# One Substance, Several Regulatory Identities

***Europe's 2026 chemicals-data reform and the unresolved problem of translating hazard evidence across food ingredients, processing aids, packaging and industrial water***

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## Abstract

The European Union's One Substance, One Assessment (OSOA) legislative package entered into force in January 2026, with a common chemicals data platform envisaged for 2028. Its promise is better reuse of evidence across regulatory regimes, but food-industry decisions expose a deeper difficulty: the same chemical identity may correspond to different mixtures, uses, exposure pathways and legal classifications. This article examines how harmonised hazard information should—and should not—travel between food additives, processing aids, food-contact materials, industrial cleaning systems and substances used in biotechnology. It distinguishes molecular identity from material identity, hazard from risk, and data interoperability from legal authorisation. Comparative analysis considers the EU, Spain, Great Britain and the United States, with particular attention to impurity profiles, transformation products, analytical detection and operator responsibility. A proposed research architecture combines substance-level identifiers with process and exposure metadata to test whether cross-regime evidence can improve early warning without creating false equivalence. The commercial lesson is that shared chemical data can sharpen decisions, but cannot replace use-specific safety demonstrations.

**Keywords:** *One Substance One Assessment; chemical identity; food-contact materials; processing aids; exposure assessment; regulatory interoperability; analytical chemistry; industrial biotechnology.*

**Meta description:** Europe's 2026 chemicals reform could reshape food-industry evidence. Explore identity, exposure, processing aids, packaging and cross-border compliance risks.

## 1. Why the 2026 reform deserves industrial attention

European chemical regulation has evolved through sector-specific statutes. A molecule may appear in a food-contact plastic, a cleaning formulation, a laboratory reagent, a processing aid or an industrial feedstock. The scientific literature may describe its toxicity in one setting while a company must establish safety in another. The result is not simply duplicated testing: it is a fragmented evidence architecture in which the same name can conceal differences in concentration, impurities, routes of exposure and the meaning of compliance.

EFSA's current chemicals-in-food information identifies 1 January 2026 as the entry-into-force date of the One Substance, One Assessment package and describes a common chemicals data platform expected to operate by 2028 [1]. The initiative seeks more consistent assessment, better reuse of information and improved early identification of risks. Those are institutional objectives, not a statement that every food-related use of a substance will become lawful through a common database. The distinction matters because the word "assessment" refers to scientific evidence, whereas authorisation and enforcement remain tied to particular legislative competences.

The most consequential question for manufacturers is therefore not whether regulators will share data. It is what, exactly, the shared data represent. A hazard study on a well-characterised reagent may be informative for a food-contact migrant, but the reagent and the migrant may differ in purity, matrix, co-exposures and reaction history. A food manufacturer that treats a common identifier as proof of interchangeability could acquire more data while making a worse decision.

### The legislative anatomy of OSOA

The reform is not a single scientific opinion or an administrative slogan. Regulation (EU) 2025/2455 establishes a common chemicals data platform and a monitoring and outlook framework; Regulation (EU) 2025/2457 reallocates and coordinates technical tasks among agencies, including amendments to the General Food Law; and the associated directive addresses the reattribution of specified tasks to ECHA. The Commission confirmed that the package entered into force on 1 January 2026. These instruments govern the circulation and governance of evidence, not a general cross-sector authorisation of every substance. Their operational significance lies in who must supply which data, which bodies can access them, how confidentiality is treated, and whether a signal identified in one regulatory field can be investigated in another [1,15–17].

The implementation horizon needs precision. EFSA states that the common platform must be functional and contain minimum datasets by the end of 2028; integration of the entire legacy and newly generated corpus extends through the end of 2036. The European Medicines Agency describes the platform as expected to be operational in 2029, which is compatible with a legal end-2028 implementation milestone but should not be conflated with it. A manufacturer planning compliance investments in 2026 must distinguish enforceable present duties from anticipated future interoperability [1,16].

The European Commission describes the ambition as earlier recognition of emerging chemical risks, more consistent assessments and reduced duplication. These are policy objectives rather than empirical proof that every dossier will become cheaper or faster. The ability to find a study

does not establish that its test material, exposure route or analytical methods are transferable. This gap between data discoverability and scientific applicability is the central subject of the present analysis [15].

