VOLUME 6 | ISSUE 2

INTERNATIONAL JOURNAL OF ADVANCED LEGAL RESEARCH

SCIENTIFIC UNCERTAINTY, LEGAL OVERSIGHT, AND CONSUMER PROTECTION: EU AND ÉIRE'S APPROACHES TO FOOD PACKAGING RISKS

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Abstract

This article examines the regulatory frameworks of the EU and Ireland concerning food contact materials (FCMs), highlighting the concerns associated with chemical migration in common packaging such as beverage cartons. Based on Regulation (EC) No 1935/2004, the framework reconciles human health safeguarding with market integration, stipulating that materials must not release dangerous compounds above permissible thresholds. Scientific studies conducted by EFSA, including BPA re-assessments, guide migration thresholds and precautionary protocols. The investigation of drinking cartons elucidates the difficulties of composite materials, non-intentionally added substances (NIAS), and regulation deficiencies with non-plastic components. The enforcement by the Food Safety Authority of Ireland (FSAI) includes inspections, traceability, and liability frameworks; nonetheless, scientific uncertainty and inconsistent harmonisation provide obstacles. The article promotes adaptations to mitigate developing dangers, guaranteeing adaptable public health protections in response to changing chemical exposure issues.

Keywords: Ireland, EU, Public Health, Regulation, Food Packaging.

INTRODUCTION

Every day, Irish consumers unwittingly interact with a remarkable array of materials that have played a role in safeguarding the safety and quality of the foods and drinks they consume. A carton of milk on a breakfast table, a tetra-pack of juice carried in a child′s schoolbag, or a takeaway coffee served in a paper-based container may seem like unremarkable objects of daily life. Yet each of these items embodies a complex system of legal rules, scientific assessment, and regulatory oversight designed to protect human health while facilitating the operation of the European internal market. These materials fall within the legal category of food contact materials, a term used in

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European Union law to describe any material or article intended to come into contact with food, already in contact with food, or reasonably expected to transfer its constituents to food under normal or foreseeable conditions of use.[2] This definition is deliberately broad. It encompasses not only obvious forms of packaging such as cartons, bottles and wrappers, but also processing equipment, storage containers, and other articles that may touch food during its production, transport or consumption.[3] In practice, if a material touches food or drink that may be consumed, it is likely to fall within the scope of food contact materials regulation.

The legal foundation for the regulation of food contact materials in Ireland is found primarily in European Union law. The cornerstone of this regime is Regulation (EC) No 1935/2004 of the European Parliament and of the Council, which establishes harmonised rules governing materials and articles intended to come into contact with food.[4] The Regulation pursues a dual objective: to ensure a high level of protection of human health and consumer interests, and to allow the free movement of goods within the internal market.[5] These objectives reflect the broader structure of EU public health law, which seeks to reconcile consumer protection with economic integration. At the heart of Regulation 1935/2004 rests a general safety requirement. Article 3 provides that food contact materials must be manufactured in such a way that, under normal or foreseeable conditions of use, they do not transfer their constituents into food in quantities that could endanger human health, bring about an unacceptable change in the composition of the food, or impair its organoleptic characteristics.[6] In ordinary terms, this means that the materials used in packaging - including the layers of cardboard, plastic, and coatings found in many drinking cartons - must not release harmful substances into food or drink at levels capable of causing harm.

Although this principle appears straightforward, its application depends heavily on scientific assessment and regulatory interpretation. The Regulation does not list all prohibited substances, nor does it define ″endanger human health” in purely legal terms. Instead, it relies on scientific risk assessment to determine whether particular substances, when used in food contact materials, may pose risks to consumers. This scientific dimension is central to the regulation of chemicals that have

[2] *European Commission, Food Contact Materials – General Information (DG SANTE)*https://food.ec.europa.eu/food-safety/chemical-safety/food-contact-materials/general-information-and-contacts_en *accessed 21 December 2025.*
[3] *European Commission, Food Contact Materials – Food Safety* https://food.ec.europa.eu/food-safety/chemical-safety/food-contact-materials_en *accessed 21 December 2025.*
[4] *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 [2004] OJ L 338/4.*
[5] *ibid art 1.*
[6] *ibid art 3.*

been associated with long-term health effects, including carcinogenicity. Ireland, as a Member State of the European Union, gives effect to Regulation 1935/2004 through domestic legislation and enforcement mechanisms. Irish statutory instruments implement specific EU measures, while EU regulations themselves apply directly within the State. Oversight and enforcement are entrusted primarily to the Food Safety Authority of Ireland (FSAI), which is responsible for ensuring that food contact materials placed on the Irish market comply with both EU and national requirements.[7] Through inspections, documentation checks and cooperation with other Member States, the FSAI plays a central role in translating EU legal standards into practical public health protection.[8]

The relevance of this regulatory framework to everyday life is easily overlooked. Consumers rarely question the safety of a juice carton or milk container, yet the materials used in such products are subject to continuous legal scrutiny. This scrutiny has intensified in recent years as scientific research has drawn attention to substances such as bisphenol A (BPA), phthalates and per- and polyfluoroalkyl substances (PFAS), which may migrate from packaging into food and have been associated with potential adverse health effects, including endocrine-mediated pathways.[9] Although EU law does not automatically classify such substances as carcinogenic in the context of food contact materials, it requires that exposure be kept below levels considered safe on the basis of current scientific knowledge.

This article examines how Irish public health law, operating within the EU regulatory framework, addresses the risks associated with chemical migration from food and drink packaging. Particular attention is paid to drinking cartons, which are widely used and often involve complex multi-layer materials. By analysing legislation, regulatory practice and scientific assessment from such sources, the article seeks to explain how the law protects consumers, where its limits sit, and how it may need to evolve in response to emerging public health concerns.

