

PIM: Plastics Regulation (Regulation (EU) No 10/2011), explained

The Plastics Regulation limits plastic food-contact materials to Union-listed substances within migration limits and requires every business operator except retailers to pass on a written declaration of compliance. It has applied since 1 May 2011; the consolidated version of 14 July 2026 carries the bisphenol A ban and the 2025 revision, whose transition ends on 16 September 2026.

Reviewed 24 September 2026 by Conphora compliance team · Next review 13 March 2027 · Not legal advice

Key facts

Reference	Regulation (EU) No 10/2011	Act type	Regulation
In force	4 February 2011	Applies from	1 May 2011
Amended by	Commission Regulation (EU) 2026/1380, Commission Regulation (EU) 2026/245, Commission Regulation (EU) 2025/351, Commission Regulation (EU) 2024/3190, Commission Regulation (EU) 2023/1627, Commission Regulation (EU) 2023/1442, Commission Regulation (EU) 2020/1245, Commission Regulation (EU) 2019/1338, Commission Regulation (EU) 2019/988, Commission Regulation (EU) 2019/37, Commission Regulation (EU) 2018/831, Commission Regulation (EU) 2018/213, Commission Regulation (EU) 2018/79, Commission Regulation (EU) 2017/752, Commission Regulation (EU) 2016/1416, Commission Regulation (EU) 2015/174, Commission Regulation (EU) No 865/2014, Commission Regulation (EU) No 202/2014, Commission Regulation (EU) No 1183/2012, Commission Regulation (EU) No 1282/2011, Commission Implementing Regulation (EU) No 321/2011	Enforced by	Member States enforce the regulation through official food controls.
CELEX	32011R0010		

Key dates

4 February 2011	Regulation (EU) No 10/2011 enters into force, on the twentieth day after its publication in OJ L 12 of 15 January 2011	Art. 23
1 May 2011	The regulation applies; Directives 80/766/EEC, 81/432/EEC and 2002/72/EC are repealed and references to them are read against the correlation tables in Annex VI; materials and articles lawfully placed on the market before this date could still be placed on the market until 31 December 2012	Art. 21, Art. 22(5) and Art. 23
1 June 2011	The prohibition on bisphenol A in polycarbonate infant feeding bottles introduced by Implementing Regulation (EU) No 321/2011 applies to placing on the market and importation into the Union, after applying to manufacture from 1 May 2011	Art. 1 and Art. 2
31 December 2015	Article 5 starts to apply to additives other than plasticisers in the plastic layers and coatings of caps and closures, and to additives used in glass fibre sizing for glass-fibre-reinforced plastics; until this date the glass fibre sizing additives not listed in Annex I had to comply with the risk assessment provisions of Article 19	Art. 22(4) and Art. 23
1 January 2016	The supporting documents required by Article 16 must be based on the migration testing rules of Article 18, ending the option of relying on the basic rules in the Annex to Directive 82/711/EEC	Art. 22(2) and Art. 22(3)
23 September 2020	Regulation (EU) 2020/1245 in force: the derogation in Article 6(3)(a) is rewritten to cover all salts of the substances marked in Table 1 of Annex II, Annex II is restructured as a single list of migration limits for 24 elements and ammonium including the four lanthanides, and Annexes I, IV and V are amended	Art. 1 and Art. 3
23 September 2022	End of the transition under Regulation (EU) 2020/1245: materials and articles first placed on the market before 23 March 2021 under the earlier rules could be placed on the market until this date and remain on the market until stocks are exhausted	Art. 2
1 August 2023	Regulation (EU) 2023/1442 in force: new total specific migration limits for the phthalates, the authorisations of untreated wood flour and fibres (FCM No 96) and salicylic acid (FCM No 121) revoked, and several new substances authorised	Art. 1 and Art. 3
31 August 2023	Regulation (EU) 2023/1627 in force, authorising bis(2-ethylhexyl)cyclohexane-1,4-dicarboxylate (DEHCH, FCM No 1079) as a plasticiser in PVC in contact with foods assigned simulants A and B at room temperature or below	Art. 1, Art. 2 and Annex
20 January 2025	Regulation (EU) 2024/3190 applies: bisphenol A and hazardous bisphenols and bisphenol derivatives are prohibited in food contact materials, the entries for FCM No 151 and FCM No 154 are deleted from Table 1 of Annex I, Article 6(6) is added to the Plastics Regulation and Regulation (EU) 2018/213 is repealed	Art. 3, Art. 10, Art. 13 and Art. 14