## 2. The same chemical name is not always the same material

### Identity exists at several levels

A chemical registry identifier normally describes a substance or class of substances, but industrial products are not always single compounds. Commercial preparations can contain counterions, hydrates, reaction by-products, stabilisers, residual catalysts, manufacturing impurities and constituents formed during storage. A formulation may also be defined by particle-size distribution, crystalline form or the presence of complexed species. Even when the principal molecule is identical, these differences can change toxicological behaviour and analytical recoverability.

Food technology adds another layer: the relevant material may be the product of a transformation rather than the substance introduced at the start of processing. Consider thermal treatment of a cereal matrix: the original ingredients, the reaction environment and the compounds present in the marketed food are distinct analytical objects. The same principle applies to fermentation, enzymatic hydrolysis and oxidation. A certificate describing an input does not automatically characterise the substances present at consumption.

This is not an argument that every process creates a new hazardous substance. It is an argument for a defensible identity chain. The operator should be able to say which chemical species were introduced, which were transformed, which remain, how they were measured and which assumptions support the conclusion. Where speciation is uncertain, uncertainty belongs in the safety case rather than being hidden by a single ingredient name.

### Impurities and non-intentionally added substances

In food-contact materials, intentionally used substances and non-intentionally added substances (NIAS) pose different evidentiary problems. NIAS may arise from impurities, reaction intermediates, degradation or interactions during processing. A nominally compliant starting monomer does not prove that a finished article has no relevant migrants. Regulation (EU) No 10/2011 governs plastic food-contact materials through substance restrictions, migration testing and associated requirements; the current consolidated text should be checked for the precise application and transitional status [2].

The scientific problem is analogous in biotechnology. A fermentation-derived ingredient may meet an activity or compositional specification while its impurity profile changes after a substrate substitution or downstream-process modification. A cross-sector chemical database may help identify hazards associated with a detected impurity, but it cannot infer the impurity's concentration or persistence in the finished food. That still requires measurement and a process-specific exposure model.

### Identity as a hierarchy, not a label

A workable identity model should distinguish molecular identity, ionic and speciation state, technical grade, mixture composition, process history, residual contaminants and the form in which a consumer encounters the material. A CAS number may identify a chemical constituent while failing to describe a commercial formulation. An E-number can identify a permitted additive but cannot, on its own, establish the legality of a use in a particular food or the purity of the supplied batch. Conversely, a change in trade name does not establish a new chemical entity. A risk assessment should therefore anchor every inference to a precisely described test article and an explicitly described exposure article.

The problem becomes acute when processing changes the chemical composition of a food. In thermal processing, reaction pathways depend on temperature, time, water activity, precursor concentrations and matrix composition. Measuring one precursor cannot establish the concentrations of all resulting reaction products. Likewise, a specification for an incoming ingredient cannot replace appropriate analysis of the processed food. The relevant question is whether the study material and the material to which consumers are exposed are demonstrably comparable.

A scientifically defensible chain of identity therefore records the initial formulation, preparation conditions, intermediate transformations, final product composition, stability and uncertainty. For a coadyuvant intended to disappear or lose its technological function, the evidence must establish what actually remains. For a substance claimed to react completely, mass balance and detection limits are decisive. This is not a presumption that all residues are unsafe; it is the minimum information required to decide whether an existing toxicological dataset applies.

## 3. Hazard, exposure and risk are not interchangeable

Hazard identifies the capacity of a substance to cause an adverse effect under some conditions. Risk depends on the probability and magnitude of exposure in the relevant context, alongside dose-response information and uncertainty. The distinction is foundational, yet easily blurred when an institutional platform presents a harmonised hazard classification beside a food-industry purchasing decision. A hazard alert can justify investigation; it is not by itself a quantitative determination that a specific food is unsafe.

Route matters. Inhalation studies on occupational dusts, oral studies on dietary exposure and migration studies on packaging each answer different questions. Duration matters as well: short-lived processing exposure may be irrelevant to the consumer if the substance is reliably removed, while persistent low-level migration may deserve scrutiny because it continues through shelf life. Vulnerable populations, cumulative exposures and toxicologically relevant metabolites may alter the evaluation. A single “safe/unsafe” label cannot faithfully encode these dimensions.

The reverse error is equally important. A substance accepted for one technological use cannot automatically be presumed suitable for every other use or concentration. Authorisation is frequently bounded by a defined category, specification and maximum level or by a particular safety basis. Cross-sector evidence should expand the investigator’s field of view, not erase those boundaries.

