

FCM: Food Contact Materials Framework Regulation (Regulation (EC) No 1935/2004), explained

The Food Contact Materials Framework Regulation requires food contact materials and articles to be made under good manufacturing practice so they do not endanger health or change the food, with labelling, traceability and declaration-of-compliance duties for business operators. It has applied since 3 December 2004; the transparency amendment of Regulation (EU) 2019/1381 since 27 March 2021.

Reviewed 24 September 2026 by Conphora compliance team · Next review 14 March 2027 · Not legal advice

Key facts

Reference	Regulation (EC) No 1935/2004	Act type	Regulation
In force	3 December 2004	Applies from	3 December 2004
Amended by	Regulation (EC) No 596/2009, Regulation (EU) 2019/1381	Enforced by	Member States carry out official controls to enforce the regulation under the Union rules on official food and feed controls; Article 24(3) still cites Regulation (EC) No 882/2004, which Regulation (EU) 2017/625 repealed with effect from 14 December 2019; the reference is read as a reference to Regulation (EU) 2017/625 (its Article 146), which the bisphenol A regulation also cites for the selection of test methods (Article 9(1)), with the EU reference laboratory for food contact materials and national reference laboratories supporting the analytical work.

Key dates

27 October 2004	Regulation (EC) No 1935/2004 adopted by the European Parliament and the Council in Strasbourg	title and signature block after Art. 28
13 November 2004	Publication in OJ L 338 of 13 November 2004	OJ L 338, 13.11.2004, p. 4
3 December 2004	Entry into force on the twentieth day after publication; Directives 80/590/EEC and 89/109/EEC repealed; materials lawfully placed on the market before this date may be marketed until stocks are exhausted	Art. 26, Art. 27 and Art. 28
13 May 2005	Deadline for Member States to communicate their rules on sanctions to the Commission	Art. 25
1 January 2006	Regulation (EC) No 1895/2005 applies: migration limits for the epoxy derivatives BADGE, BFDGE and NOGE in plastics, surface coatings and adhesives	Art. 1, Art. 2 and Art. 8
27 October 2006	Article 17 on traceability applies: systems to identify the businesses from which and to which materials, articles and substances were supplied	Art. 17 and Art. 28
20 July 2007	Directive 2007/42/EC in force: the codified specific directive on regenerated cellulose film, replacing Directive 93/10/EEC	Art. 1, Art. 7 and Art. 8
1 August 2008	Regulation (EC) No 2023/2006 on good manufacturing practice applies to all sectors and all stages of manufacture, processing and distribution of food contact materials	Art. 2 and Art. 8
7 August 2009	Regulation (EC) No 596/2009 in force: specific measures, Union authorisations and Annex amendments move to the regulatory procedure with scrutiny (Articles 5, 11(3), 12(6), 22 and 23)	Annex, point 5.17, and Art. 3
19 December 2009	Regulation (EC) No 450/2009 on active and intelligent materials: the labelling and declaration-of-compliance provisions of Article 4(f), Article 11(1) and (2) and Chapter IV apply	Art. 14

1 May 2011	Regulation (EU) No 10/2011 on plastic materials and articles applies: Union list of authorised substances, migration limits, declaration of compliance and supporting documents	Art. 1, Art. 15, Art. 16 and Art. 23
1 July 2020	Danish executive order nr. 681 of 25 May 2020 on food contact materials in force, replacing order nr. 1248 of 30 October 2018; it bans PFAS in paper and board, sets lead and cadmium limits for ceramics, enamel and glass, requires a declaration of compliance for all food contact materials and penalises the EU articles	§ 8, § 14, § 15, §§ 17-24 and § 25
23 September 2020	Regulation (EU) 2020/1245 amending and correcting the plastics regulation in force; plastics complying with the previous rules and first placed on the market before 23 March 2021 could still be placed on the market until 23 September 2022	Art. 4 and Art. 5
27 March 2021	Regulation (EU) 2019/1381 applies: EFSA publishes authorisation applications and supporting information, and the confidentiality rules of Articles 19 and 20 follow Regulation (EC) No 178/2002	Art. 5, Art. 10(1) and Art. 11
10 October 2022	Regulation (EU) 2022/1616 on recycled plastic materials and articles in force, replacing Regulation (EC) No 282/2008; Article 6(3)(c) and Article 13(2) apply from 10 October 2024	Art. 1 and Art. 33
20 January 2025	Regulation (EU) 2024/3190 in force: bisphenol A banned in adhesives, rubbers, ion-exchange resins, plastics, printing inks, silicones and varnishes and coatings for food contact, Regulation (EU) 2018/213 repealed, BPA and bisphenol S removed from the plastics Union list	Art. 1, Art. 3, Art. 10, Art. 13 and Art. 14
16 March 2025	Regulation (EU) 2025/351 in force: amendments to the plastics regulation, the recycled-plastic regulation and the GMP annex on quality control, reprocessing of plastic by-products and repeat-use articles	title, Art. 2, Art. 3 and Art. 5
16 December 2025	Intermediate plastic products and substances first placed on the market	Art. 4(2)

