When a Smoke Flavouring Loses Its Licence

The November 2026 Kerry judgment, genotoxic mixtures and the industrial science of replacing smoke-derived ingredients

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Abstract

The General Court's judgment of 11 November 2026 in Case T-523/24 confirms the European Commission's refusal to renew three smoke-flavouring authorisations. Its significance extends beyond a particular supplier: the applicant bears the evidential burden of demonstrating safety, while complex mixtures containing known and insufficiently characterised constituents resist simple ingredient-by-ingredient reassurance. This article examines the scientific logic of genotoxicity assessment, exposure modelling and uncertainty; distinguishes the legal withdrawal of smoke-flavouring primary products from traditional smoking; and analyses transitional arrangements and reformulation options for meat, fish, dairy, sauces and savoury foods. It compares the EU and Spain with Great Britain and the United States without presuming that one jurisdiction's authorisation travels to another. A proposed research programme investigates whether integrated chemical fingerprinting, process controls and sensory design can generate defensible alternatives without replacing one uncharacterised exposure with another. The central conclusion is that flavour substitution is simultaneously an analytical, toxicological, technological and legal problem.

Keywords: smoke flavourings; genotoxicity; pyrolysis; chemical mixtures; reformulation; exposure assessment; food law; analytical chemistry.

1. A judgment that clarifies who must prove safety

On 11 November 2026 the General Court dismissed the action brought by Kerry Inc. and Kerry Ingredients (UK) Ltd against the Commission's refusal to renew authorisations for three smoke-flavouring primary products (Case T-523/24). The Court's press release states the operative proposition with unusual clarity: the undertaking seeking renewal must demonstrate that the product does not pose a risk to human health. The ruling follows EFSA scientific opinions issued in September 2023 and Commission non-renewal decisions adopted in July 2024. It is therefore inaccurate to present the judgment as a new prohibition first introduced in November 2026. It is judicial scrutiny of an earlier risk-management decision. [1–3]

The distinction matters commercially. An authorisation is not an indefinitely transferable property of a flavour profile. It is a legal permission attached to a defined product, composition, manufacturing process and conditions of use. Renewal can demand an updated scientific case even where a material has been sold for years. Historical market presence does not reverse the burden of proof.

Equally, the judgment should not be simplified into a finding that all smoky-tasting foods are unsafe or that every constituent of every smoke flavouring is genotoxic.

2. The material under assessment is a mixture, not a single aroma molecule

Smoke-flavouring primary products are typically derived from the controlled pyrolysis of wood, followed by collection, fractionation and purification of smoke condensates. Their composition depends on feedstock, moisture, combustion or pyrolysis conditions, oxygen supply, condensate collection and downstream separation. Phenolic compounds contribute characteristic smoky notes; carbonyls and organic acids contribute other sensory and technological effects. Polycyclic aromatic hydrocarbons, reactive carbonyls and numerous minor constituents create a separate safety question. A specification based only on sensory strength or a few marker compounds cannot establish comprehensive toxicological equivalence. [3–5]

The regulatory object is also distinct from conventional smoking of foods. Traditional smoking involves process-generated smoke in contact with the food; smoke flavourings are intentionally manufactured preparations added as ingredients or used to generate derived flavourings. Both may create chemical exposure, but they are governed through different combinations of food-safety, contaminant, flavouring and process rules. Substituting direct smoking for a discontinued liquid smoke flavouring is therefore neither automatically safer nor necessarily a like-for-like regulatory solution.

