ORIGINAL RESEARCH & COMPARATIVE REGULATORY ANALYSIS

The Substitute Has Its Own Toxicology

Europe's October 2026 Bisphenol Guidance, the Limits of BPA-Free Claims, and the Evidence Needed for Safer Food-Contact Innovation

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EXECUTIVE ABSTRACT

The European Food Safety Authority's guidance published on 16 October 2026 changes the evidentiary expectations for bisphenols proposed as alternatives to bisphenol A in food-contact materials. Its central implication is easily missed: low migration, absence of harmonised hazard classification and a BPA-free label are three different propositions, none of which establishes the others. The guidance calls for immunological, developmental, reproductive, metabolic and toxicokinetic evidence even at migration below 0.05 mg/kg food, while the European Union's binding restrictions and transitional deadlines operate through a separate legal mechanism. This article examines the scientific basis for those requirements, the analytical distinction between residual monomers and non-intentionally added substances, and the engineering risks of changing coatings, membranes and packaging. It compares the EU and Spanish regime with Great Britain, Northern Ireland and the United States, and develops a testable research agenda for evaluating substitutions against chemical safety, food preservation and industrial performance simultaneously. Proposed innovation concepts are explicitly distinguished from established evidence and existing patented approaches.

KEYWORDS: *bisphenol alternatives; food-contact materials; immunotoxicity; chemical migration; non-intentionally added substances; comparative food law; packaging innovation; toxicokinetics*

CATEGORY Food Safety & Regulatory Affairs | Packaging & Emerging Research

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META DESCRIPTION EFSA's October 2026 bisphenol guidance exposes the limits of BPA-free claims and calls for robust migration, toxicology and packaging validation across markets.

INTERNAL TAGS Bisphenols; Food Contact Materials; Toxicology; Chemical Migration; Packaging; Regulatory Affairs; Processing Technologies; Emerging Research

01 | The October 2026 event: a guidance document, not an approval

On 16 October 2026, the European Food Safety Authority (EFSA) published guidance on the data requirements for assessing bisphenols other than bisphenol A (BPA) and their derivatives when used in food-contact materials. Adopted by EFSA's Food Contact Materials Panel on 16 September, the document responds to the mandate in Article 6(4) of Commission Regulation (EU) 2024/3190 and complements EFSA's established food-contact-materials Note for Guidance. The publication is an important regulatory-science event because it turns a concern about replacing BPA with related molecules into an explicit framework for the evidence expected from applicants. It does not, by itself, prohibit every bisphenol, authorise any candidate, or certify that a packaging formulation is safe. [1–3]

The industrial relevance extends beyond the manufacturers of polymers. A food company may change a can lining, adhesive, closure, filtration membrane or processing component without changing the ingredient declaration on its food. That alteration can nevertheless affect migration, corrosion, flavour stability, microbial shelf life and market access. The immediate question for R&D is therefore not simply whether a supplier can offer a material described as 'BPA-free', but what precisely is known about its chemical identity, potential migrants, toxicological profile and performance in the intended food and process. The new guidance sharpens this question while leaving the legal authorisation decision to the competent EU institutions. [1,2]

02 | Three claims that must not be confused

A BPA-free claim addresses the presence or deliberate use of one defined substance, subject to the claim's wording and applicable law. A migration result measures transfer under specified analytical and contact conditions. A safety conclusion integrates identity, hazard, exposure, uncertainty and legally relevant use. These statements are related but not interchangeable: a material may contain no intentionally added BPA and still release another bisphenol, a degradation product or an unrelated non-intentionally added substance (NIAS). Conversely, a measured trace does not automatically establish an adverse health outcome, and a low result in one simulant does not prove low migration in every food. [1,4,5]

This is more than a semantic distinction. Marketing often treats substitution as a binary change in raw-material identity, whereas chemical risk assessment treats it as a new exposure scenario. The burden of demonstration depends on the chemical, its classification, the material, the actual intended use and the regulatory route. The appropriate commercial dossier should therefore separate compositional declarations, validated migration results, toxicological evaluations and legally binding permissions, rather than placing all four under one undifferentiated 'food-grade' certificate.