### Cumulative exposure and the mixture problem

The move toward shared chemical information also exposes a limitation of single-use assessments: a person can encounter the same substance or substances with related toxicological modes of action through food ingredients, packaging, drinking water and environmental contamination. Summing concentrations is not automatically equivalent to summing risks. A cumulative assessment must establish whether dose addition, response addition or an interaction model is appropriate, identify common endpoints, quantify background exposure and evaluate uncertainty in co-occurrence. EFSA's chemical-mixtures programme explicitly addresses grouping, combined exposure and the conditions under which such models can be used [18].

A practical example is a packaging-related contaminant present at low concentrations in several foods. A single migration experiment may satisfy a defined test scenario while underestimating aggregate intake if the substance is encountered from multiple materials. Conversely, adding worst-case migration estimates for mutually exclusive uses can exaggerate plausible exposure. The correct response is not to abandon conservative assumptions but to label them, quantify their contribution and refine them when reliable use and consumption data become available.

Exposure reconstruction should describe the relevant population, duration and matrix. Infants, children, pregnant people and consumers of specialised diets may differ substantially in consumption per kilogram of body weight. Industrial workers may encounter aerosols or dust by inhalation, whereas consumers encounter residues orally. A hazard result from one route may provide mechanistic context for another, but extrapolation requires toxicokinetic and biological justification. The OSOA platform can help identify such studies; it cannot automatically resolve the route-to-route extrapolation.

## 4. Four industrial situations that expose the classification problem

### A. An additive that also appears in processing chemistry

A substance may have an E-number and be authorised for specified additive functions in defined foods under Regulation (EC) No 1333/2008 [3]. That fact does not resolve whether a particular industrial use is an additive use, a processing-aid use or another legally distinct operation. Classification turns on function, intentional use, residual presence and the applicable definitions and not merely the supplier's preferred terminology. The presence of a substance on an additive list is not a universal permit to deploy it anywhere in a plant.

A rigorous dossier should document the technological purpose, introduction point, process chemistry, residual concentration and functional effect in the final food. If the substance performs a technological function in the marketed product, a processing-aid narrative may be untenable. Conversely, the mere detection of a residue does not automatically establish that the residue has an additive function. The relevant legal test must be applied to the actual operation, with national rules considered where EU harmonisation is incomplete.

### B. Thermal processing and reaction-product formation

Thermal processing illustrates why input composition, and final exposure cannot be conflated. Roasting, baking and extrusion can change the distribution of constituents and generate reaction products whose formation depends on the food matrix and operating conditions. An incoming ingredient specification is not a substitute for characterising relevant process-generated compounds and the final product under its intended conditions of use.

The applicable regulatory analysis depends on the nature of the resulting material, the food category and the evidence of exposure. A substance identified in a general chemical database may provide a useful hazard signal, but the presence and concentration of that substance in a specific food must be established by suitable analytical methods. A shared data platform can improve the identification of relevant studies; it does not determine the risk of a particular manufacturing process without exposure data.

### C. Recycled packaging and migration

Recycled materials create a particularly visible gap between nominal polymer identity and real material history. A PET article can have the same polymer designation as a virgin article while carrying different contaminants introduced by prior use, collection or recycling. The European regime for recycled plastic food-contact materials, including Regulation (EU) 2022/1616, addresses processes and controls that cannot be inferred from the polymer name alone [4]. EFSA's October 2026 assessment activity on a recycled-PET process confirms that process-specific safety questions remain active [5].

For procurement, this means recycled-content percentage, migration performance and lawful process status are distinct attributes. None is a proxy for the others. A supplier's declaration should be supported by the appropriate compliance documentation, intended-use conditions and, where necessary, migration evidence. This becomes especially consequential for acidic beverages, fatty foods, elevated temperatures and long storage periods.

### D. Fermentation-derived ingredients

Fermentation brings together organism identity, genetic stability, substrate quality, metabolites, purification and final formulation. The same target enzyme or protein may be produced by different strains or processes, yielding preparations with different residual profiles. A chemical hazard database may flag a metabolite or impurity, but an enzyme authorisation or safety assessment remains material- and use-specific. EFSA's November 2026 food-enzyme publications demonstrate continued case-by-case review rather than a general exemption for fermentation-derived substances [6].