2.1 Genotoxicity cannot be averaged away

Genotoxicity concerns the capacity of a substance or mixture to damage genetic material through direct or indirect mechanisms. For DNA-reactive mutagenic or carcinogenic substances, regulators commonly avoid assuming a simple safe threshold in the absence of substance-specific evidence. In the decisions affecting the Kerry products, EFSA identified constituents with established in-vivo genotoxic concern, exposure estimates exceeding the relevant threshold of toxicological concern, and additional unresolved components. The Commission’s decision concerning SmokEz Enviro-23 (SF-006), for example, refers to a TTC of 0.0025 micrograms per kilogram body weight per day, equivalent to 2.5 nanograms/kg/day. That number is a toxicological screening benchmark, not a permitted concentration in a food product. [2,4]

A mixture presents a difficult asymmetry: detecting one concerning constituent may be sufficient to demand further evidence, whereas finding no signal in a limited analytical panel cannot demonstrate that every unmeasured component is harmless. A negative result has meaning only relative to the analytes, extraction method, reporting limits, matrix and validated scope. This is why an apparently detailed chromatogram can still leave the decisive question unanswered.

3. The limits of constituent-by-constituent reassurance

A scientifically mature assessment begins by mapping the chemical composition as far as practicable, then prioritises known hazards, uncertain constituents and realistic exposures. Gas chromatography–mass spectrometry can resolve volatile and semi-volatile constituents; liquid chromatography and high-resolution mass spectrometry may reveal fewer volatile species. Neither platform identifies all peaks automatically. Tentative library matches are not confirmed structures, and non-detection does not establish zero concentration. Reference standards, recovery, blank controls and interlaboratory reproducibility remain indispensable.

The 2019 EFSA statement on genotoxicity assessment of chemical mixtures provides a relevant methodological foundation. It does not turn mixture assessment into a mechanical sum of hazard labels: constituent coverage, toxicological mode of action, unidentified fractions and the limits of read-across all matter. A developer claiming a safer replacement must explain whether it reduced hazardous constituents, reduced exposure, changed the underlying manufacturing chemistry, or merely moved outside a particular regulatory definition. Those are materially different achievements. [6]

3.1 The exposure denominator matters

Exposure is not determined by concentration in the flavouring alone. It depends on addition rate, food consumption, carry-over, processing loss or formation, and the distribution of uses across product categories. A low inclusion rate in a frequently consumed food can matter more than a higher concentration in a rarely consumed speciality. Children and high consumers may materially influence exposure estimates. For any relevant substance, the calculation should connect the measured concentration in the primary product to the concentration in the finished food and to body-weight-normalised intake, with explicit assumptions about multiple sources.

A reformulation dossier should therefore preserve both a compositional fingerprint and a use-specific exposure model. A new concentrate with fewer detectable compounds but a substantially higher dosage is not necessarily an exposure improvement. Nor does an unchanged sensory profile prove comparable chemistry.

4. The legal chronology: non-renewal, deletion and transition

Regulation (EC) No 2065/2003 establishes the EU framework for smoke flavourings. Implementing Regulation (EU) No 1321/2013 originally established the Union list of authorised primary products. Following the renewal assessments, Commission Implementing Regulation (EU) 2024/2067 removed the relevant entries from that list, while linked implementing decisions refused renewal of the eight products for which applications had been made. The legal chronology must be read together: scientific opinions in 2023, Commission acts in 2024, and judicial review in November 2026. [2,3,7]

The transition is not equivalent to continuing authorisation without conditions. For the specifically identified primary product SF-006, Decision (EU) 2024/2078 permits continued placing on the market until 1 July 2029 in connection with the transitional regime. The wider regulation establishes differentiated transition arrangements by food category and use. Operators must consult the operative consolidated provisions and the exact primary-product identification rather than extrapolate one date to every food, ingredient or stock position. [2,3]

A business should distinguish at least four dates: the expiry or non-renewal of the underlying authorisation, the last lawful date for placing the primary product on the market, the date until which particular foods may be produced or placed on the market under transitional provisions, and any separate sell-through treatment of lawfully marketed food. These are different legal events. Inventory software that records only “approved/not approved” is inadequate for such a transition.

4.1 Spain and the European Union

Spain applies the directly applicable EU instruments. The Commission adopts relevant implementing measures; EFSA supplies scientific risk assessment; national and autonomous-community competent authorities participate in official control. Food businesses must also comply with the general food-safety requirements of Regulation (EC) No 178/2002, hygiene obligations and

applicable flavouring and labelling provisions. A supplier certificate cannot enlarge the legal scope of an expired authorisation. Conversely, a flavouring-free reformulation must still meet general safety and truthful-labelling requirements.