03 | What the EFSA guidance actually asks for

EFSA defines hazardous bisphenols and derivatives by reference to harmonised classifications under Regulation (EC) No 1272/2008: category 1A or 1B carcinogenicity, mutagenicity or reproductive toxicity, or category 1 endocrine disruption for human health. The 2026 guidance applies to substances meeting that definition and also recommends its data requirements for applications involving bisphenols not classified as hazardous, specifically to reduce the risk of regrettable substitution. This latter recommendation is a scientific expectation within an application, not a newly enacted blanket statutory prohibition on all unclassified analogues. [1,2]

The most consequential technical point is EFSA's treatment of low migration. At concentrations below 0.05 mg/kg food or food simulant, the authority requests evidence beyond the conventional genotoxicity package, because low-dose immune, developmental, reproductive and metabolic effects cannot necessarily be excluded by a low mass-transfer result alone. It recommends an extended one-generation reproductive toxicity study under OECD Test Guideline 443, including cohorts 1 and 3 and additional endpoints, while allowing scientifically justified reliance on existing studies and appropriate new-approach

methods. It also seeks information on absorption, distribution, metabolism and excretion, comparative metabolism and intrinsic clearance. Requirements may be adjusted when an applicant supplies a defensible scientific justification. [1]

04 | A migration tier is an evidence trigger, not a safe-dose declaration

The guidance distinguishes the lowest migration tier (below 0.05 mg/kg food), an intermediate tier (0.05–5 mg/kg) and a highest tier (above 5 mg/kg). Its design is notable because the lowest tier already carries an expanded toxicological expectation. For the intermediate tier, an extended one-generation study with a sufficiently long pre-mating exposure can also cover the information ordinarily sought from a 90-day study; above 5 mg/kg, the guidance adds the long-term toxicity and carcinogenicity information described in the underlying Note for Guidance. These are tiers for compiling an assessment dossier, not permitted migration limits or proof that a substance at 0.049 mg/kg is harmless. [1]

A numerical illustration shows why this distinction matters. A migration result of 0.04 mg/kg food corresponds to 40 micrograms per kilogram of food. If 0.5 kg of that food were consumed, the arithmetic intake attributable to that material would be 20 micrograms, before any adjustment for body weight, other foods or other exposure sources. This hypothetical calculation neither estimates an actual market exposure nor establishes a tolerable intake. It merely demonstrates that a concentration tier, a dietary dose and a health-based guidance value occupy different units and scientific roles. The assessor must connect them with justified assumptions rather than collapse them into a single threshold.

05 | Why the 2023 BPA reassessment changed the toxicological questions

EFSA's April 2023 BPA reassessment identified immune-system effects, particularly changes in T-helper 17 cells in experimental animals, as the critical basis for a tolerable daily intake (TDI) of 0.2 nanograms per kilogram body weight per day. That value was 20,000-fold below the temporary TDI set in 2015. The authority also considered reproductive, developmental and metabolic evidence, while acknowledging uncertainties in extrapolating the experimental evidence to human health. Its exposure comparison relied on earlier dietary estimates rather than a wholly updated 2023 market-exposure survey. The 2026 guidance does not assert that every bisphenol has the same potency as BPA; it instead asks for substance-specific evidence on endpoints that may be relevant to structurally related chemicals. [1,6]

A rigorous interpretation must also recognise scientific disagreement. Different authorities have weighed elements of the BPA evidence differently, and the British consultation record explicitly refers to differing expert positions. Such disagreement does not suspend binding EU law, but it makes the quality of study design, dose metrics, biological relevance and uncertainty analysis especially important. It would be equally unsound to describe every bisphenol analogue as proven equally hazardous or to treat a lack of harmonised classification as proof of toxicological innocence. [1,6,7]