A useful industrial specification therefore distinguishes active substance, total organic solids where relevant, residual host-cell material, relevant secondary metabolites, microbial limits, allergenicity evidence and validated removal or inactivation steps. The level of detail should be proportionate to the actual hazard and use, rather than copied mechanically from unrelated dossiers.

### Case analysis: heat-induced contaminants in cereal processing

Consider a hypothetical producer modifying the roasting conditions of a cereal-based ingredient to improve flavour and throughput. The relevant questions concern precursor

composition, time–temperature profile, water activity, the identity and concentration of process-generated compounds, and the exposure associated with the intended food applications. A result obtained in one cereal formulation cannot automatically be transferred to another with different reducing sugars, amino-acid composition or moisture. The process history, rather than the ingredient name alone, determines which analytical comparisons are justified.

A defensible assessment would first identify the relevant reaction products and distinguish substances already characterised in authoritative assessments from compounds for which the evidence is incomplete. The applicable food-safety duties and any specific contaminant limits must then be examined for the actual product and market. A hazard classification alone cannot establish consumer risk, and compliance with one analytical specification cannot establish the absence of all other relevant hazards. The regulatory conclusion should identify the jurisdiction, food category, analytical method, exposure assumptions and limits of the available evidence.

Industrial validation should compare the existing process with the proposed process over realistic ranges of raw-material variability, residence time and temperature. Where relevant, targeted contaminant analysis can be complemented by broader chemical screening and appropriate toxicological prioritisation. Sampling plans should capture process heterogeneity, and exposure estimates should reflect the intended uses of the ingredient. The objective is a reproducible account of process-dependent chemical changes and their significance for food safety.

### Case analysis: recycled packaging and unknown history

Recycled polymers make the identity problem concrete. The polymer backbone may remain nominally unchanged while its prior-use history, absorbed contaminants, degradation products and processing-induced reaction products differ. EFSA explains that recycled food-contact plastics can carry contamination from previous uses or waste streams and that the safety assessment examines the recycling process and intended uses, not simply the polymer name [19]. Under Regulation (EU) 2022/1616, the applicable technology, process authorisation or registration conditions and traceability must be assessed together. A declaration of recycled content is neither a migration result nor evidence of lawful food contact.

An industrial due-diligence file should distinguish input-stream controls, decontamination challenge tests, critical process parameters, migration testing, intended food type, contact time and temperature, and any limitations attached to the applicable regulatory route. Non-intentionally added substances require a reasoned assessment where relevant. The economically difficult issue is that a process change intended to improve recycling yield may also alter decontamination performance. Change control must therefore connect production optimisation to the safety case rather than treating it as a purely mechanical adjustment.

### Case analysis: fermentation as a moving chemical system

A fermentation-derived ingredient is a product of a living process rather than an isolated molecular label. Strain identity, genetic stability, carbon and nitrogen sources, aeration, stress response, harvest and purification affect the residual mixture. Two lots with equivalent declared enzyme activity may contain different concentrations of host-cell proteins, metabolites, antifoam residues or degradation products. For enzymes, the assessment may use total organic

solids as an exposure convention, but that quantity does not uniquely identify every component. Where the ingredient is a novel food, strain and manufacturing specifications may form part of the legally authorised identity.

This suggests a useful procurement principle: analytical comparability must be established for the properties that determine risk and technological function. Routine release testing may be sufficient for stable, validated processes; a substantial change in organism, feedstock or purification can require additional analytical work and legal review. The goal is proportionality, not endless testing. A quality-by-design programme should identify critical material attributes, critical process parameters and meaningful impurity limits before selecting a minimal monitoring panel.

## 5. The European legal architecture: interoperability without automatic mutual recognition

Regulation (EC) No 178/2002 establishes general food-law principles, including operator responsibility and the prohibition on placing unsafe food on the market [7]. Food additives, enzymes, novel foods and food-contact materials operate under additional, partly distinct regimes. Regulation (EC) No 1333/2008 addresses additives; Regulation (EC) No 1332/2008 addresses food enzymes; Regulation (EU) 2015/2283 addresses novel foods; and Regulation (EC) No 1935/2004 establishes the overarching food-contact-material framework [3,8–10]. Each answers a different regulatory question.

