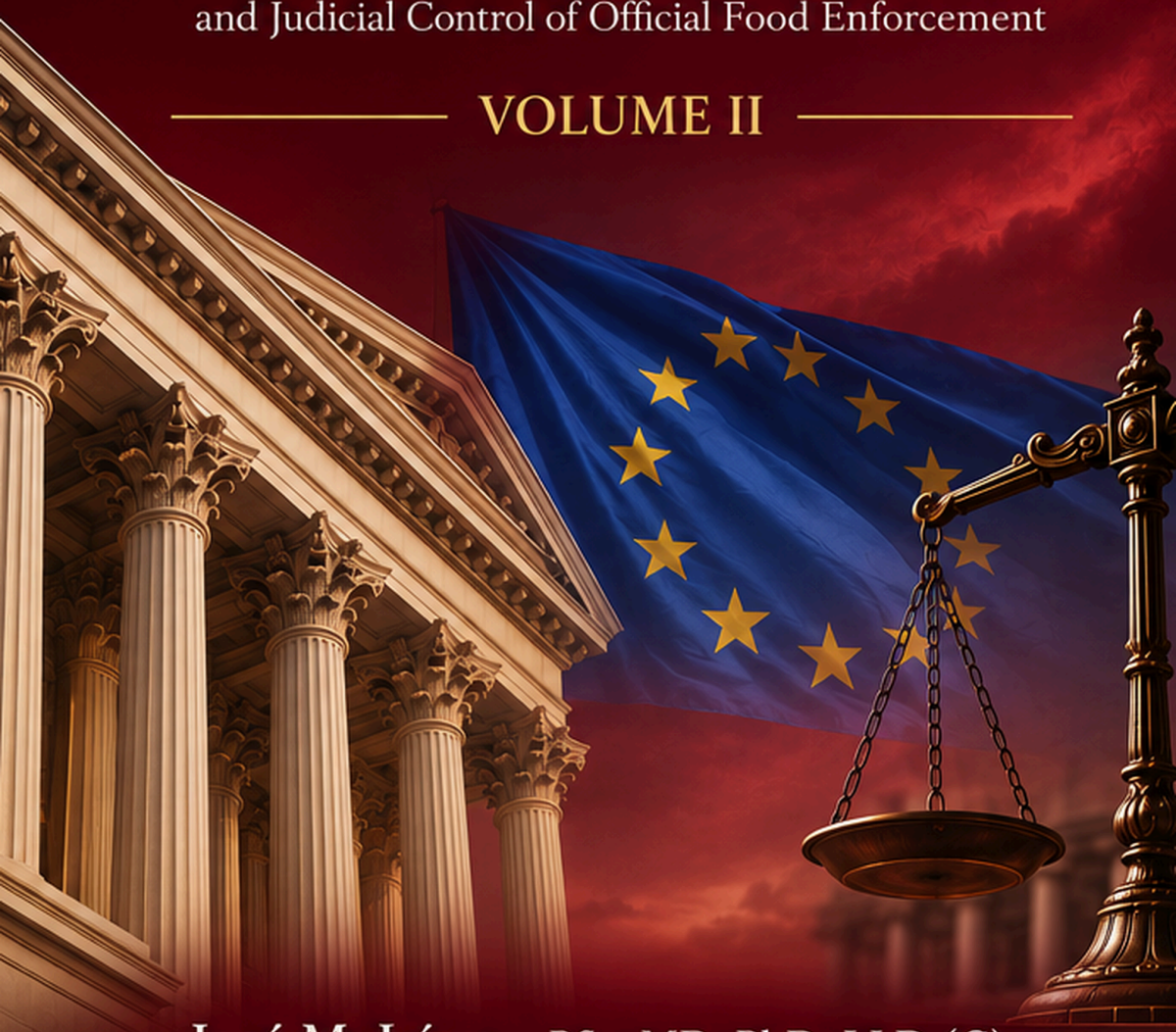
FOOD SAFETY ENFORCEMENT AND THE LIMITS OF ADMINISTRATIVE POWER

Constitutional Jurisprudence, Scientific Evidence and Judicial Control of Official Food Enforcement

VOLUME II



José M. López, BSc, MD, PhD, LLD (C)

A legal research monograph · October 2026

Spanish Constitutional and Administrative Law
European Union Food Law

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Publication and research notice

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This volume examines constitutional, administrative, evidentiary and scientific limits on official food controls in Spain and the European Union. It distinguishes judicial holdings, statutory obligations, legal analogies and original academic propositions. Conclusions must be interpreted within the relevant legal and factual context.

The book reproduces the author's research, arranged for editorial purposes. This editorial process does not constitute independent verification of every cited judgment, statutory amendment, citation or legal proposition.

Continuity of the collection

The first volume contains Chapters 1–14. This second volume comprises Chapters 15–30 and concludes with the burden of proof in food safety enforcement. Existing section identifiers are retained to allow cross-volume citation without renumbering, and this is an improvement from the Volume I.

Editorial principles

Substantive passages, legally material examples, explanatory models and the original tables are retained. The volumes are divided only at a complete chapter boundary.

About the author

José M. López is Technical and Research director operating in Biotech and Food industries with a long and extensive trajectory dedicated to research, education, clinical and advancement of science activities as well as regulatory issues in complex environments. He is also a consultant for a variety of organisations and companies result from his expertise and capacity. He holds degrees at graduate and doctoral level in Medicine, Neuroscience, Business and Legal areas.