06 | Toxicokinetics: the parent molecule is not the whole internal dose

A food-contact migration assay measures what leaves the material under specified conditions; it does not establish the concentration of the biologically active form reaching a tissue. Absorption, first-pass metabolism, conjugation, distribution and elimination influence internal exposure. EFSA's new guidance accordingly requests in-vivo ADME evidence, comparative in-vitro metabolism involving relevant species and human systems, and intrinsic-clearance data capable of supporting physiologically based kinetic (PBK) models. It highlights the importance of measuring parent compounds and metabolites separately, rather than treating total radiolabel or nominal in-vitro concentration as an adequate description of the active dose. [1]

For industrial decision-making, this has two consequences. First, a promising analogue cannot be ranked solely by its external migration concentration; two compounds with the same migration may differ in

metabolic activation, persistence or receptor engagement. Second, computational read-across and quantitative structure–activity models can assist early screening but cannot automatically replace missing metabolic data. A useful model must document its applicability domain, uncertainty and validation against appropriate measurements. The novelty lies neither in PBK modelling nor in chemical screening, both of which are established disciplines, but potentially in using them coherently to prevent poorly evidenced substitutions.

07 | Immunotoxicity is more demanding than a generic endocrine screen

The guidance asks for a wider set of immune endpoints than a simple receptor-binding test. In addition to reproductive and developmental cohorts, it discusses immunoglobulin isotypes, inflammatory mediators, lymphocyte populations, T-helper differentiation, natural-killer-cell function, macrophage activity and, where appropriate, assays designed to investigate unintended immune stimulation or suppression. It also identifies serum and hepatic uric acid among the metabolic indicators requiring attention. The objective is to detect biologically relevant adverse pathways that a conventional genotoxicity-only screen might overlook. [1]

However, more assays do not automatically produce more reliable evidence. Differences in metabolic competence, free concentration in culture media, test-system uptake and assay interference can distort comparisons between chemicals. EFSA specifically cautions against treating nominal in-vitro dose as the actual cellular dose and requests distribution information to improve interpretation. Any proposal to replace animal testing with a battery of in-vitro methods should therefore specify how results are integrated, what adverse outcomes the battery can detect, and which gaps remain. An unvalidated assay collection is not an accepted regulatory alternative merely because it uses modern terminology.

08 | The chemistry of substitution: monomers, derivatives and NIAS

Changing a coating or polymer can change several chemical inventories at once. The intentionally added monomer or resin precursor is only one. Residual catalysts, oligomers, curing agents, reaction by-products, thermal degradation products, additives and contaminants may appear as non-intentionally added substances. Their identity and migration depend on formulation, processing temperature, curing conditions, storage, contact time and the composition of the food. The literature on food-contact chemicals and non-targeted analysis predates 2026 and documents both the analytical difficulty and the existence of human exposure to numerous food-contact chemicals. [8–11]

A targeted LC-MS/MS method for BPA, BPS and BPF can answer whether those analytes are present above specified detection limits; it cannot rule out every unidentified migrant. High-resolution mass spectrometry can broaden the search, but identification confidence, response-factor uncertainty, matrix suppression and the availability of authentic standards limit quantitative conclusions. The scientifically defensible strategy combines targeted quantification for regulated or prioritised substances with a risk-ranked NIAS investigation. It must state which hazards remain outside the analytical window. A ‘no bisphenols detected’ claim should never be extrapolated into ‘no chemicals migrate’.

09 | The overlooked variable is the food itself

Migration is not an intrinsic constant of a container independent of use. An acidic tomato sauce, an oil-rich emulsion, an aqueous soft drink and a dry powder can interact differently with the same coating. Retort treatment, hot filling, long ambient storage and repeated cleaning alter diffusion, partitioning and chemical stability. Surface-area-to-food-mass ratio also matters: the same material can yield a different concentration in a small serving container than in a large tank. The EU framework accordingly requires appropriate testing conditions, while EFSA’s 2026 Appendix A recognises direct food measurements, food simulants and modelling as complementary approaches for non-plastic materials. Where reliable results in

real food are available, the guidance gives them precedence for risk assessment over potentially unrepresentative simulants. [1,3,12]

A qualification programme should therefore define the actual worst-case food–material pair rather than merely select the harshest-looking laboratory condition. Excessively aggressive simulants may generate artefacts, while insufficiently challenging tests can miss genuine migration during processing or storage. The appropriate design uses measured pH, fat content, temperature history, contact duration, package geometry and intended reuse cycles, with an explanation of why each condition is representative or conservative. The analytical plan should distinguish migration from extraction of the material itself, because the two experiments answer different regulatory questions.