OSOA does not collapse these instruments into a single licence. The value of shared chemical information is that a newly recognised hazard in one domain may become visible to assessors working in another. The legal consequences, however, depend on whether the evidence is relevant to the particular use, whether existing authorisations require review and which institution has the relevant competence. A risk-management measure should not be inferred from the mere existence of a data record.

For Spain, directly applicable EU regulations provide much of the substantive framework, while competent national and regional authorities participate in implementation and official controls. Operators must still establish the status of their particular substance and intended application, retain traceable specifications and respond to findings that change the safety assessment. A harmonised European data infrastructure will not transfer those obligations to the platform operator.

### The classification decision tree

A substance used in food manufacturing may fall under several legal regimes depending on purpose and conditions. Regulation (EC) No 1333/2008 governs authorised food additives and their uses; Regulation (EC) No 1332/2008 governs food enzymes; Regulation (EU) 2015/2283 addresses novel foods; Regulation (EC) No 1935/2004 and specific measures regulate food-contact materials; and Regulation (EC) No 178/2002 imposes overarching food-safety duties. The fact that one chemical appears in more than one regime does not make the regimes interchangeable. Classification depends on the actual product and activity, not merely on the supplier’s description [3,7–10].

Processing aids illustrate the limits of generalisation. Their treatment under food-information rules, additive law and applicable national measures depends on the legal definition, function and circumstances of use. An additive that is authorised in one context cannot automatically be assumed permissible as a processing aid for every food process. Conversely, an ingredient may require declaration or assessment for reasons independent of its technological purpose. Legal analysis should identify whether a sector-specific EU rule, national provision or harmonised list actually covers the substance and use.

The 2025/2455 platform regulation contains provisions for the traceability of studies, access to data and confidentiality. Its design distinguishes public information from protected or confidential data and includes coordination of study-notification systems. This matters for applicants because access to a published conclusion is not necessarily access to the underlying full dossier, and access to a dossier does not automatically confer permission to rely on protected studies for a new authorisation. Data governance, intellectual property and regulatory reliance are related but distinct legal questions [16].

For Spain, the primary legal position often derives directly from EU regulations, but enforcement, official controls and some processing-aid questions can require examination of Spanish measures and the competent authorities' interpretation. A compliance opinion should specify whether it addresses the EU market generally or a concrete Spanish establishment and product. The latter requires facts about intended use, process, labelling, destination and analytical evidence. A generic assertion that a material is food grade cannot substitute for this assessment.

## 6. Comparison with Great Britain and the United States

Great Britain applies a separate domestic regulatory architecture, including assimilated and amended food-law provisions, and requires attention to current FSA and Food Standards Scotland guidance. Northern Ireland cannot simply be treated as identical to Great Britain because relevant EU-linked arrangements may apply. An EU chemical-data finding can be scientifically useful in a British dossier without automatically changing British legal status. Exporters should verify the specific product, substance, use and territorial rule.

In the United States, the FDA's food-additive and generally recognised as safe (GRAS) pathways focus on the substance and intended conditions of use, while food-contact substances have their own legal mechanisms and evidentiary expectations [11]. A European hazard classification or an EFSA assessment can inform a US analysis but is not itself an FDA authorisation or a GRAS determination. Conversely, a US GRAS conclusion does not confer EU market access.

A practical multinational dossier should therefore have a common scientific core and separate jurisdictional modules. The core would include identity, manufacture, impurities, toxicology, analytical methods and exposure scenarios. Each module would map those facts to the relevant definitions, positive lists, restrictions, authorisation status, labelling and enforcement expectations. The point is not bureaucratic duplication; it is to prevent a scientifically plausible inference from being mistaken for a legal permission.

### Jurisdictional differences are functional, not merely administrative

Great Britain must be analysed using its own applicable, amended food legislation and relevant decisions of the Food Standards Agency and Food Standards Scotland. Northern Ireland has a distinct position under the post-withdrawal arrangements. The EU OSOA platform does not automatically update British authorisations or confer rights in the United Kingdom. Scientific information may be relevant across borders, but the legal status of an ingredient, enzyme, processing aid or food-contact substance remains tied to the applicable territorial framework.

In the United States, the distinction between a food additive and a substance generally recognised as safe for its intended use is fundamental. GRAS is not a universal designation detached from conditions of use, and an EU authorisation does not establish a US GRAS conclusion. Food-contact substances have their own regulatory routes, including context-specific notifications and exemptions. An operator comparing jurisdictions should document the exact intended use, exposure estimate, identity and purity specifications, and any restrictions rather than translating an EU status into an American marketing claim [11].