1 February 2025	End of the transition under Regulation (EU) 2023/1442: plastic materials and articles first placed on the market before this date under the earlier rules may remain on the market until stocks are exhausted, while salicylic acid and untreated wood flour or fibres may continue only under a valid application filed before 1 August 2024	Art. 2
16 March 2025	Regulation (EU) 2025/351 in force: the definitions of additive, reprocessing of plastic and UVCB substance, the new Article 3a on a high degree of purity, the rewritten Articles 8, 10 and 16, the new labelling Article 14a and the alignment with the recycled-plastic and good-manufacturing-practice regulations start to apply	Art. 1, Art. 2, Art. 3 and Art. 5
16 December 2025	From this date the declaration of compliance of an intermediate product or substance that complies with the earlier rules but not with Regulation (EU) 2025/351 must say so, and must state that it may only be used for plastic materials and articles placed on the market before 16 September 2026	Art. 4(2)
23 February 2026	Regulation (EU) 2026/245 in force, authorising six further additives and monomers in Annex I and renaming FCM No 768	Art. 1, Art. 2 and Annex
14 July 2026	Regulation (EU) 2026/1380 in force, correcting the Estonian language version of Article 8(1); the other language versions, including English, are not affected. This is the date of the current consolidated text	recital 2, Art. 1 and Art. 2
20 July 2026	End of the main bisphenol A transition: single-use final food contact articles made with BPA under the earlier rules may no longer be placed on the market, and repeat-use final articles may no longer be first placed on the market, after this date	Art. 11(1) and Art. 12(1)
16 September 2026	End of the transition under Regulation (EU) 2025/351: plastic materials and articles first placed on the market before this date under the earlier rules may continue to be placed on the market until stocks are exhausted; everything first placed on the market later must meet the 2025 text	Art. 4(1)
20 January 2028	End of the extended bisphenol A transition for single-use articles preserving fruit, vegetables or fishery products and for articles whose BPA varnish or coating is only on the exterior metal surface, and for repeat-use articles used as professional food production equipment	Art. 11(2) and Art. 12(2)
20 January 2029	Last date on which repeat-use final food contact articles made with bisphenol A and first placed on the market under the transitional provisions may remain on the market	Art. 12(3)