4.2 Great Britain, Northern Ireland and the United States

Great Britain must be assessed against its domestic food-flavouring and regulated-product rules as currently in force. The European judgment does not itself amend British law. The UK–EU sanitary and phytosanitary negotiations may affect future alignment, but proposals or consultations are not yet a substitute for operative authorisations. Northern Ireland requires a separate assessment under its applicable arrangements. An exporter should therefore obtain a dated territory-specific legal opinion for the actual formulation. [8]

In the United States, FDA oversight of flavouring substances and food ingredients follows the Federal Food, Drug, and Cosmetic Act, applicable food-additive provisions and potentially GRAS-based routes where legally supportable. US legality cannot be inferred from an EU listing, nor can EU permission be inferred from a US safety conclusion. The relevant identity, conditions of intended use and supporting evidence must be established independently. The absence of a single equivalent US prohibition should never be described as proof of toxicological safety. [9]

5. Why replacement is more than a sensory exercise

Smoke-derived flavourings serve as aroma systems, but some formulations also influence perceived saltiness, colour, acidity or microbial behaviour. Their removal can affect product identity, consumer acceptance, processing conditions and shelf life. The first design question is therefore functional decomposition: which effects are truly needed, and which are incidental properties of the existing preparation? A flavour-only substitute may be adequate for a sauce but insufficient for a cured-meat product whose sensory profile depends on interactions among fat, protein, salt, heat and smoke-derived volatiles.

Possible technical pathways include mixtures of individually permitted flavouring substances, yeast- or fermentation-derived savoury notes, controlled thermal reaction flavours where authorised, natural extracts with substantiated specifications, and process changes such as roasting. These are categories for investigation, not blanket endorsements. Each route can generate its own reaction products, allergen questions, labelling consequences or novel-food issues. The objective is to avoid exchanging an unresolved complex-mixture hazard for another.

5.1 Reformulation in protein-rich and lipid-rich foods

In meat analogues, processed meat, fish and cheese, smoky notes partition differently between aqueous and lipid phases. Lipid oxidation can alter aroma stability; protein binding can suppress release of phenolic volatiles; packaging and heating can change headspace composition. A replacement designed in water may fail in a high-fat matrix. Sensory equivalence must be tested after processing and throughout shelf life, not merely in the concentrate. Where microbiological preservation is claimed, separate challenge tests and validated process controls are required. A smoky aroma is not evidence of antimicrobial performance.

For low-salt products, reformulation may be especially difficult because flavour and salt perception interact. An ingredient strategy that reduces sodium but increases reactive aroma compounds would require a balanced toxicological and nutritional evaluation. For INTABIOTECH-relevant sectors, (functional ingredients, savoury preparations, protein formulations and industrial

preservation), the defensible opportunity is analytical formulation support and application-specific validation, not an unsupported claim that any existing company product replaces smoke flavourings.

6. Industrial governance: the evidence package that procurement should demand

A transition programme should begin with a bill-of-materials audit that identifies each primary product by regulatory code, supplier, formulation, use category and market. Product-development teams should record whether the ingredient is a smoke-flavouring primary product, a derived smoke flavouring, a conventional flavouring or a result of a direct smoking process. Commercial shorthand such as “natural smoke” is not sufficient legal identification.

Supplier qualification should require a compositional and impurity specification; analytical methods and limits; traceable batch data; evidence of change control; intended-use restrictions; and an explicit statement of legal status for each destination. Regulatory and R&D teams should maintain a dated change log when a raw-material source, process, purification step or inclusion rate changes. The evidence package should be usable by independent reviewers and should not depend on an inaccessible proprietary assurance that a preparation is “clean”.

Management must also consider contract allocation of risk. A supply agreement may contain warranties and indemnities, but these cannot displace statutory food-business obligations. Transition stocks, product recalls, reformulation costs and labelling changes may create separate commercial disputes. Procurement and legal teams should examine the relevant contractual definitions before relying on a supplier’s promise of regulatory continuity.

