and [search](#) the database.

Disclaimer: *Under no circumstances shall COLEAD be liable for any loss, damage, liability or expense incurred or suffered that is claimed to have resulted from the use of information available on this website or any link to external sites. The use of the website is at the user's sole risk and responsibility. This information platform was created and maintained with the financial support of the European Union. Its contents do not, however, reflect the views of the European Union.*