[7] *Food Safety Authority of Ireland, Materials and Articles in Contact with Foodstuffs – Legislation* https://www.fsai.ie/enforcement-and-legislation/legislation/food-legislation/materials-and-articles-in-contact-with-foodstuffs/legislation *accessed 21 December 2025.*

[8] *Institute of Food Science & Technology, 'Audit of Official Controls Carried Out by the HSE Published – FSAI.'* https://www.ifst.org/news/audit-official-controls-carried-out-hse-published-%E2%80%93-fsai-0 *accessed 22 December 2025.*

[9] *Madeline Tanzer et al, Phthalates, bisphenols and per‐and polyfluoroalkyl substances migration from food packaging into food: a systematic review (2025) Rev Environ Health.* https://pubmed.ncbi.nlm.nih.gov/40665485/ *accessed 22 December 2025.*

THE LEGAL FRAMEWORK GOVERNING FOOD CONTACT MATERIALS IN IRELAND AND THE EUROPEAN UNION

Irish law governing food contact materials cannot be understood in isolation from the wider European Union legal order. As a Member State, Ireland participates in a harmonised regulatory system in which substantive rules governing food safety are largely determined at the EU level and enforced domestically through national authorities. This structure reflects the EU′s long-standing recognition that divergent national standards for food safety and packaging would undermine both consumer protection and the functioning of the internal market.

The primary legal instrument governing food contact materials across the Union is Regulation (EC) No 1935/2004. Unlike directives, which require transposition into national law, EU regulations are directly applicable in all Member States.[10] As a result, the core obligations imposed by Regulation 1935/2004 apply in Ireland as a matter of law without the need for domestic enactment. Irish legislation and statutory instruments operate alongside the Regulation, not to replace it, but to provide enforcement mechanisms, administrative structures, and penalties for non-compliance. Regulation 1935/2004 establishes a framework regime rather than a comprehensive code. Its purpose is to set general principles applicable to all food contact materials while allowing for the adoption of specific measures for particular categories of materials, such as plastics.[11] This approach reflects the diversity and technical complexity of materials used in modern food packaging. A single set of prescriptive rules would be ill-suited to regulate products ranging from glass bottles and metal cans to multi-layer cartons combining paperboard, polymers, and aluminium foil. Article 3 of the Regulation, already introduced in Part 1 of this article, forms the cornerstone of the legal framework. It imposes a general safety obligation requiring that materials do not transfer constituents into food in quantities that could endanger human health.[12] Crucially, this obligation applies regardless of whether a specific measure exists for a particular material. In this way, Article 3 functions as a legal safety net, ensuring that even novel or unregulated materials remain subject to public health scrutiny.

Beyond this general obligation, Regulation 1935/2004 also introduces requirements relating to traceability and compliance documentation. Article 17 provides that food contact materials must be

[10] *Consolidated Version of the Treaty on the Functioning of the European Union [2012] OJ C 326/47, art 288.*
[11] *Regulation (EC) No 1935/2004 (n 3) art 5.*
[12] *ibid art 3.*

traceable at all stages of manufacture, processing, and distribution.[13] This requirement is particularly significant in the context of drinking cartons, which are often manufactured through complex international supply chains involving multiple component suppliers. Traceability allows enforcement authorities to identify the source of non-compliant materials and to take corrective action efficiently. Article 16 further requires that materials subject to specific measures be accompanied by a written Declaration of Compliance.[14] This document must confirm that the material complies with applicable EU legislation and must be supported by appropriate documentation demonstrating such compliance. Although this requirement is technical in nature, it plays a vital role in enforcement, enabling authorities such as the Food Safety Authority of Ireland (FSAI) to verify that manufacturers and importers have assessed chemical migration risks in accordance with legal standards.

One of the most significant specific measures adopted under Regulation 1935/2004 is Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.[15] This Regulation lays down detailed rules governing plastic components of food contact materials, including those used as linings or coatings in beverage cartons. It establishes a Union list of authorised substances, sets overall and specific migration limits, and prescribes testing conditions designed to simulate realistic or worst-case use scenarios. Although cartons are often perceived as "paper-based", their plastic layers bring them squarely within the scope of Regulation 10/2011. Ireland gives practical effect to these EU rules through domestic statutory instruments. The most important of these is the European Union (Plastics and other Materials) (Contact with Food) Regulations 2017 (S.I. No 49 of 2017).[16] This instrument designates competent authorities, provides inspection and enforcement powers, and establishes offences and penalties for non-compliance. While it does not restate the substantive EU standards, it ensures that those standards can be enforced effectively within the Irish legal system. Earlier statutory instruments, including the European Communities (Plastics and Other Materials) (Contact with Food) Regulations 2007 (S.I. No 587 of 2007), continue to inform the regulatory landscape, particularly in relation to imported

[13] *ibid art 17.*
[14] *ibid art 16.*
[15] *Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food [2011] OJ L 12/1.*
[16] *European Union (Plastics and other Materials) (Contact with Food) Regulations 2017 (S.I. No 49/2017).*

materials and transitional arrangements.[17] Together, these instruments form a domestic enforcement framework that complements directly applicable EU law.