Obligations by role

Manufacturer of plastic materials, articles and intermediate products

- Use only substances included in the Union list of authorised monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids in Table 1 of Annex I, or substances covered by an Article 6 derogation, and use a substance in nanoform only where Annex I explicitly authorises it and says so in the specifications. Art. 5(1), Art. 6 and Art. 9(2)
- Ensure every substance that may be present in the final plastic is of a high degree of purity and of a technical quality suitable for the intended and foreseeable use, with its composition known to the substance manufacturer; a substance qualifies as pure where its constituents correspond to its identity and any non-intentionally added substances meet one of the four conditions of Article 3a, the strictest of which is a foreseeable migration at or below 0,00015 mg/kg food. Art. 3a and Art. 8
- Respect the restrictions and specifications in column 10 of Table 1 of Annex I, the group restrictions of Table 2, the detailed specifications of point 4 of Annex I and the Annex II limits: the migration limits for the 24 listed elements and ammonium, from aluminium at 1 mg/kg and nickel at 0,02 mg/kg to lead, mercury and arsenic, which must not be detectable, and the rule that primary aromatic amines without their own limit must not be detectable at 0,002 mg/kg each, with the sum of unlisted ones not exceeding 0,01 mg/kg. Art. 9(1), Art. 10(1) and Annex II, points 1 and 2
- Keep the finished material within the overall migration limit of 10 mg of total constituents released per square decimetre of food contact surface, or 60 mg per kg of food simulant for material intended for food for infants and young children, and within every applicable specific migration limit, expressed in mg per kg of food using the real surface-to-volume ratio in actual or foreseen use and the derogations of Article 17 for small, very large or awkwardly shaped articles and for closures. Art. 11, Art. 12 and Art. 17
- Demonstrate compliance by migration testing under Article 18: food simulants A, B, C, D1, D2 and E assigned to the food categories in Annex III, the test time and temperature selected from Tables 1 and 2 of Chapter 2 of Annex V for specific migration, one of the eight standardised tests OM0 to OM7 for overall migration, ten days at 60 degrees Celsius for long-term storage at room temperature or below, and an analytical method meeting Article 34 of Regulation (EU) 2017/625; results in food prevail over results in simulant, which prevail over screening results. Art. 18, Annex III and Annex V, Chapters 2 and 3
- Manufacture under the good manufacturing practice of Regulation (EC) No 2023/2006 with a documented quality assurance system, a quality control system and documentation of specifications, formulae, processing and quality control results; if you reprocess off-cuts and scraps, meet the Article 10(2) conditions and the separate collection, containment, batch and traceability rules of section C of its Annex. Art. 4, Art. 5, Art. 6 and Art. 7; Art. 4(d) and Art. 10(2)
- Issue a written declaration of compliance at every marketing stage other than retail with the eleven items of Annex IV, including the identity of the issuer and of the manufacturer or importer, the identity of the material, the date, the confirmation of compliance with this regulation and with Articles 3, 11(5), 15 and 17 of Regulation (EC) No 1935/2004, the information downstream users need on restricted substances and non-intentionally added substances, the specifications of use covering food types, time and temperature and the highest surface-to-volume ratio verified, and the functional barrier, reprocessing and waste-derived substance confirmations; renew it when the composition or production changes materially or new scientific data appears. Art. 15 and Annex IV
- Keep the supporting documentation, including the conditions and results of testing, calculations and modelling, other analyses and the reasoning demonstrating compliance, and documentation on the composition and degree of purity of the substances used, available to the national competent authorities on request, and allow them to take samples during official controls; for repeat-use articles, supply users with instructions that slow deterioration, a description of observable changes and a warning where

damage or foreseeable misuse would increase migration, and give consumers instructions of use where Annex I restricts the food types, contact conditions or heating. Art. 14a, Art. 16(1) to Art. 16(4)

- Keep the supporting documentation demonstrating compliance, including test conditions and results, calculations, modelling, other analyses and the reasoning, and documentation on the composition and purity of the substances used, available to the competent authorities on request, and allow them to take samples during official controls. Art. 16(1) to Art. 16(4)
- For repeat-use articles, supply users with instructions that slow deterioration, a description of observable changes and a warning where damage or foreseeable misuse would increase migration; give consumers instructions of use where Annex I restricts the food types, contact conditions or heating.

Art. 14a

Supplier of substances and starting materials

- Make a written declaration of compliance available for the substances intended for the manufacture of plastic food contact materials and for products from intermediate stages of manufacture, at every marketing stage other than retail, containing the Annex IV information and allowing easy identification of what it covers. Art. 15(1) to Art. 15(3) and Annex IV
- At intermediate stages, state in the declaration the identification and amount of the substances contained in the intermediate material that are subject to restrictions or specifications in Annex II, and of substances for which genotoxicity has not been ruled out that originate from an intentional use and could foreseeably give rise to an individual migration above 0,00015 mg/kg food from the final article.