A multinational evidence package should therefore separate three layers. The first is a shared scientific record of composition, manufacture, toxicology and exposure. The second is a regulatory mapping of each use to the correct statutory route. The third is a commercial decision layer identifying authorised suppliers, data-access rights, conditions of use and contractual responsibilities. A failure in any layer can invalidate a launch even when the underlying material is technically satisfactory.

## 7. What the common data platform should be able to represent

The planned EU chemicals data platform is an opportunity to improve retrieval and reuse of evidence, but a food-industry implementation requires more than a chemical name and a toxicological endpoint. It needs explicit relationships among substance identifiers, material specifications, analytical methods, exposure routes, manufacturing context, transformation products and regulatory decisions. The same study may be highly relevant to one question and marginal to another. That relevance should be recorded rather than assumed.

A useful evidence object would include the tested material’s identity and purity, batch, preparation, route, dose, duration, endpoint, analytical uncertainty and source. A separate use object would describe the industrial process, food matrix, consumption scenario and any removal or transformation step. A third object would capture the legal basis and jurisdiction. Connecting these objects allows a reviewer to see where evidence is directly applicable, where read-across is justified and where an untested assumption remains.

This architecture also exposes a governance issue. Public data should be accessible and auditable, while legitimately confidential manufacturing information may require controlled disclosure. If confidentiality prevents verification of a decisive safety claim, the solution is not to present the claim as certain. Regulators and operators need procedures for independently reviewing protected evidence while preserving an accurate public account of the conclusion’s scope.

### From FAIR data to decision-grade evidence

Findable, accessible, interoperable and reusable data are necessary foundations but not sufficient for regulatory inference. A chemical evidence record should retain the original study context: tested batch, composition, impurities, analytical method, route, dose, species or in-vitro system, duration, endpoint, statistical uncertainty, and quality assessment. It should also preserve the legal source and date of the assessment, because a historical opinion can remain scientifically informative after a legal rule or permitted use has changed.

Interoperability requires a controlled vocabulary for chemical species, material types and transformations. For example, a sodium measurement expressed as milligrams per litre is not interchangeable with a molar concentration of a particular sodium salt; a pH value is not a measure of alkalinity; and a migration result in milligrams per kilogram of food cannot be directly compared with an occupational air concentration without an exposure model. Automated systems should flag these dimensional and conceptual incompatibilities before presenting an apparent consensus.

Provenance must also survive aggregation. A database entry should show whether it derives from a peer-reviewed study, an applicant's confidential dossier, an official assessment, a monitoring campaign or a model prediction. A generative AI summary may help retrieve relevant evidence but should never silently promote a hypothesis or secondary description into a primary measurement. Where the source is inaccessible or the test article cannot be matched, the system should return an explicit uncertainty state rather than a falsely precise classification.

## 8. Research & Innovation Opportunity

### A process-aware chemical evidence graph for food manufacturing

The unresolved problem is whether cross-regulatory chemical data can be translated into food-industry decisions without confusing a substance's nominal identity with its actual industrial form. Existing chemical databases, ontologies, exposure models and knowledge graphs provide substantial foundations. It would be inaccurate to describe the use of graph methods or chemical identifiers as novel. The more specific, testable opportunity is to integrate process transformation, impurity provenance and jurisdiction-specific legal status in a validated decision framework for food-related applications.

The proposed hypothesis is that a process-aware evidence graph will reduce both missed hazard signals and false equivalence compared with conventional substance-name matching. The model would distinguish observed analytical facts, documented supplier declarations, mechanistic inferences and unknowns. Its outputs would be prioritised questions and evidence gaps, not automatic declarations of safety or legality. This is a research proposal; no performance advantage is asserted without prospective validation.

A first work package would assemble representative use cases from packaging migration, fermentation, thermal processing and food-additive or processing-aid classification. Each case would have a curated identity chain, relevant chemical analyses and an independently reviewed legal interpretation. A second package would construct links among source substances,

process events, transformation products, exposure estimates and regulatory instruments. Uncertainty would be explicit at every link.

A third package would benchmark the system against expert review using blinded cases, including intentionally ambiguous material names, incomplete certificates, changed production substrates and conflicting hazard evidence. Primary endpoints would include missed relevant hazards, unsupported regulatory conclusions, time to identify decisive evidence, reviewer agreement and auditability. External validation should use companies and product categories that are not present in model development. Poor generalisation or systematic false reassurance would be a failure, not a result to explain away.