The enforcement of food contact materials law in Ireland is entrusted primarily to the Food Safety Authority of Ireland, acting through official agencies such as environmental health services. The FSAI operates under the Food Safety Authority of Ireland Act 1998, which empowers it to ensure that food placed on the market is safe and compliant with applicable legislation.[18] In practice, this means that the FSAI monitors compliance with EU food contact materials law through inspections, audits of documentation, sampling, and laboratory analysis. This multi-layered legal framework reflects a deliberate policy choice. By combining broad EU-level principles with detailed technical measures and national enforcement mechanisms, the law seeks to ensure a high level of public health protection while remaining adaptable to scientific and technological change. For Irish consumers, the result is a system in which the safety of something as ordinary as a juice carton is underpinned by binding legal obligations that extend from Brussels to Dublin and into the manufacturing facilities of packaging producers across Europe and beyond.[19]

The crucial role of the FSAI could be seen in the pork dioxin crisis of 2008. In late 2008, a significant contamination incident occurred in Ireland when routine laboratory testing confirmed the presence of dioxins and dioxin‑like PCBs at toxicologically concerning levels in pork fat samples. The contamination had arisen earlier that autumn as a result of animal feed being produced using hot air contaminated by dioxin‑laden fuel, which was then fed to pigs and other livestock. Because of the way pork was processed and commingled across the national supply, it was impossible to distinguish contaminated consumer products from uncontaminated ones. On 6 December 2008, Irish authorities - notably the Food Safety Authority of Ireland (FSAI) along with its official agencies - ordered the largest food recall in the State′s history. This meant that all Irish pork and pork products produced between 1 September and 6 December 2008 were withdrawn from both domestic and international markets. This recall was precautionary and comprehensive because traceability of final consumer products back to specific farms was impractical due to the mixing of

[17] *European Communities (Plastics and Other Materials) (Contact with Food) Regulations 2007 (S.I. No 587/2007).*
[18] *Food Safety Authority of Ireland Act 1998, s 11.*
[19] *Ekaterina Karamfilova, 'Food Contact Materials - Regulation (EC) 1935/2004 - European Implementation Assessment' (European Parliamentary Research Service, May 2016) https://www.europarl.europa.eu/RegData/etudes/STUD/2016/581411/EPRS_STU(2016)581411_EN.pdf accessed 22 December 2025.*

pork from many animals in processing plants. The FSAI, through its routine national residue monitoring programme, was instrumental in identifying the problem, assessing the risk to consumer health, and mandating the removal of contaminated products from the market. Within a matter of days, contaminated products were replaced with pork from animals that had not received the contaminated feed. Throughout the process, there was full compliance throughout the food chain, and consumers ′health was effectively protected. The article emphasises that the swift regulatory action demonstrated the effectiveness of Ireland′s food safety control system in responding to an unprecedented food safety crisis. It also notes the challenges of communicating accurate information amid extensive media coverage and the need to restore public confidence in the safety of Irish food.[20] Although the pork dioxin incident did not concern food contact materials as such, it illustrates the central role of the Food Safety Authority of Ireland in translating scientific detection, precautionary decision-making, and traceability obligations into decisive regulatory action - functions that are equally critical to the effective oversight of food contact materials under EU and Irish law.

CORE SAFETY STANDARDS AND THE PROTECTION OF PUBLIC HEALTH

At the centre of the legal regime governing food contact materials sits a simple but powerful objective: the protection of human health. While the language of EU legislation is often technical, its underlying concern is easily understood. Materials that come into contact with food and drink must not expose consumers to chemical substances at levels that could cause harm, whether immediately or over the long term. This concern is particularly acute where exposure is chronic, subtle, and largely invisible to the consumer, as is the case with chemical migration from packaging into food. The legal mechanism through which this objective is achieved is the concept of chemical migration. Migration refers to the transfer of chemical substances from a food contact material into food or drink. EU law does not prohibit migration as such; rather, it seeks to ensure that migration occurs only within limits that are scientifically assessed as safe.[21] This distinction is crucial. Many materials used in packaging, including plastics and coatings used in drinking cartons, would be impossible to manufacture without the use of additives, stabilisers, or processing aids. The law therefore focuses not on absolute purity, but on acceptable exposure.

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[20] *C Tlustos, The Dioxin Crisis in Ireland 2008 — Challenges in Risk Management (Organohalogen Compounds, Vol 71, 2009) https://dioxin20xx.org/wp-content/uploads/pdfs/2009/09-234.pdf accessed 22 December 2025.*

[21] *European Commission, Food Contact Materials – Food Safety https://food.ec.europa.eu/food-safety/chemical-safety/food-contact-materials_en accessed 21 December 2025.*

Under Regulation (EC) No 1935/2004, the general requirement is that migration must not occur in quantities that endanger human health.[22] However, this general standard is given practical effect through specific migration limits (SMLs) and overall migration limits (OMLs) laid down in more detailed legislation, most notably Commission Regulation (EU) No 10/2011.[23] These limits are expressed in quantitative terms and are designed to reflect worst-case consumption scenarios, including vulnerable populations such as children. The scientific basis for these limits is provided by the European Food Safety Authority (EFSA). EFSA plays a central role in the EU′s food safety system by conducting independent risk assessments of substances used in food contact materials.[24] When assessing a substance, EFSA considers toxicological data, including evidence of carcinogenicity, endocrine disruption, reproductive toxicity, and other long-term health effects. From this data, EFSA may establish a tolerable daily intake (TDI), representing the amount of a substance that can be ingested daily over a lifetime without appreciable health risk.

One of the most prominent examples of this process concerns bisphenol A (BPA), a substance historically used in the manufacture of polycarbonate plastics and epoxy resins, including coatings used in food and drink packaging. BPA has attracted sustained scientific and regulatory attention due to concerns about its endocrine-disrupting properties and potential links to cancer and other adverse health outcomes.[25] Although BPA is not classified as a carcinogen per se under EU chemicals legislation, EFSA has repeatedly reassessed its safety in light of emerging evidence.