Annex IV, point 6

- Know the composition of the substance you supply, keep it to a high degree of purity and of a technical quality suitable for the intended and foreseeable use, and make the documentation on composition and degree of purity available to the competent authorities on request; a UVCB substance named after a natural multi-constituent material may be supplied as obtained from its natural origin only if it contains nothing outside that identity and meets any Annex I specification. Art. 8(1), Art. 8(2) and Art. 16(1)
- Where an intermediate product or substance first placed on the market after 16 December 2025 complies with the earlier text but not with Regulation (EU) 2025/351, say so in its declaration of compliance and state that it may only be used to make plastic materials and articles placed on the market before 16 September 2026. Art. 4(2)
- For bisphenols and bisphenol derivatives intended to be used as monomers or other starting substances, supply the separate declaration of compliance required by the bisphenol A regulation, listing every bisphenol or bisphenol derivative used and confirming compliance with that regulation and with Articles 3, 15 and 17 of Regulation (EC) No 1935/2004. Art. 8 and Annex III

Importer

- Place plastic food contact materials on the Union market only if they satisfy Article 3 of Regulation (EC) No 1935/2004, the labelling and traceability articles, good manufacturing practice and Chapters II, III and IV of the Plastics Regulation, and if they fall within its scope, Regulation (EU) 2022/1616 on recycled plastic; imported material is judged by exactly the same rules as material made in the Union.

Art. 4; Art. 3, Art. 15 and Art. 17

- Obtain and hold the written declaration of compliance for everything you import other than at retail stage, check that its specifications of use cover the food types, contact times and temperatures and the surface-to-volume ratio your customers will apply, and be able to produce the supporting documentation to Fødevarestyrelsen on request; in Denmark all food contact materials must be accompanied by a declaration of compliance meeting Annex 5 of the executive order.

Art. 15, Art. 16 and Annex IV, point 8; § 15

- Obtain and hold the written declaration of compliance for everything you import other than at retail stage; in Denmark all food contact materials must be accompanied by a declaration of compliance meeting Annex 5 of the executive order. Art. 15 and Annex IV; § 15
- Check that the declaration's specifications of use cover the food types, contact times and temperatures and the surface-to-volume ratio your customers will apply. Annex IV, point 8
- Be able to produce the supporting documentation behind the declaration of compliance to Fødevarestyrelsen on request. Art. 16
- Verify that nothing you import is manufactured using bisphenol A or another hazardous bisphenol or bisphenol derivative outside the two Annex II applications, that any transitional article is still within its period, and that material made with another bisphenol contains no residual BPA; hold the separate bisphenol declaration of compliance. Art. 3, Art. 4, Art. 8, Art. 11 and Art. 12
- Register the import of food contact materials with Fødevarestyrelsen through the food business start-up form unless the activity stays at or below 1 000 units and a turnover of DKK 50 000 a year, remembering that the rules apply whether or not you have to register.
- If you assume or have reason to believe that material you imported fails the food safety requirements and is no longer under your control, withdraw it from the market, notify Fødevarestyrelsen immediately and, where it has reached consumers, inform them effectively and precisely about why the product is withdrawn, recalling it from consumers where necessary. § 7
- Make sure the material carries the framework regulation's labelling, the words for food contact or an equivalent indication, the special instructions for safe use, the name and address of the responsible business established in the Union and the traceability identification, and that consumer articles made with substances whose Annex I restrictions concern specific foods, contact time or temperature or heating are supplied with instructions of use. Art. 15(1) and Art. 17; Art. 14a(2)