A fourth package would assess commercial value. The relevant metric is not the number of records linked but the reduction in avoidable laboratory work, delayed approvals, supplier disputes and incorrect market-entry decisions, subject to a non-negotiable safety constraint. Patent and freedom-to-operate analysis would be needed before claiming protectable novelty. The industrial rationale is plausible because chemical identity, processing and regulation are already documented separately; the research question is whether connecting them improves decisions measurably.

### Scientific hypothesis, validation and failure conditions

The proposed evidence graph should not be described as a new discovery merely because it combines chemistry and digital methods. Knowledge graphs, read-across, computational toxicology, quality-by-design and chemical ontologies already exist. The potentially distinctive research question is whether a graph that represents process transformations and exposure contexts can outperform substance-name matching on real regulatory decisions in food manufacturing. That claim is untested and should be benchmarked against established approaches before originality, patentability or superiority is asserted.

A prospective study could assemble anonymised industrial cases in four domains: food-contact migration, heat-induced reaction products, fermentation-derived ingredients and processing-aid classification. Expert panels would independently adjudicate the relevant identity and exposure questions using source dossiers. Competing systems would then be evaluated against this reference set on false equivalence, missed hazards, correct recognition of non-transferable studies, time to defensible decision and traceability of supporting evidence. The design should include cases with identical chemical names but different impurity profiles, and cases in which different manufacturing conditions generate materially different exposures.

The modelling architecture should combine deterministic chemical constraints with statistical inference. Mass-balance and charge-balance checks can identify impossible transformations; speciation models can estimate plausible equilibrium distributions within validated conditions; machine-learning tools can prioritise candidate impurities or flag inconsistent records. None can replace empirical measurement when the reaction pathway or matrix is insufficiently characterised. Uncertainty must be propagated from input measurements through transformation models to the final decision. External validation on unseen production sites is essential to test generalisability.

A research programme should predefine failure criteria. If the model repeatedly misclassifies processing aids as additives, treats denaturation as physical removal, fails to detect relevant

non-intentionally added substances, or overstates confidence when processing conditions or raw-material composition change, it is unsuitable for regulatory decision support. Likewise, a system that improves document retrieval but not adjudication quality should be described as information management, not validated risk assessment.

Potential relevance to industry is methodological: a multidisciplinary analytical and regulatory service could link pilot-process measurements, validated assays and jurisdiction-specific dossiers. It would be premature to claim a proprietary mechanism, a compliant status for any particular product or an established reduction in toxicological testing. The first credible output is a reproducible protocol and independently reviewed set of use cases, followed by prospective industrial validation.

## 9. Implications for industrial procurement, R&D and quality systems

Procurement should request specifications that describe the supplied material, not merely its principal ingredient name. For relevant substances this may include impurity limits, production route, analytical methods, intended-use restrictions and change-notification duties. Quality teams should maintain traceability between supplier batch, industrial process and final-food exposure assumptions. R&D should document when a proposed process change invalidates earlier safety or legal conclusions.

For innovative food and biotechnology businesses, the strongest opportunity is a disciplined evidence service: analytical characterisation, process mapping, risk interpretation and market-specific dossier preparation. No technology should be declared safe solely because the principal ingredients are familiar or food grade. A defensible conclusion must account for the actual formulation, intended use, manufacturing conditions and relevant exposure profile.

Management should also resist an unhelpful dichotomy between data science and laboratory science. Machine learning can rank plausible impurities or detect inconsistencies in dossiers, but analytical chemistry must establish what is present and legal analysis must determine the significance of its intended use. The most valuable workflow is multidisciplinary by design, with clear responsibility for each inference and a documented path for resolving uncertainty.

### An operational evidence architecture

For procurement, the minimum useful supplier dossier should answer: what precisely is supplied; by what process; to which specifications; with what variability; for which uses; and under which change-control obligations? Depending on the material, that may require impurity and contaminant profiles, residual process aids, relevant microbiological specifications, stability data and analytical methods. A certificate of analysis is a batch snapshot, not a substitute for a validated manufacturing and traceability system.