In 2023, EFSA published a comprehensive re-evaluation of BPA, concluding that exposure to the substance posed a health concern at much lower levels than previously understood.[26] EFSA significantly reduced the tolerable daily intake for BPA, reflecting new evidence relating to immune system effects. While this opinion did not itself change the law, it has profound legal significance. Under EU food law, scientific opinions issued by EFSA form the basis for regulatory action, including amendments to existing migration limits or the introduction of bans and restrictions.

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[22] 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 [2004] OJ L 338/4, art 3.

[23] Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food [2011] OJ L 12/1.

[24] European Food Safety Authority, Food Contact Materials https://www.efsa.europa.eu/en/topics/topic/food-contact-materials accessed 21 December 2025.

[25] European Food Safety Authority, Bisphenol A https://www.efsa.europa.eu/en/topics/topic/bisphenol accessed 21 December 2025.

[26] EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP), Re‐evaluation of the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs EFSA Journal 2023, 21(4): e06857 https://doi.org/10.2903/j.efsa.2023.6857 accessed 22 December 2025.

The relevance of such scientific reassessments to drinking cartons is clear. Many cartons rely on plastic linings or coatings to ensure liquid containment and shelf stability. Where these components contain substances such as BPA or similar chemicals, even low-level migration can become legally significant if it exceeds newly revised safety thresholds. The law′s responsiveness to changing science is therefore a key feature of public health protection in this area.[27][28]

In addition to substance-specific limits, EU law also imposes an overall migration limit, designed to cap the total quantity of non-volatile substances that may migrate from a material into food.[29] This limit reflects a precautionary approach, recognising that consumers are often exposed to multiple substances simultaneously and that cumulative effects may not be fully understood. While overall migration limits do not distinguish between carcinogenic and non-carcinogenic substances, they provide an additional layer of protection against excessive chemical exposure. Irish enforcement authorities apply these standards through inspection, sampling, and laboratory testing. The Food Safety Authority of Ireland, acting through authorised officers, may assess whether packaging materials comply with both specific and overall migration limits.[30] Where non-compliance is identified, enforcement measures may include product withdrawal, corrective action, or prosecution under domestic regulations.[31] In this way, abstract scientific thresholds are translated into concrete legal consequences.

What emerges from this system is a regulatory model that places science at the heart of public health law. Legal standards are not static; they evolve as scientific understanding advances. For consumers, this means that the safety of everyday products such as drinking cartons is continually reassessed against the best available evidence. For regulators and manufacturers, it imposes a legal

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[27] *Commission, ′Commission Adopts Ban of Bisphenol A in Food Contact Materials ′(European Commission, 19 December 2024) https://food.ec.europa.eu/food-safety-news-0/commission-adopts-ban-bisphenol-food-contact-materials-2024-12-19_en accessed 23 December 2025.*

[28] *EFSA (2023). 'Bisphenol A in food is a health risk.' https://www.efsa.europa.eu/en/news/bisphenol-food-health-risk accessed 23 December 2025.*

[29] *Commission Regulation (EU) No 10/2011, art 12.*

[30] *Food Safety Authority of Ireland, Food Contact Materials – Compliance and Enforcement https://www.fsai.ie/business-advice/running-a-food-business/food-safety-and-hygiene/food-contact-materials accessed 21 December 2025.*

[31] *'Food Safety Authority of Ireland – Inspections and Enforcements in Numbers' (Ian Thompson Associates, 2025) https://ianthomasassociates.com/food-safety-authority-of-ireland-inspections-and-enforcements-in-numbers/ accessed 22 December 2025.*

duty to remain responsive to emerging risks, including those associated with substances that may contribute to long-term conditions such as cancer.

DRINKING CARTONS AS A CASE STUDY IN CHEMICAL RISK AND REGULATION

Drinking cartons occupy a distinctive place within the law on food contact materials. To the ordinary consumer, they appear simple, even wholesome: paper-based containers often associated with milk, juice, and products marketed as healthy or environmentally conscious. Legally and scientifically, however, they are among the most complex food contact materials on the market. Their multi-layer construction raises particular challenges for regulation, enforcement, and public understanding, making them a useful case study for examining how Irish public health law addresses chemical risk in food consumption. A typical drinking carton is not composed solely of paper or cardboard. Instead, it is a composite material, combining layers of paperboard with thin coatings of plastic polymers and, in some cases, aluminium foil.[32] Each layer performs a specific function. The paperboard provides structural strength, the plastic layers ensure liquid tightness and heat sealing, and the aluminium layer, where present, acts as a barrier against light and oxygen.[33] From a legal perspective, this layered structure means that cartons fall simultaneously within multiple regulatory categories under EU food contact materials law.

Although Regulation (EC) No 1935/2004 applies to all food contact materials as a general matter, its operation in the context of composite materials is particularly intricate.[34] Where a carton contains plastic layers, those components are subject to Commission Regulation (EU) No 10/2011, even if the consumer perceives the product as "paper-based".[35] This has important consequences. Substances used in plastic linings, such as monomers, additives, and degradation products, must appear on the Union list of authorised substances and must comply with applicable specific migration limits. In addition to intentionally added substances, drinking cartons may also contain non-intentionally added substances (NIAS). These include impurities in raw materials, reaction by-