Distributor, wholesaler or retailer

- Do not market plastic food contact materials that fail the general requirements of Regulation (EC) No 1935/2004 and the rules made under it, which in Denmark is a separate offence under the executive order regardless of where in the chain the defect arose. § 6, stk. 1; Art. 3
- Pass the written declaration of compliance on to the next link in the chain at every marketing stage other than retail; in Denmark the duty is met if the declarations are published on the producer's or importer's website and the next link is informed of that. Art. 15(1); § 15, stk. 1 and stk. 2
- Keep systems and procedures that identify the businesses from which and to which you were supplied, and make that information available to the competent authorities on demand, so that a defective batch can be traced and recalled. Art. 17
- At the retail stage, display the words for food contact or an equivalent indication, the special instructions for safe use and, for active materials, the required information, on the article, its packaging, a label or a clearly visible notice, in a language easily understood by purchasers. Art. 15(4), Art. 15(5) and Art. 15(7)
- Cooperate in withdrawals: where material you distributed fails the food safety requirements, the producer or importer must withdraw it, notify Fødevarestyrelsen and inform consumers, and you must be able to say who supplied you and whom you supplied. § 7; Art. 17(2)
- Register wholesale of food contact materials with Fødevarestyrelsen unless the activity stays at or below 1 000 units and a turnover of DKK 50 000 a year.

Food business using plastic food contact materials

- Do not use plastic food contact materials that fail the general requirements of Regulation (EC) No 1935/2004 and the rules made under it, and use them only for the purposes for which they are intended. § 6, stk. 2
- Obtain the declaration of compliance from every supplier of food contact material and keep it as part of your own-check system; Fødevarestyrelsen treats the declaration as the summary of the supplier's control work and expects the restrictions on use, such as which foods the material may be used for, to appear in it. § 15
- Check that the specifications of use in the declaration actually cover your process: the types of food, the time and temperature of treatment and storage in contact with the food, and the highest food contact surface area to volume ratio for which compliance was verified. Annex IV, point 8
- Follow the manufacturer's instructions for repeat-use articles, watch for the observable changes it describes as signs of deterioration and heed the warnings about damage or foreseeable misuse that would increase migration or make the article unsuitable for further food contact. Art. 14a(1) and Art. 10(3)
- Keep traceability of the materials and articles you receive and use, and make that information available to the competent authorities on demand. Art. 17

Penalties

The Plastics Regulation contains no penalty article of its own. Article 25 of the framework Regulation (EC) No 1935/2004 requires Member States to lay down rules on sanctions applicable to infringements of that regulation and to take all measures necessary to ensure that they are implemented, and the sanctions must be effective, proportionate and dissuasive; because the Plastics Regulation is a specific measure adopted under Article 5 of the framework regulation, Member States sanction infringements of it in the same national instrument. Enforcement runs through official food controls under Article 24 of the framework regulation, carried out under Regulation (EU) 2017/625, which replaced Regulation (EC) No 882/2004 from 14 December 2019, and a Member State that has detailed grounds for concluding that a material endangers human health although it complies with the specific measure may temporarily suspend or restrict the provisions on its territory under the safeguard clause. In Denmark, executive order nr. 681 of 25 May 2020 prohibits the marketing of non-compliant food contact materials and their use by food businesses, requires the producer or importer to withdraw non-compliant material, notify Fødevarestyrelsen immediately and inform consumers, and in § 23 punishes with a fine the infringement of Articles 4, 5, 6(3), 8, 9, 10, 11, 12, 13, 14(1), 14(3) and 14(5), 15, 16 and 17 of Regulation (EU) No 10/2011, that is the placing-on-the-market conditions, the Union list and its derogations, the general and specific requirements on substances, the composition rules, the specific and overall migration limits, the multi-layer rules, the declaration of compliance, the supporting documents and the expression of test results. The list has thirteen entries and was written in 2020: it does not reach Article 3a on a high degree of purity, Article 6(6) on bisphenols or Article 14a on labelling, all of which were added to the Plastics Regulation later, so those provisions are not themselves backed by the Danish fine provision even though they apply directly. The fine rises to imprisonment of up to 2 years where the infringement was committed intentionally or by gross negligence and health was harmed or endangered or an economic advantage was obtained or sought, and companies can be held criminally liable under chapter 5 of the Danish criminal code. The order was issued by Fødevarestyrelsen under sections 25, 25 a, 49(1) and 60(3) of the Danish food act and the delegation in section 7(3) of executive order nr. 596 of 7 May 2020 on Fødevarestyrelsen's tasks and powers, which is what carries the fine provisions. Its § 17 punishes infringements of the order's own §§ 6 to 12 and §§ 14 to 15 — the marketing and use prohibitions, PFAS in paper and board, surface biocides, vinyl chloride, regenerated cellulose film, lead and cadmium in ceramics, enamelled articles and glassware, and the declaration of compliance — and parallel provisions punish infringements of the framework regulation (§ 18), the good manufacturing practice regulation (§ 19), the epoxy derivatives regulation (§ 20) and the active and intelligent materials regulation (§ 22).