after this date that do not yet comply with Regulation (EU) 2025/351 must say so in their declaration of compliance

23 February 2026	Regulation (EU) 2026/245 (new substances in Annex I to the plastics regulation) and Regulation (EU) 2026/250 (corrections to the bisphenol A regulation, including the transitional dates) in force	Art. 1 and Art. 2; Art. 1 and Art. 2
20 July 2026	End of the general bisphenol A transition: single-use and repeat-use final food contact articles made with BPA under the old rules may be first placed on the market until this date; single-use articles may then be filled and sealed for 12 months	Art. 11(1), Art. 11(3) and Art. 12(1); Art. 1, points (4) and (5)
16 September 2026	End of the Regulation (EU) 2025/351 transition: plastics complying with the previous rules and first placed on the market before this date may continue to be placed on the market until stocks are exhausted	Art. 4(1)
20 July 2027	Repeat-use BPA articles first placed on the market under the general transition may remain on the market until this date	Art. 1, point (5) (Art. 12(3) of Regulation (EU) 2024/3190)
20 January 2028	End of the extended bisphenol A transition for single-use articles preserving fruit, vegetables or fishery products, single-use articles with a BPA coating only on the exterior metal surface, and repeat-use professional food production equipment	Art. 11(2) and Art. 12(2)
20 January 2029	Repeat-use professional food production equipment made with BPA and first placed on the market under the extended transition may remain on the market until this date	Art. 12(3); Art. 1, point (5)

Obligations by role

Business operator (any stage of manufacture, processing or distribution)

- Manufacture materials and articles in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer constituents to food in quantities that could endanger human health, bring about an unacceptable change in the composition of the food or deteriorate its organoleptic characteristics, and never mislead consumers through labelling, advertising or presentation. Art. 3
- Run an effective, documented quality assurance system proportionate to the size of the business, select starting materials against pre-established specifications, work to pre-established instructions, maintain a quality control system that monitors GMP and corrects failures without delay, and keep documentation on specifications, formulae, processing and quality control results available to the authorities. Art. 4, Art. 5, Art. 6 and Art. 7
- Run an effective, documented quality assurance system proportionate to the size of the business, select starting materials against pre-established specifications, work to pre-established instructions, and maintain a quality control system that monitors GMP and corrects failures without delay. Art. 4, Art. 5 and Art. 6
- Keep documentation on specifications, formulae, processing and quality control results, and make it available to the competent authorities on request. Art. 7
- Have systems and procedures in place to identify the businesses from which and to which materials, articles and, where appropriate, the substances used in their manufacture were supplied, make that information available to the competent authorities on demand, and make sure the materials placed on the market are identifiable by labelling or documentation. Art. 17
- Have systems and procedures in place to identify the businesses from which and to which materials, articles and, where appropriate, the substances used in their manufacture were supplied, and make that information available to the competent authorities on demand. Art. 17(2)
- Make sure the materials and articles you place on the market are identifiable by labelling or documentation that ensures their traceability. Art. 17(3)
- Where a specific measure applies, accompany the materials and articles with a written declaration of compliance and hold appropriate documentation demonstrating compliance, to be made available to the competent authorities on demand; in Denmark every food contact material must be accompanied by a declaration of compliance, which may be published on the producer's or importer's website if the next operators in the chain are informed. Art. 16; § 15
- Where a specific measure applies, accompany the materials and articles with a written declaration of compliance; in Denmark every food contact material must be accompanied by one, which may be published on the producer's or importer's website if the next operators in the chain are informed. Art. 16(1); § 15
- Hold appropriate documentation demonstrating compliance with the specific measure and make it available to the competent authorities on demand. Art. 16(1)
- Comply with any condition or restriction attached to the authorisation of a substance you use, and immediately inform the Commission of any new scientific or technical information that might affect the safety assessment of an authorised substance. Art. 11(4) and Art. 11(5)
- Comply with any condition or restriction attached to the authorisation of a substance you use. Art. 11(4)
- Immediately inform the Commission of any new scientific or technical information that might affect the safety assessment of an authorised substance you use. Art. 11(5)