[32] *European Commission, Food Contact Materials – General Information https://food.ec.europa.eu/food-safety/chemical-safety/food-contact-materials/general-information-and-contacts_en accessed 21 December 2025.*
[33] *Claire Jenns, 'Unpacking beverage carton sustainability.' Inside Packaging https://inside-packaging.nridigital.com/inside_packaging_aug24/unpacking_beverage_carton_sustainability accessed 22 December 2025.*
[34] *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 [2004] OJ L 338/4.*
[35] *Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food [2011] OJ L 12/1.*

products formed during manufacturing, and substances generated through degradation over time.[36] NIAS present particular regulatory challenges because they are not always identifiable in advance and may not be subject to specific migration limits. Nevertheless, EU law requires that their presence be assessed as part of the overall safety evaluation of the material. EFSA has acknowledged the complexity posed by NIAS in food contact materials, noting that their identification and risk assessment can be scientifically demanding but are essential to ensuring consumer protection.[37] Under the legal framework, manufacturers bear primary responsibility for assessing the safety of NIAS and demonstrating compliance with the general safety requirement laid down in Article 3 of Regulation 1935/2004. This obligation applies regardless of whether a substance has been formally authorised at EU level.

Another area of concern in relation to drinking cartons is the use of printing inks, adhesives, and coatings. These materials are often applied to the external layers of cartons, yet they may still pose a risk of migration into food, either directly or through set-off during storage and transport. Unlike plastics, printing inks are not yet subject to fully harmonised EU-specific measures.[38] As a result, their regulation relies heavily on the general principles of Regulation 1935/2004 and on compliance with good manufacturing practice requirements under Commission Regulation (EC) No 2023/2006.[39] The absence of detailed, substance-specific EU rules for certain components of drinking cartons has led to concerns about regulatory gaps. While national authorities may take enforcement action where a material is found to be unsafe, the lack of harmonised standards can make it more difficult to ensure consistent levels of protection across the internal market. From an Irish perspective, this places additional importance on the role of the Food Safety Authority of Ireland in monitoring compliance and responding to potential risks as they arise. Scientific debate has further intensified scrutiny of drinking cartons in recent years, particularly in relation to substances suspected of having endocrine-disrupting or carcinogenic properties. While EU food contact materials law does not classify packaging materials themselves as carcinogenic, it does recognise that long-term exposure to low levels of certain chemicals may contribute to adverse

[36] *European Food Safety Authority, Non-intentionally added substances (NIAS) in food contact materials* https://www.efsa.europa.eu/en/topics/topic/food-contact-materials *accessed 21 December 2025.*
[37] *ibid.*
[38] *'EuPIA Guideline on Printing Inks applied to Food Contact Materials' (2023)* https://www.eupia.org/wp-content/uploads/2023/06/2023-05-18_EuPIA-Guideline-on-Printing-Inks-applied-to-Food-Contact-Materials.pdf *accessed 21 December 2025.*
[39] *Commission Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food [2006] OJ L 384/75.*

health outcomes.[40] This is especially relevant for products consumed regularly over long periods, such as milk or juice packaged in cartons and consumed daily by children.

The legal framework addresses this concern indirectly, through conservative exposure assumptions and the application of the precautionary principle. Migration limits are set on the basis of lifetime exposure, not occasional consumption. Where scientific uncertainty persists, regulators may impose stricter limits or revise existing standards in light of new evidence. The reassessment of substances such as bisphenol A, discussed in the previous section, illustrates how this process can affect materials used in carton linings, even where no immediate risk is apparent. For Irish consumers, the complexity of drinking carton regulation is largely invisible. The law does not require prominent labelling of chemical constituents, and compliance is presumed unless evidence to the contrary emerges. This reliance on upstream regulation and enforcement reflects a broader model of public health protection in food law, one that prioritises systemic control over individual consumer choice. Whether this model remains sufficient in the face of increasing concern about cumulative chemical exposure is a question that continues to shape legal and scientific debate.[41][42]

Drinking cartons thus exemplify both the strengths and the limitations of the current regulatory regime. They demonstrate the law′s capacity to address sophisticated materials through layered regulation and scientific assessment, while also highlighting areas where harmonisation remains incomplete and public awareness limited. In doing so, they provide a concrete lens through which to assess how Irish public health law responds to the evolving challenges of food consumption in a chemically complex world.

ENFORCEMENT, LIABILITY, AND CONSUMER PROTECTION UNDER IRISH LAW

The effectiveness of any public health regime ultimately depends not on the elegance of its principles, but on the strength of its enforcement.[43] In the context of food contact materials, Irish law relies on a combination of EU-level obligations and national enforcement powers to ensure that

[40] *EU Parliament Committee on the Environment, Public Health and Food Safety, 'Report on the implementation of the Food Contact Materials Regulation ((EC) No 1935/2004).' https://www.europarl.europa.eu/doceo/document/A-8-2016-0237_EN.html accessed 21 December 2025.*

[41] *Food Safety Authority of Ireland, General Principles of Food Law (FSAI) https://www.fsai.ie/enforcement-and-legislation/legislation/food-legislation/general-principles-of-food-law accessed 22 December 2025.*

[42] *European Food Safety Authority, Risk assessment of food contact materials (EFSA Journal, 30 November 2023) https://doi.org/10.2903/j.efsa.2023.e211015 accessed 23 December 2025.*

[43] *FAO, Food Control Systems (Rome: Food and Agriculture Organization of the UN, 2003) http://www.fao.org/3/y1579e/y1579e04.htm accessed 22 December 2025.*

legal standards translate into real-world consumer protection. This enforcement framework reflects a preventative approach, seeking to identify and address risks before harm occurs, rather than relying solely on ex post remedies after damage has been done. In Ireland, responsibility for enforcing food contact materials legislation rests primarily with the Food Safety Authority of Ireland (FSAI), acting through official agencies such as the Health Service Executive and local authorities.[44] The FSAI derives its powers from the Food Safety Authority of Ireland Act 1998, which mandates it to ensure that food placed on the market complies with food legislation and is safe for consumption.[45] Although food contact materials are not themselves food, they are regulated as an integral part of the food safety system, given their capacity to affect the safety and composition of food.