10 | Packaging performance is a food-safety endpoint

A substitute coating can reduce exposure to a particular monomer while compromising the barrier that prevents corrosion, oxygen ingress, package failure or microbial spoilage. In acidic or high-salt foods, the consequences can include metal release, off-flavours, loss of vacuum or shortened shelf life. The European Commission acknowledged these practical constraints when designing longer transition periods for certain preserved fruits, vegetables and fishery products. That recognition is not an exemption from proving safety; it reflects the need to avoid exchanging a chemical concern for an inadequately controlled preservation failure. [3,4]

A defensible substitution trial should assess coating adhesion, porosity, corrosion resistance, seam and closure integrity, retort stability, organoleptic effects and microbiological performance alongside chemical migration. For a shelf-stable canned food, challenge and incubation studies may be relevant to process and package validation, but they must not be confused with an authorisation for the replacement chemistry. For a beverage, dissolved oxygen, colour, acidity and flavour stability may be decisive. An ingredient developer working with acidic functional beverages should include packaging compatibility in its formulation programme even where no bisphenol is intentionally added to the beverage itself.

11 | The EU prohibition is already operative, but not without boundaries

Commission Regulation (EU) 2024/3190, corrected by Regulation (EU) 2026/250, is directly applicable in EU Member States. It prohibits the use of BPA in manufacturing the specified food-contact material groups—adhesives, rubbers, ion-exchange resins, plastics, printing inks, silicones and varnishes or coatings—and prohibits the placing on the Union market of articles manufactured using BPA, subject to defined derogations and transitions. Other bisphenols or derivatives with the specified harmonised hazardous classifications are controlled through a separate prohibition and specific-use authorisation mechanism. The legal definition is therefore narrower than the casual statement that ‘all bisphenols are banned’. [2–4]

Two narrowly defined BPA applications remain in Annex II: certain liquid epoxy resin coatings for self-supporting food-contact articles exceeding 1,000 litres, and polysulfone filtration membrane assemblies. Both are subject to restrictions including non-detectable migration into food and cleaning or flushing before first use. These exceptions are operationally relevant to industrial tanks and membrane systems; they do not create a general right to use BPA in small containers or ordinary packaging. The legal status of another derivative must be checked against its classification, material type, specific-use permissions and any applicable transitional provisions. [2,3]

12 | The dates: first placing, filling and sell-through are different acts

The principal transition for first placing non-compliant BPA-manufactured single-use food-contact articles on the EU market ended on 20 July 2026. Specific categories, including certain preservation packaging for fruit, vegetables and fishery products and coatings applied only to the exterior metal surface, benefit from an extended first-placement deadline of 20 January 2028. Qualifying single-use articles placed on the

market within the relevant transition can generally be filled and sealed for a further twelve months, after which the resulting packaged foods may continue to be marketed until stocks are exhausted. Reusable articles have distinct provisions, and the February 2026 correction must be consulted when determining the relevant final circulation date. [3,4,13]

A manufacturing audit should not treat 'made before July 2026', 'first placed on the market before July 2026', 'filled in 2027' and 'sold to a consumer in 2028' as equivalent events. Evidence of first placement, transfer between economic operators, the status of unfilled stocks, and the precise food category is essential. These details matter for Spanish exporters, importers and private-label businesses that handle packaging inventories across multiple sites. They also explain why an apparently old BPA-containing can may lawfully remain in a retail supply chain without implying that new non-compliant packaging can still be introduced.