7. Research & Innovation Opportunity

7.1 The question that remains open

The literature already contains extensive work on smoke condensates, pyrolysis chemistry, phenolic flavour compounds, PAH reduction, toxicological testing and aroma substitution. It would be inaccurate to claim that chemical fingerprinting or smoke-free flavour design is new. The narrower research gap proposed here is the lack of an independently benchmarked, application-specific framework that simultaneously optimises sensory fidelity, genotoxic-hazard reduction, realistic dietary exposure and manufacturing reproducibility across different food matrices. This is a research proposition, not a claim of patentable novelty.

7.2 Hypothesis and experimental programme

Hypothesis (unproven): a constrained design framework combining high-resolution chemical characterisation, targeted genotoxicity assessment, matrix-specific aroma release and exposure modelling can identify replacement systems that are both sensorially acceptable and better characterised toxicologically than simple one-to-one substitution. Its plausibility rests on established analytical and sensory methods; its incremental value remains to be demonstrated.

Phase one should review peer-reviewed research, published patent families, regulatory opinions and commercial disclosures to define the existing design space. Phase two should assemble a reference library of relevant smoke-derived products and candidate alternative systems, including blinded sensory data and targeted and non-target chemical profiles. Phase three should test candidate systems in at least three distinct matrices, for example, a high-fat savoury product, an aqueous

sauce and a plant-protein product, using realistic processing and storage conditions. Phase four should model consumer exposure under defined use scenarios and subject priority uncertainties to independent toxicological review.

The study should preregister failure criteria: missed genotoxic signals, unstable analytical identification, unacceptable sensory drift during storage, excessive inclusion rates, or legal incompatibility with a target market. Positive results would justify further assessment, not automatic authorisation. A viable industrial output could be a transparent reformulation protocol, reference analytical library and decision tree for selecting decisive experiments. It should never be marketed as an algorithm that certifies safety.

8. A practical decision pathway for 2027

First, identify products exposed to the transition and distinguish those requiring urgent reformulation from those legally covered for a defined period. Second, establish whether the ingredient's function is sensory, technological or both. Third, specify replacement performance in measurable terms: target aroma profile, permissible processing changes, shelf-life criteria, toxicological evidence and territory-specific labelling. Fourth, conduct pilot trials and independent analytical review before approving a new supplier. Fifth, document the final legal route and maintain surveillance for subsequent regulatory changes.

The order matters. Beginning with a marketing claim such as "smoke-free" or "clean label" can create a false target if the replacement fails sensory acceptance or introduces uncharacterised process contaminants. Conversely, postponing formulation work until the last transition date creates capacity and validation bottlenecks. The rational strategy is parallel development: legal mapping, analytical characterisation, sensory engineering and industrial validation.

9. Conclusions

The November 2026 Kerry judgment reinforces a basic but demanding principle: the applicant seeking to renew a regulated food ingredient must substantiate safety under the applicable legal framework. For chemically complex smoke flavourings, incomplete mixture characterisation and genotoxicity concerns cannot be neutralised by commercial familiarity, an attractive flavour profile or an undifferentiated assertion that exposure is low.

For manufacturers, the response should be precise rather than alarmist. Traditional smoking, smoke-derived flavourings and alternative aroma systems must be evaluated according to their actual chemistry, use and legal classification. The strongest competitive advantage will belong to organisations able to link formulation choices with reproducible analytical evidence, realistic exposure estimates, sound sensory performance and jurisdiction-specific legal status. That evidence chain is the genuine subject of the reformulation challenge.

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Evidence classification: the judgment, legislative chronology and transition provisions derive from cited primary legal sources; chemical and analytical principles are established scientific background; industrial recommendations are expert interpretation; the integrated reformulation framework is an unvalidated research hypothesis.

Related INTABIOTECH Knowledge Areas: Food Safety · Regulatory Affairs · Functional Ingredients · Processing Technologies · Biotechnology · Emerging Research

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