Enforcement activity in this area typically takes the form of official controls, including inspections of manufacturing premises, audits of documentation such as Declarations of Compliance, sampling of materials, and laboratory testing to assess chemical migration.[46] These controls are carried out in accordance with EU rules on official controls, which require Member States to maintain effective, proportionate, and dissuasive enforcement mechanisms.[47] The emphasis on documentation and traceability is particularly important in relation to drinking cartons, which often involve multiple stages of production and international supply chains. Where non-compliance is identified, Irish law provides a range of enforcement tools. Under the European Union (Plastics and other Materials) (Contact with Food) Regulations 2017, authorised officers may issue compliance notices requiring corrective action, prohibit the placing of materials on the market, or initiate prosecutions.[48] These measures are designed to be flexible, allowing authorities to respond proportionately to the nature and severity of the breach. In cases involving potential risks to public health, swift intervention may be required to prevent continued exposure.

Criminal liability plays an important, if carefully circumscribed, role in this framework. Breaches of food contact materials legislation may constitute criminal offences under Irish statutory instruments,

[44] *Food Safety Authority of Ireland, Official Controls and Enforcement* https://www.fsai.ie/enforcement-and-legislation/official-controls *accessed 22 December 2025.*
[45] *Food Safety Authority of Ireland Act 1998, s 11.*
[46] *Food Safety Authority of Ireland, Importing Food Contact Materials* https://www.fsai.ie/enforcement-and-legislation/legislation/food-legislation/imports/importing-food-contact-materials *accessed 22 December 2025.*
[47] *Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls [2017] OJ L 95/1.*
[48] *European Union (Plastics and other Materials) (Contact with Food) Regulations 2017 (S.I. No 49/2017).*

carrying penalties including fines and, in serious cases, imprisonment.[49] While prosecutions in this area are relatively rare, the existence of criminal sanctions underscores the seriousness with which the law treats compliance failures that may endanger health. From a public health perspective, the deterrent effect of such sanctions is as significant as the punitive function. Civil liability provides an additional, though more indirect, avenue of consumer protection. Where a consumer suffers harm as a result of exposure to harmful substances migrating from food packaging, claims may arise under Irish product liability law, including the Liability for Defective Products Act 1991, which implements the EU Product Liability Directive.[50] Under this regime, a producer may be held strictly liable for damage caused by a defective product, without the need to prove fault. A product may be considered defective if it does not provide the safety which a person is entitled to expect, taking all circumstances into account.

In practice, however, civil claims relating to food contact materials present significant evidential challenges. Establishing a causal link between long-term exposure to low levels of chemicals from packaging and specific health outcomes, such as cancer, is scientifically complex and legally demanding. This difficulty reinforces the importance of preventative regulation and enforcement, rather than reliance on individual litigation as the primary means of protecting public health.

Consumer protection law also plays a supporting role. While Irish and EU law does not generally require detailed chemical labelling of food contact materials, misleading claims about safety or environmental friendliness may fall within the scope of consumer protection legislation.[51] For example, representations suggesting that a carton is wholly ″natural” or ″chemical-free” could be legally problematic if they obscure the presence of regulated materials subject to migration limits. Such issues highlight the intersection between food law, consumer law, and public trust.

The enforcement framework is further shaped by the principle of shared responsibility. Manufacturers bear primary responsibility for ensuring that food contact materials are compliant before they are placed on the market. Importers and distributors also have obligations, particularly where materials are sourced from outside the European Union.[52] This shared responsibility model reflects the reality of modern supply chains and seeks to prevent regulatory gaps through which

[49] *ibid regs 9–11.*
[50] *Liability for Defective Products Act 1991.*
[51] *Consumer Protection Act 2007.*
[52] *Regulation (EC) No 1935/2004 art 17.*

unsafe materials might otherwise pass. Taken together, these enforcement and liability mechanisms illustrate the preventative orientation of Irish public health law. Rather than waiting for harm to manifest, the law seeks to control risk at its source, through regulatory oversight, scientific assessment, and enforceable legal obligations.[53] For consumers, this means that the safety of everyday items such as drinking cartons depends less on individual vigilance and more on the effectiveness of institutions charged with protecting the public interest.

REGULATORY GAPS, SCIENTIFIC UNCERTAINTY, AND THE CASE FOR REFORM

Despite the sophistication of the legal framework governing food contact materials, it is widely acknowledged - by regulators themselves - that the system is not without its limitations. Irish public health law, operating within the EU regulatory architecture, is designed to be precautionary and science-based, yet it must continually contend with uncertainty, technological change, and the inherent complexity of chemical exposure. Drinking cartons, as composite and chemically diverse products, bring many of these challenges into sharp relief. One of the most persistent difficulties arises from the uneven harmonisation of EU rules. While plastics are subject to detailed regulation under Commission Regulation (EU) No 10/2011, other materials commonly used in drinking cartons - such as paper, board, adhesives, and printing inks - remain governed largely by the general principles of Regulation (EC) No 1935/2004 and good manufacturing practice requirements.[54] The European Commission has repeatedly acknowledged that not all food contact materials are covered by specific EU measures, leaving certain substances regulated only through broad safety obligations rather than precise migration limits.[55]

This reliance on general principles places a heavy burden on manufacturers to conduct comprehensive safety assessments, particularly in relation to non-intentionally added substances (NIAS). As discussed earlier, NIAS may arise unpredictably during manufacturing or through chemical interactions over time. EFSA has recognised that the identification and toxicological assessment of NIAS is scientifically demanding and often constrained by limited data.[56][57] Where