- For active and intelligent materials, ensure that changes to the food comply with the food rules, that released substances are authorised as food ingredients, that the materials do not mask spoilage or give misleading information, and that they are labelled to identify non-edible parts and as active or intelligent. Art. 4
- For active and intelligent materials, ensure that changes to the food comply with the food rules, that released substances are authorised as food ingredients, and that the materials do not mask spoilage or give misleading information about the condition of the food. Art. 4(1) to Art. 4(4)
- Label active and intelligent materials and articles so that non-edible parts can be identified and so that they are identified as active or intelligent. Art. 4(5) and Art. 4(6)
- Stop using bisphenol A in the manufacture of adhesives, rubbers, ion-exchange resins, plastics, printing inks, silicones and varnishes and coatings for food contact, respect the transitional deadlines of 20 July 2026 and 20 January 2028, and accompany those materials with a declaration of compliance containing the Annex III information. Art. 1(2), Art. 3, Art. 8, Art. 11 and Art. 12; Art. 1
- Stop using bisphenol A in the manufacture of adhesives, rubbers, ion-exchange resins, plastics, printing inks, silicones and varnishes and coatings for food contact, respecting the transitional deadlines of 20 July 2026 and 20 January 2028. Art. 1(2), Art. 3, Art. 8 and Art. 11; Art. 1
- Accompany materials and articles covered by the bisphenol regulation with a declaration of compliance containing the Annex III information. Art. 12
- If you are a food business that imports, manufactures or packs food, use only food contact materials that meet the general requirements and only for the purposes for which they are intended, and obtain the declaration of compliance from your supplier. § 6(2) and § 15

Manufacturer or processor responsible for placing on the market

- Label materials and articles not yet in contact with food with the words for food contact, a specific indication of use such as coffee machine, wine bottle or soup spoon, or the glass-and-fork symbol of Annex II, unless the article is clearly intended for food contact by its characteristics, and add special instructions for safe and appropriate use where necessary. Art. 15(1)(a), Art. 15(1)(b) and Art. 15(2)
- Put your name or trade name and address or registered office, as the manufacturer, processor or seller established in the Union responsible for placing on the market, on the material, its packaging, a label or the accompanying documents, together with the labelling or identification that ensures traceability, and make all labelling conspicuous, clearly legible and indelible. Art. 15(1)(c), Art. 15(1)(d), Art. 15(3) and Art. 15(8)
- Put your name or trade name and address or registered office, as the manufacturer, processor or seller established in the Union responsible for placing on the market, on the material, its packaging, a label or the accompanying documents, conspicuously, clearly legibly and indelibly.
Art. 15(1)(c), Art. 15(3) and Art. 15(8)
- Label or otherwise identify the materials and articles so that they can be traced. Art. 15(1)(d)
- For active materials, give information on the permitted uses and the name and quantity of the substances released by the active component so that food businesses can comply with the food rules, including food labelling. Art. 15(1)(e)
- Use the for-food-contact information only on materials and articles that comply with the general requirements and with the specific measures or, in their absence, the applicable national provisions.
Art. 15(9)
- For plastics, issue the written declaration of compliance with the Annex IV information for materials, articles, intermediate products and substances at every stage other than retail, renew it when composition or production changes alter migration or when new scientific data appears, and hold supporting documents with test conditions and results, calculations and modelling, including evidence of compliance with the Article 8 purity and composition rules, and let authorities take samples.
Art. 15 and Art. 16
- For plastics, issue the written declaration of compliance with the Annex IV information for materials, articles, intermediate products and substances at every marketing stage other than retail, and renew it when changes in composition or production alter migration or when new scientific data appears. Art. 15
- Hold the supporting documents for the plastics declaration, with test conditions and results, calculations and modelling, including evidence of compliance with the Article 8 purity and composition rules, make them available to the authorities on request and let them take samples. Art. 16
- For ceramics, issue the written declaration of compliance with the Annex III information up to and including the retail stage and hold the analysis results, test conditions and laboratory details demonstrating compliance with the lead and cadmium limits. Art. 2a
- For ceramics, issue the written declaration of compliance with the Annex III information so that it accompanies the articles up to and including the retail stage. Art. 2a(1)
- For ceramics, hold the analysis results, test conditions and laboratory details demonstrating compliance with the lead and cadmium limits, and make them available to the authorities on request. Art. 2a(2)
- Where printing inks are applied to the non-food-contact side, formulate, apply, handle and store the printed materials so that substances are not transferred to the food-contact side through the substrate or by set-off in the stack or reel, and never let printed surfaces touch food. Annex, points 1 to 3
- If you consider or have reason to believe that materials you produced do not meet the food-safety requirements and are no longer under your control, withdraw them from the market, notify