For R&D, experimental design should compare the actual process against a justified control and include relevant worst-case conditions. For thermal processing, test representative raw-material compositions and time–temperature profiles rather than a single laboratory matrix. Where a fermentation ingredient is modified, measure both the intended technological effect and potential changes to residual constituents. For recycled packaging, verify the applicable

process status, intended contact conditions and migration assumptions. These are domain-specific questions; a single universal assay panel would create false reassurance.

For quality and legal teams, establish a change-trigger matrix. Changes to raw materials, organism or strain, reaction conditions, purification, packaging feedstock, intended use, dosage or market destination should prompt documented screening for scientific and legal consequences. The decision may be no additional work, targeted testing, an updated risk assessment or a new authorisation pathway. The important control is that the decision is explicit, justified and retrievable.

The commercial case for evidence integration should be measured in reduced avoidable retesting, shorter justified qualification cycles, fewer failed customer audits, improved control of nonconforming batches and faster response to emerging hazard signals. No generic savings percentage can be claimed without baseline and follow-up measurements. Strong technical governance is valuable precisely because it prevents an attractive business narrative from outrunning the underlying evidence.

## 10. Conclusions

The 2026 OSOA reform is significant because it may make chemical evidence more visible across institutional boundaries. Its deeper industrial test will be whether visibility improves the quality of use-specific decisions. A shared identifier does not erase differences in material purity, reaction history, exposure route or legal function. Nor does a common data platform confer market authorisation.

For food and biotechnology operators, the defensible strategy is to build evidence around a chain: identity, process, transformation, residual material, exposure, hazard and jurisdiction. Each link should be measured or justified, and uncertainty should remain visible. The next frontier is not to replace expert judgement with a larger database, but to make that judgement more traceable, reproducible and responsive to emerging chemical evidence.

## 11. Extended synthesis: a practical regulatory-evidence matrix

The following matrix is an analytical decision aid, not a replacement for statutory interpretation. Its purpose is to prevent a shared chemical identifier from being mistaken for shared legal status or equivalent exposure.

| Industrial situation | Primary evidence | Critical uncertainty | Regulatory gate |
|---|---|---|---|
| **Thermally processed cereal ingredient** | Precursors, time–temperature profile, reaction products, exposure | Raw-material variability; process-generated contaminants | General food safety law and applicable contaminant limits |
| **Fermentation ingredient** | Strain, process, impurities, activity, exposure | Lot and process comparability | Enzyme, additive or novel-food status as applicable |
| **Recycled food-contact plastic** | Input controls, decontamination, migration | NIAS and prior-use contamination | Reg. 1935/2004, 2022/1616 and applicable specific measures |

| | | | |
|---|---|---|---|
| **Food additive** | Identity, purity, technological function, category and dose | Whether conditions of use are met | Reg. 1333/2008 and relevant specifications |
| **Cross-border commercialisation** | Shared scientific core plus territory-specific legal file | Non-transferability of authorisations | EU/Spain, GB/NI and US routes separately |

The matrix demonstrates a recurring asymmetry. The more efficiently regulators share hazard data, the more important it becomes to identify the specific material and exposure to which those data apply. Data integration can reduce redundant work only if it also exposes the limits of comparability. Otherwise, interoperability can amplify error by distributing an unjustified conclusion more rapidly.

## 12. Conclusions: the scientific meaning of regulatory convergence

The most defensible reading of OSOA is neither that Europe has created a single universal chemical safety approval nor that sectoral fragmentation must remain untouched. The reform creates the institutional infrastructure for better evidence reuse, earlier warning and more coordinated assessments. The decisive industrial challenge is to preserve context: substance identity, process history, impurity profile, transformation, exposure, endpoint and legal purpose must remain linked when data move between sectors.

For food biotechnology, this shifts the locus of competitive expertise. A company able to demonstrate how its material is manufactured, what it becomes during processing, what remains in food and which legal route applies can respond more credibly to regulators and customers than one relying on a chemical name or generic food-grade declaration. This is especially important for fermentation ingredients, thermally processed foods, processing aids and recycled contact materials, where manufacturing history can be as consequential as nominal substance identity.

The research opportunity is to test whether process-aware evidence systems improve decisions under realistic uncertainty. Until such validation exists, the proposal remains a hypothesis and development agenda. Scientific transparency requires saying so. The purpose of a modern regulatory evidence architecture is not to manufacture certainty, but to distinguish justified conclusions from assumptions that still require measurement.

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