[53] *Food Safety Authority of Ireland, FSAI Strategy 2025–2029 (FSAI) https://www.fsai.ie/getattachment/1cd53677-ad10-43f0-8cb9-47fdca212098/fsai-strategy-2025-2029-final-accessible-%282%29.pdf accessed 22 December 2025.*

[54] *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 [2004] OJ L 338/4; Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food [2011] OJ L 12/1.*

[55] *European Commission, Food Contact Materials – Food Safety https://food.ec.europa.eu/food-safety/chemical-safety/food-contact-materials_en accessed 21 December 2025.*

[56] *European Food Safety Authority, Food Contact Materials and Non-Intentionally Added Substances https://www.efsa.europa.eu/en/topics/topic/food-contact-materials accessed 21 December 2025.*

toxicological profiles are incomplete, regulators must rely on conservative assumptions, yet the absence of clear thresholds can complicate enforcement decisions. Scientific uncertainty is especially significant in relation to substances suspected of contributing to long-term health effects, including carcinogenicity. Cancer risk is inherently difficult to assess in the context of food contact materials because exposure levels are typically low, cumulative, and occur over extended periods. EU food contact materials law does not require proof of carcinogenicity before regulatory action can be taken; rather, it is designed to prevent exposure above levels considered safe on the basis of current evidence.[58] Nevertheless, where evidence evolves - as in the case of bisphenol A - existing legal limits may lag behind scientific understanding.

The EU legal order seeks to address this tension through the precautionary principle, a cornerstone of European public health and environmental law. Enshrined in Article 191 of the Treaty on the Functioning of the European Union, the precautionary principle permits regulatory action where scientific uncertainty exists but there are reasonable grounds for concern about potential harm.[59] In the context of food contact materials, this principle underpins conservative migration limits and justifies regulatory revision when new data emerges. However, its application is not automatic; it requires institutional willingness to reassess existing standards and, where necessary, to impose restrictions that may have economic consequences. From an Irish perspective, these dynamics raise important questions about regulatory responsiveness and transparency. While Irish authorities are bound by EU law, they also play a role in monitoring emerging risks, contributing to EU-level discussions, and enforcing standards domestically. The Food Safety Authority of Ireland has emphasised the importance of science-based decision-making and cooperation with EFSA and other Member States in responding to new evidence.[60] Yet the visibility of this process to the public remains limited. Consumers are generally unaware of how safety thresholds are set or revised, and there is little scope for individual choice in relation to food contact materials. This lack of visibility has prompted debate about whether existing consumer protection mechanisms are sufficient. Some commentators have argued for enhanced labelling or disclosure requirements, particularly where packaging contains substances that are subject to ongoing scientific debate. While EU law has

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[57] European Food Safety Authority, Food contact materials: building on scientific developments (EFSA press release) https://www.efsa.europa.eu/en/press/news/food-contact-materials-building-scientific-developments accessed 22 December 2025.

[58] Regulation (EC) No 1935/2004, art 3.

[59] Consolidated Version of the Treaty on the Functioning of the European Union [2012] OJ C 326/47, art 191(2).

[60] Food Safety Authority of Ireland. 'EFSA.' https://www.fsai.ie/about/what-we-do/international-networks/efsa accessed 23 December 2025.

traditionally prioritised upstream regulation over consumer-facing information, the growing public interest in chemical exposure may place pressure on this model. Any move towards greater transparency would need to balance consumer understanding against the risk of unnecessary alarm.

The precautionary principle, as articulated in Article 7 of Regulation (EC) No 178/2002 (the General Food Law Regulation), permits the adoption of provisional risk management measures in the field of food and feed safety where an assessment of available information identifies the possibility of harmful effects on human health, animal health, or the environment, yet scientific uncertainty persists. Such measures must be proportionate, no more restrictive of trade than necessary to achieve the high level of health protection chosen within the European Union, and take account of technical and economic feasibility alongside other legitimate factors. They are temporary in nature, subject to review within a reasonable timeframe as further scientific evidence becomes available to enable a more comprehensive risk assessment. This provision embodies a core tenet of EU public health law, enabling swift protective action in the face of emerging or incompletely understood risks while maintaining compatibility with internal market principles.[61]

Future reform at EU level is already under consideration. The European Commission has signalled its intention to modernise food contact materials legislation as part of broader chemicals and sustainability initiatives, including efforts to address cumulative chemical exposure and to promote safer alternatives.[62] For drinking cartons, such reforms may involve clearer rules for composite materials, improved assessment of NIAS, and closer alignment between food contact materials law and wider chemicals regulation, such as REACH.

In this still developing landscape, Irish public health law remains both robust and provisional. It provides meaningful protection against known risks, yet it must remain adaptable in the face of scientific uncertainty and emerging evidence.[63] The challenge for lawmakers and regulators is to ensure that precaution does not give way to complacency, particularly where the health effects of low-level, long-term exposure may take years or decades to become apparent. Drinking cartons,

[61] *Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L 31/1, art 7.*

[62] *European Commission, Chemicals Strategy for Sustainability https://environment.ec.europa.eu/strategy/chemicals-strategy_en accessed 24 December 2025.*

[63] *World Health Organization, Essential Public Health Functions in Ireland: Perspectives to Strengthen Public Health Capacities and Stewardship (WHO, 2023) https://www.who.int/publications/i/item/9789240057449 accessed 24 December 2025.*

consumed daily and often by vulnerable groups, such as infants and other children, remind us that the most familiar products can raise the most complex regulatory questions in the EU.[64]