13 | Compliance declarations must describe a real material

Article 8 and Annex III of Regulation 2024/3190 require a declaration of compliance for covered materials and articles at relevant marketing stages other than retail, supported by documentation available to competent authorities. The declaration includes the identity of the operators and material, its date, a list of bisphenols or derivatives used in manufacture, and a compliance statement. Article 9 addresses analytical verification, including appropriate methods and a general detection-limit criterion of 1 microgram per kilogram unless a different applicable method or limit is specified. The verification of absence from a material and the measurement of migration into food are not identical analytical exercises. [3]

A useful purchasing dossier should additionally identify coating and substrate specifications, intended food types, processing and storage conditions, testing method and scope, relevant limits, uncertainty, change-control obligations and the supplier's responsibilities. Confidential formulation information may require appropriate protection, but confidentiality cannot justify a content-free declaration. A one-page statement that 'the packaging is BPA-free and compliant with all regulations' is not adequate when the operator cannot establish the intended application or identify which rules were considered. Legal conformity is a documented conclusion tied to a specific article and use.

14 | Spain: directly applicable law and a practical enforcement chain

Spain applies the EU food-contact framework directly, including Regulations (EC) 1935/2004 and 2023/2006 and the bisphenol-specific rules. The Spanish Agency for Food Safety and Nutrition (AESAN) lists Regulation 2024/3190 and its 2026 correction among the applicable instruments. Official controls are conducted within the competent national and autonomous-community arrangements under Regulation (EU) 2017/625. For an operator in Spain, the relevant compliance question is not whether a packaging supplier is based in the EU but whether the exact material placed on the Spanish or other EU market meets the applicable conditions and can be evidenced. [3,12,14]

If a migration dispute arises, preservation of the technical record matters: sample identity, material batch, contact conditions, analytical method, chromatograms, calibration, uncertainty, reference standards, extraction or migration protocol and traceability of the finished food. The objective is to resolve whether a finding is technically reliable and legally consequential, not simply to obtain a second result below a limit. For companies supplying ingredients rather than finished packaging, the relevant duty is to define the food matrix and processing requirements accurately so that the packer can select and validate an appropriate food-contact article.

15 | Great Britain and Northern Ireland: an unusually clear territorial divergence

Great Britain and Northern Ireland cannot be described as operating one identical bisphenol regime. Food Standards Scotland's June 2026 guidance confirms that the EU restrictions apply to the EU and Northern

Ireland under the Windsor Framework, subject to relevant movement arrangements, while the EU ban did not directly apply to the domestic Great Britain market at that date. The Food Standards Agency and Food Standards Scotland consulted on prospective restrictions, and the FSA published a summary of responses on 4 March 2026. A consultation outcome and an intention to legislate are not themselves an enacted GB prohibition. The live domestic legal position should be checked before shipment or certification. [7,15]

The British consultation is scientifically informative because respondents identified the possibility of substituting BPA with insufficiently characterised analogues, difficulties with coating performance and recycling, and the need for proportionate derogations for critical equipment. It also records divergent views about the toxicological basis for a broad ban. These comments are stakeholder evidence, not independent validation of any alternative material. A supplier serving both Spain and Great Britain should therefore maintain destination-specific legal assessments and avoid using 'UK-compliant' as a substitute for identifying the precise territory and applicable rules.

16 | The United States: a different risk-management and authorisation architecture

The US Food and Drug Administration's publicly stated position has continued to differ from EFSA's 2023 conclusion: its food-contact information page says the available evidence supports the safety of BPA at current levels for authorised uses, while explaining the removal of authorisations for baby bottles, sippy cups and infant-formula packaging following abandonment of those uses. The United States regulates food-contact substances through the Federal Food, Drug, and Cosmetic Act, applicable food-additive regulations and the food-contact-notification route. An EU prohibition does not automatically invalidate a US food-contact authorisation, and a US authorisation does not create EU market permission. [16]

The distinction is not evidence that toxicological science follows national borders. It reflects different assessments, evidentiary histories and regulatory decisions. For a multinational packaging project, the appropriate matrix records the precise substance, article, intended conditions of use, US regulatory basis and EU or GB destination status. It should also monitor state-level requirements where relevant; a federal assessment alone should not be presented as a universal clearance for every US jurisdiction. Claims about comparative stringency are meaningful only after the substance, use, exposure assumptions and legal instrument have been aligned.