Fødevarestyrelsen immediately and, where they have reached consumers, inform consumers effectively and precisely. § 7

Importer or seller responsible for placing on the market in the Union

- Place on the Union market only materials and articles that comply with the general requirements, the applicable specific measures and, in their absence, the national provisions of the Member State of marketing; in Denmark non-compliant food contact materials may not be marketed.

Art. 3, Art. 5, Art. 6 and Art. 15(9); § 6(1)

- As the seller established in the Union responsible for placing on the market, put your name or trade name and address or registered office on the material, its packaging, a label or the accompanying documents. Art. 15(1)(c) and Art. 15(8)
- Obtain the written declaration of compliance from the non-EU manufacturer where a specific measure requires one, keep the supporting documentation available for the competent authorities, and for ceramics hold the migration test results, test conditions and laboratory details yourself.

Art. 16(1); Art. 2a(2); Art. 16(1)

- Obtain the written declaration of compliance from the non-EU manufacturer where a specific measure requires one. Art. 16(1); Art. 16(1)
- Keep the supporting documentation for the declaration available for the competent authorities, and for ceramics hold the migration test results, test conditions and laboratory details yourself. Art. 16(1); Art. 2a(2)
- Keep traceability records identifying the businesses from which you sourced and to which you supplied materials, articles and substances, and hand them to the authorities on demand. Art. 17(2)
- In Denmark, register the import of food contact materials with Fødevarestyrelsen through the food-business start-up form unless your imports stay at or below 1 000 units and DKK 50 000 a year, and withdraw and notify Fødevarestyrelsen when imported materials fail the food-safety requirements. § 7
- In Denmark, register the import of food contact materials with Fødevarestyrelsen through the food-business start-up form unless your imports stay at or below 1 000 units and DKK 50 000 a year. § 7
- In Denmark, withdraw imported food contact materials that fail the food-safety requirements and notify Fødevarestyrelsen. § 7
- Check that bisphenol A articles you import fall within the transitional windows: general first placing on the market until 20 July 2026, fruit, vegetable and fishery packaging, exterior-coated single-use articles and professional equipment until 20 January 2028, and that they carry the Annex III declaration.

Art. 8, Art. 11 and Art. 12; Art. 1, points (4) and (5)

Distributor, wholesaler or retailer

- Do not sell at retail materials and articles whose for-food-contact indication, instructions for use and active-material information are not given in a language easily understood by purchasers; in Denmark the labelling must be in Danish or a language that differs from Danish only in insignificant spelling.