CONCLUSION

The regulation of food contact materials in Ireland illustrates the distinctive character of modern public health law. Rather than responding to harm after it has occurred, the legal framework governing food and drink packaging seeks to anticipate and prevent risk before it reaches the consumer. This preventative orientation is particularly evident in the treatment of drinking cartons, which, despite their everyday familiarity, are subject to one of the most scientifically and legally complex regulatory regimes in Irish consumer life. At its core, the system rests on a deceptively simple legal principle: materials intended to come into contact with food must not endanger human health. That principle, enshrined in Regulation (EC) No 1935/2004, operates as both a legal standard and a public health commitment.[65] It binds manufacturers, importers, regulators and enforcement authorities to a shared objective, while allowing scientific expertise to shape the content of what safety requires at any given time. In this respect, the law governing food contact materials is neither static nor purely technical; it is adaptive, responsive, and deeply dependent on evolving scientific knowledge.

Drinking cartons reveal the strengths of this approach. Through harmonised EU legislation, detailed migration limits, scientific risk assessment by EFSA, and domestic enforcement by the Food Safety Authority of Ireland, the law provides a high level of protection against chemical exposure that is largely invisible to consumers. The absence of widespread public concern about the safety of everyday packaging is not evidence of regulatory neglect, but rather a reflection of the system′s success in managing risk upstream. Consumers are protected precisely because they are not required to make informed choices about chemical composition at the point of purchase. At the same time, this invisibility raises difficult questions about trust, transparency, and accountability. The law asks consumers to rely on regulatory institutions to identify, assess, and control risks associated with substances that may contribute to long-term health effects, including carcinogenic outcomes. Where scientific uncertainty exists - as it inevitably does in relation to cumulative, low-dose exposure - the legitimacy of this reliance depends on the continued independence, rigour, and responsiveness of

[64] *NSF, Is Food Packaging Safe? (27 August 2025) https://www.nsf.org/ie/en/knowledge-library/is-food-packaging-safe accessed 24 December 2025.*
[65] *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 [2004] OJ L 338/4, art 3.*

regulatory decision-making. The reassessment of substances such as bisphenol A demonstrates both the capacity of the system to evolve and the challenges inherent in keeping law aligned with science.

Long before the emergence of contemporary analytical methods or modern toxicological frameworks, concerns were occasionally expressed - often intuitively rather than empirically - about the repeated use of plastic food containers. There has been renewed public and professional attention in Ireland focused on the potential health and environmental implications of plastic food and beverage containers.[666768] A 2021 article by 'That's Farming' pointed to historical research and commentary into plastic milk bottles by the veterinarian Dr. Timothy Stephen Quill (d. 1970), which asserted that repeated use of such containers could result in the ingestion of significant numbers of micro-plastic particles. The presence of chemical additives commonly found in plastics, including phthalates and bisphenol A (BPA), has been associated in toxicological studies with adverse biological effects, ranging from endocrine disruption to potential links with carcinogenic processes. While the precise human health impacts of long-term exposure remain under investigation, these findings have prompted discussion in agricultural and scientific circles about the benefits of alternative packaging materials, such as glass, and the broader implications for public health policy. Figures in the Irish agricultural sector have since recognised the early consideration of these issues as an important contribution to the ongoing discourse on sustainable and safe food packaging.[69] What distinguishes contemporary regulatory approaches from these earlier concerns is not the intensity of anxiety, but the institutional capacity to test, quantify, and regulate risk.

Irish public health law does not operate in isolation, nor does it possess unlimited autonomy in this field. As a Member State of the European Union, Ireland participates in a shared regulatory project that seeks to balance health protection with market integration. This balance is reflected in the layered nature of the legal framework: broad EU principles, specific technical measures, national

[66] *Kevin O'Sullivan, Why do plastics shed tiny particles into our food? Irish scientists have the answer (The Irish Times, 14 May 2025) https://www.irishtimes.com/environment/2025/05/14/irish-scientists-reveal-why-everyday-plastics-shred-tiny-pollutants/ accessed 23 December 2025.*

[67] *Joanne Hunt, Microplastics: Avoid plastic in your food and drink with these kitchen detox tips The Irish Times (12 November 2025) https://www.irishtimes.com/food/2025/11/12/microplastics-avoid-plastic-in-your-food-and-drink-with-these-kitchen-detox-tips/ accessed 23 December 2025.*

[68] *Amudalat Ajasa, How to eat and drink fewer microplastics The Irish News (5 March 2025) https://www.irishnews.com/life/health/how-to-eat-and-drink-fewer-microplastics-4DTV4EMQI5F6HBAKYINC545SGU/ accessed 23 December 2023.*

[69] *'Glass bottles: What do they have in store for the dairy industry?' That's Farming (2 September 2021).*

enforcement powers, and overarching commitments to precaution and consumer safety.[70] Drinking cartons, as composite products circulating freely across borders, exemplify the necessity of this integrated approach. Looking forward, the challenges facing food contact materials regulation are unlikely to diminish. Advances in material science, heightened awareness of chemical exposure, and increasing concern about environmental and health sustainability will continue to place pressure on existing legal structures. For Irish law, the task will not be to abandon the current model, but to refine it - by closing regulatory gaps, improving the assessment of non-intentionally added substances, and ensuring that enforcement remains robust in an increasingly complex market.

In conclusion, the law governing food contact materials reminds us that public health protection often operates at the margins of daily life, shaping outcomes without drawing attention to itself. The humble drinking carton stands as a quiet testament to this reality: a commonplace object underpinned by dense layers of law, science, and regulation, all directed towards a single aim - the protection of human health.

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