17 | Industrial filtration: the exception that reveals the engineering problem

The Annex II derogation for polysulfone filtration membrane assemblies illustrates why a simple 'replace the molecule' strategy may be inadequate. Membrane materials can be critical to microfiltration, ultrafiltration and certain separation systems, and their performance depends on chemical resistance, mechanical integrity, pore characteristics, cleaning tolerance and service life. A replacement must be qualified not only for migration but also for retention performance and resistance to cleaning agents and thermal cycles. The regulation's non-detectable migration and pre-use flushing conditions remain mandatory for the derogated application. [3]

For beverage and dairy operations, the design of a comparative trial should include the feed matrix, membrane surface area, residence time, pressure, cleaning regime, fouling behaviour, permeate quality, microbiological performance and target migrants. A material that reduces one chemical signal while allowing loss of microbial retention would not be a safer system. Conversely, a functioning legacy membrane that falls within a valid derogation should not be described as unlawful merely because BPA was used as a starting substance. The technical and legal questions must be answered together.

18 | The patent record prevents easy claims of novelty

BPA-free and BADGE-free coating technologies have been described in patent literature for many years. Publications such as EP1957579A1, WO2007143407A1 and WO2014205043A1 describe alternative resin

and coating approaches, including polyester-based formulations intended for food and beverage containers. These disclosures establish that developing coatings without conventional BPA-based epoxy systems is not an invention of 2026. They do not, however, establish that every disclosed composition is currently authorised, commercially available, free of all relevant migrants or suitable for every food and retort process. [17–19]

A serious innovation claim must distinguish a new chemical formulation from a new test method, a new use condition and a new data-integration protocol. Patent publication alone is not proof of independent industrial validation, freedom to operate or legal permission. Before claiming a novel platform, a company would need a claims-level patent search, current legal-status review and technical comparison against existing commercial systems. The potential contribution identified here is not a newly discovered polymer but a more reproducible, decision-grade way to compare candidate materials across toxicology, migration and food preservation.

19 | What should a food manufacturer request tomorrow?

A pragmatic first step is to create a material-use inventory that identifies every food-contact surface relevant to a product: can lining, closure, gasket, seal, adhesive, ink, transfer tubing, pump component and membrane, rather than the primary package alone. The inventory should record supplier, formulation identifier or controlled specification, intended food, time–temperature profile, replacement history and destination markets. It should then distinguish legal requirements from voluntary performance specifications and rank items by foreseeable exposure and failure severity. [3,12]

For each proposed substitution, procurement should request a legally adequate declaration of compliance, evidence of substance identity and any bisphenol derivatives used, validated targeted migration data, a justified NIAS strategy, and processing-performance results in the intended food. Quality assurance should retain representative samples and establish a change-control rule for coating reformulation, resin supplier changes or modified curing schedules. R&D should assess sensory, corrosion and microbial shelf-life outcomes, and regulatory staff should sign off the exact destination-specific permission. A laboratory report is one element of this chain; it is not a substitute for the chain itself.

20 | Research & Innovation Opportunity

UNRESOLVED PROBLEM. Existing literature and regulatory guidance address migration testing, toxicological evaluation, NIAS screening and packaging performance, but publicly available comparative datasets often do not connect all four dimensions for the same replacement coating across multiple food matrices and realistic industrial conditions. The question is whether an integrated protocol can reduce false assurance and unnecessary rejection more effectively than separate, poorly connected supplier certificates and end-product tests. The gap is one of prospective validation and interoperability, not the invention of migration science or safer coatings. [1,8–11,17–19]

WHAT IS ESTABLISHED. EFSA provides tiered toxicological expectations; EU law sets specific restrictions and documentary obligations; analytical chemistry can quantify selected migrants and screen additional compounds; packaging engineering can measure corrosion, barrier and shelf-life performance. Published patents and reviews demonstrate substantial prior art. None of these facts proves that a particular new substitute is safe or that an integrated digital record would improve outcomes. [1–4,8–11]

PROPOSED HYPOTHESIS — NOT ESTABLISHED FACT. A ‘Matrix-Conditioned Substitution Passport’ combining verified material identity, targeted and non-targeted migration results, toxicokinetic evidence, food-specific performance data and jurisdiction-specific legal status could predict unsuitable substitutions earlier and make approval decisions more reproducible than a BPA-free declaration plus a single standard migration test. The proposed name denotes a research architecture, not a regulatory certificate, patented invention or demonstrated industrial product.