Art. 15(4) and Art. 15(5)

- At the retail stage, display the required information on the materials or their packaging, on labels affixed to them, or on a clearly visible notice in their immediate vicinity, using the notice for the name and address only where a label cannot be affixed for technical reasons. Art. 15(7)
- At the wholesale stage, pass the labelling information on in the accompanying documents, on the labels or packaging or on the materials themselves, and pass on the declaration of compliance where a specific measure requires it. Art. 15(8) and Art. 16(1)
- Keep systems and procedures to identify your suppliers and your business customers and make that information available to the competent authorities on demand. Art. 17(2)
- In Denmark, register wholesale of food contact materials with Fødevarestyrelsen unless the activity stays at or below 1 000 units and DKK 50 000 a year, and cooperate in withdrawals of materials that fail the food-safety requirements. § 7
- In Denmark, register wholesale of food contact materials with Fødevarestyrelsen unless the activity stays at or below 1 000 units and DKK 50 000 a year. § 7
- In Denmark, cooperate in withdrawals of food contact materials that fail the food-safety requirements.

§ 7

Penalties

Member States lay down the rules on sanctions for infringements of the regulation and take all measures necessary to ensure they are implemented; the sanctions must be effective, proportionate and dissuasive. Member States enforce the regulation through official controls under the Union rules on official food and feed controls, and a Member State that has detailed grounds for concluding that a material endangers human health although it complies with a specific measure may temporarily suspend or restrict the provisions in question on its territory pending a Union decision. 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, obliges the producer or importer to withdraw non-compliant materials, notify Fødevarestyrelsen and inform consumers, and punishes with a fine infringements of Articles 3, 4(1) and (3) to (6), 11(5), 15 and 17 of the regulation, Articles 4 to 7 of the GMP regulation, the epoxy, active-and-intelligent and plastics regulations, the former recycled-plastic regulation (EC) No 282/2008 and the former bisphenol A regulation (EU) 2018/213 (§§ 21 and 24 still cite those repealed acts; the order has not yet been updated to Regulations (EU) 2022/1616 and 2024/3190) and the national rules on PFAS in paper and board, lead and cadmium and the declaration of compliance; the penalty rises to imprisonment of up to two years where the infringement was intentional or grossly negligent and harmed or endangered health or sought an economic gain, and companies can be held criminally liable.

Art. 18, Art. 24 and Art. 25; § 6, § 7 and §§ 17-24

Checklist

- 1. Confirm the product is a material or article intended for, already in or reasonably expected to come into contact with food in its finished state, and that it is not an antique, an edible covering or fixed water supply equipment (Article 1).
- 2. Assign each product to its Annex I material group and list the specific measures that apply: Regulation (EU) No 10/2011 for plastics, Regulation (EU) 2022/1616 for recycled plastic, Regulation (EC) No 450/2009 for active and intelligent materials, Directive 84/500/EEC for ceramics, Directive 2007/42/EC for regenerated cellulose, Regulation (EC) No 1895/2005 for epoxy derivatives and Regulation (EU) 2024/3190 for bisphenol A (Article 5).
- 3. Demonstrate the Article 3 general requirement with migration testing, modelling or other evidence, applying the positive lists and migration limits of the relevant specific measure and, for Denmark, the national lead, cadmium and PFAS rules.
- 4. Implement good manufacturing practice under Regulation (EC) No 2023/2006: a documented quality assurance system, a quality control system, records of specifications, formulae and processing, and set-off controls for printed materials.
- 5. Remove bisphenol A from adhesives, rubbers, ion-exchange resins, plastics, printing inks, silicones and varnishes and coatings, and plan the transition around 20 July 2026 and 20 January 2028 (Regulation (EU) 2024/3190, Articles 3, 11 and 12).
- 6. Issue or obtain the written declaration of compliance with the content required by the specific measure, hold the supporting documentation, and renew the declaration when composition, process or science changes (Article 16; Regulation (EU) No 10/2011, Articles 15 and 16).
- 7. Label the product with the for-food-contact wording, use indication or glass-and-fork symbol, instructions for safe use, the responsible operator's name and address, traceability identification and, for active materials, the released substances, in the language of the market (Article 15).
- 8. Set up one-step-up, one-step-down traceability records for materials, articles and substances and be able to hand them to the authority on demand (Article 17).
- 9. In Denmark, register the manufacture, import or wholesale of food contact materials with Fødevarestyrelsen unless you stay at or below 1 000 units and DKK 50 000 a year, and keep a withdrawal and notification procedure ready (executive order nr. 681 of 25 May 2020, § 7).

Sources

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15. Commission Regulation (EC) No 1895/2005 on epoxy derivatives in food contact materials (EUR-Lex) — <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32005R1895>
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