Art. 18, Art. 24 and Art. 25; Art. 146; § 6, § 7, § 17, § 18, § 19 and § 23

Checklist

1. Establish which category of Article 2(1) your material falls into, whether it is one of the three excluded groups, ion exchange resins, rubber or silicones, and whether it is also covered by the recycled-plastic regulation, and record the conclusion in your technical file (Articles 1, 2 and 4).
2. Build the formulation only from substances in the Union list in Table 1 of Annex I or from a substance expressly allowed by an Article 6 derogation, check each entry's column 10 restrictions, its group restriction in Table 2 and the detailed specifications in point 4, and risk-assess under Article 19 anything that relies on a derogation (Articles 5, 6, 9 and 19).
3. Document that every substance is of a high degree of purity within the meaning of Article 3a, that its composition is known, and that any non-intentionally added substance meets one of the four conditions, then keep the purity and composition documentation with the file (Articles 3a, 8 and 16).
4. Check the material against the Annex II limits for the 24 listed elements and ammonium and against the primary aromatic amines rule, and against the vinyl chloride monomer restriction for every plastic layer, including layers behind a functional barrier (Article 10(1), Annex II and Articles 13(2) and 14(5)).
5. Choose the food simulants from Annex III for the food categories the article will contact, select the test time and temperature from Tables 1 and 2 of Chapter 2 of Annex V and the standardised overall migration test OM0 to OM7 that matches the intended contact conditions, and run the tests with a method meeting Article 34 of Regulation (EU) 2017/625 (Article 18 and Annexes III and V).
6. Compare the results against the overall migration limit of 10 mg per square decimetre, or 60 mg per kg of simulant for food for infants and young children, and against every applicable specific migration limit, applying the correction factors of point 3 of Annex III and Chapter 4 of Annex V and the surface-to-volume rules of Article 17 before you conclude (Articles 11, 12, 17 and 18).
7. Confirm that no bisphenol A, other hazardous bisphenol or hazardous bisphenol derivative is used outside the two Annex II applications of Regulation (EU) 2024/3190, that no residual BPA remains where another bisphenol is used, and that any stock relying on a transitional period is still inside it (Article 6(6) and Regulation (EU) 2024/3190, Articles 3, 4, 5, 11 and 12).
8. Write the declaration of compliance with all eleven Annex IV items, including the specifications of use and the highest surface-to-volume ratio verified, add the separate bisphenol declaration where that regulation applies, and renew the declaration when the composition or production changes materially (Article 15, Annex IV and Regulation (EU) 2024/3190, Article 8).
9. Run manufacture under a documented good manufacturing practice quality assurance and quality control system, and where you reprocess off-cuts and scraps, meet the Article 10(2) conditions and the separate collection, containment and batch traceability rules of section C of the Annex to Regulation (EC) No 2023/2006.
10. In Denmark, register manufacture, import or wholesale of food contact materials with Fødevarestyrelsen unless the activity stays at or below 1 000 units and a turnover of DKK 50 000 a year, keep the declaration of compliance available per § 15 of executive order nr. 681 of 25 May 2020, and have a withdrawal, notification and consumer-information procedure ready per § 7.

Sources

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