VALIDATION PATHWAY. Compare at least three materially different food-contact applications: an acidic retorted product in a coated metal container, a lipid-rich ambient-stable food and a continuously operated beverage or dairy filtration system. For each, select a reference material and at least two legally plausible alternatives. Pre-register contact conditions and analytical endpoints; use validated targeted LC-MS/MS with isotope-labelled standards where appropriate, orthogonal high-resolution screening for NIAS, and realistic processing and ageing studies. Quantify coating or membrane integrity, microbial and sensory shelf life, migrant mass balance, measurement uncertainty, cost per accepted lot and false-acceptance or false-rejection rates. Include independent laboratories, blinded comparisons and change-control challenges. Where toxicological data are missing, classify the candidate as unresolved rather than imputing safety from a predictive score.

REGULATORY AND INDUSTRIAL CONSTRAINTS. Research must not replace any mandatory EU authorisation, restriction, migration method or declaration, and it must not place experimental non-compliant packaging on the food market. Personal or proprietary formulation data require controlled access; AI models require transparent training data, external validation and a defined decision role. If the proposed protocol is shown to improve qualification accuracy without sacrificing food preservation or increasing total environmental burden, it could be useful for food manufacturers, coating suppliers and ingredient companies designing new matrices. Until such results exist, its benefits remain hypothetical.

21 | Evidence classification and critical appraisal

ESTABLISHED LEGAL FACT. Regulation (EU) 2024/3190, as corrected, imposes binding restrictions and differentiated transition rules in the EU; Spain applies that framework directly; Northern Ireland has relevant EU-linked requirements. EFSA's October 2026 guidance is scientific guidance, not an implementing authorisation. Great Britain's consultation does not itself enact the EU ban, and the FDA has a separate food-contact regime. [1–4,7,14–16]

ESTABLISHED SCIENTIFIC EVIDENCE. BPA and some analogues raise toxicological concerns; migration depends on material and food conditions; low migration does not by itself characterise every biological endpoint; and NIAS can be relevant to safety assessment. These propositions are supported by authoritative assessments and prior literature, but they do not establish equivalent potency for all bisphenols. [1,6,8–11]

EMERGING EVIDENCE AND EXPERT INTERPRETATION. The 2026 guidance strengthens expectations for immune, reproductive, metabolic and kinetic evidence and may influence future applications. The industrial recommendation to evaluate chemical safety and package performance together is a reasoned interpretation of existing law and technology, not a claim that a new validated international standard already exists. [1–4]

HYPOTHESIS AND RESEARCH AGENDA. The proposed integrated passport could improve supplier qualification and substitution decisions. That proposition has not been prospectively validated in the form described here; measurable performance against conventional practice, not rhetorical novelty, is the appropriate test.

22 | Conclusions: substitution must be proved, not advertised

The October 2026 EFSA guidance marks a shift from treating BPA replacement as a compositional declaration toward requiring a more complete account of low-dose toxicology and internal exposure for other bisphenols. Its importance lies not in creating a new prohibition, but in clarifying why the absence of one familiar chemical cannot carry the evidentiary weight of a safety assessment. The existing EU restrictions, including specific derogations and transition rules, remain a separate and immediately relevant legal question. [1–4]

For the food and biotechnology industries, the defensible sequence is to establish the material and its legal route, identify potential migrants, test under representative food and processing conditions, evaluate toxicological evidence and preserve the package's protective function. Companies should resist both complacency about unclassified substitutes and the opposite error of assuming that every analogue has identical hazards. The research opportunity is to make these decisions more integrated, auditable and predictive, while recognising that no data architecture can replace valid chemistry, sound toxicology or compliance with the law.

Related Knowledge Areas

Food Safety; Biotechnology; Regulatory Affairs; Processing Technologies; Functional Ingredients; Sustainability; AI & Food; Emerging Research.

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