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CHAPTER 15

167. Spanish Constitutional and Supreme Court Jurisprudence on Administrative Inspection, Proportionality, Presumption of Innocence and Abuse of Power

Judicial doctrine as a test of regulatory legitimacy: inspection powers, evidentiary presumptions, sanctioning guarantees, technical discretion and the constitutional limits of administrative intervention.

Abstract

The preceding fourteen chapters developed a systematic account of the constitutional and administrative limitations governing official food controls in Spain. That analysis identified the principles of legality, proportionality, scientific justification, procedural fairness, evidentiary reliability and effective judicial protection as essential conditions of legitimate enforcement. The Book names as Volume II is devoted to the examination of the judicial foundations of those propositions. Its central methodological concern is the distinction between what Spanish courts have actually decided, what can reasonably be inferred from their reasoning and what remains an original doctrinal proposal. The analysis focuses upon constitutional jurisprudence concerning administrative sanctioning, the presumption of innocence, the evidentiary value of official reports, the inviolability of protected premises and the judicial control of administrative discretion. Particular attention is devoted to the danger of transferring judicial holdings from taxation, competition law or other regulatory fields into food safety enforcement without examining differences in statutory powers, factual circumstances and procedural safeguards. The chapter develops a Judicial Authority and Doctrinal Transferability Test (JADTT) designed to assess the relevance of judicial precedents to specific food inspection disputes. The principal thesis is that the constitutional legitimacy of food safety enforcement must be established through identifiable legal rules and judicially supportable reasoning,

not through unexamined assertions that public health objectives automatically justify administrative intervention.

Keywords: *Spanish Constitutional Court; Supreme Court; administrative inspection; constitutional jurisprudence; food safety; presumption of innocence; inspection reports; proportionality; inviolability of premises; administrative discretion; judicial precedent.*

167.1. Why judicial doctrine must follow legislative analysis

A legal research programme that examines administrative inspection powers cannot rely exclusively upon statutory interpretation. Legislation identifies powers, obligations and procedural requirements. Judicial decisions clarify how those provisions operate when competing rights and public interests come into conflict. This is particularly important in food safety enforcement. An inspector may possess statutory authority to enter certain premises, but the exercise of that power may encounter constitutional protections.

An official report may possess legally recognised evidentiary value, but that value does not necessarily extend to every inference or legal conclusion expressed by its author. An administrative authority may act preventively in the presence of uncertainty, but its decision remains subject to judicial control. The relationship between legislation and jurisprudence is therefore essential.

Nevertheless, legal research must avoid a recurring methodological error: presenting broad principles extracted from judicial decisions as though they constituted specific holdings concerning food inspection. A Constitutional Court judgment concerning tax inspections may establish a constitutional principle relevant to administrative entry. That does not mean the judgment resolved the precise powers of food inspectors under Regulation (EU) 2017/625.

The correct method requires identification of the judgment, its facts, the legal issue decided and the scope of its reasoning.

168. A methodology for judicial authority and doctrinal transferability

The analysis adopts four levels of judicial relevance.

Level	Classification	Legal significance
I	Directly applicable judicial holding	The decision addresses the same legal provision or materially equivalent legal question
II	Governing constitutional principle	The decision establishes a principle applicable across administrative fields
III	Persuasive doctrinal analogy	The reasoning may assist interpretation, subject to relevant differences
IV	Original academic proposition	The argument is proposed by this research and is not established judicial doctrine

These levels must remain distinct.

168.1. Direct application

A judgment interpreting the statutory evidentiary presumption applicable to administrative reports may have direct relevance where the same procedural provision governs a food safety proceeding. Even then, the particular facts and subsequent legislative amendments must be considered.

168.2. Constitutional transferability

Certain constitutional guarantees extend across administrative sanctioning regimes. The presumption of innocence is a central example. However, the precise procedural consequences may depend upon the nature of the proceedings and the applicable legislation.

168.3. Analogical reasoning

Judgments concerning other regulated industries may offer useful reasoning about proportionality, administrative discretion or access to premises. Such

decisions should be presented as analogies where their holdings do not directly resolve the food safety issue.

168.4. Original doctrinal development

The integrated regulatory frameworks proposed in Part I belong to this fourth category unless and until particular propositions are independently supported by applicable legislation or judicial decisions. They should not be described as judicially established tests.

169. STC 76/1990: The evidentiary limits of inspection reports

169.1. Identification of the judgment

Spanish Constitutional Court · STC 76/1990 · 26 April 1990 · Official constitutional jurisprudence

STC 76/1990 examined constitutional challenges to amendments of Spanish tax legislation, including the evidentiary status of documents prepared by tax inspectors. Although the judgment arose from taxation rather than food safety, it establishes principles of considerable relevance to administrative sanctioning and official inspection reports. The Court considered whether statutory recognition of the evidentiary value of inspection records was compatible with the presumption of innocence.

Its answer was qualified. Inspection records may constitute legally admissible evidence. Their official character does not, however, make their contents indisputable.

169.2. The distinction between observed facts and professional conclusions

The judgment distinguishes facts directly verified by an inspector from legal classifications, value judgments and opinions. This distinction is central to food safety enforcement.

Consider an inspection report containing the following statements:

1. A production line was operating at a recorded temperature.
2. The temperature was insufficient to achieve the required microbiological reduction.
3. The manufacturer infringed the applicable hygiene legislation.
4. The technical director acted negligently.

These statements are not evidentially identical. The first concerns an observable fact, assuming the measurement was properly performed. The second is a technical conclusion requiring an appropriate scientific foundation. The third is a legal classification. The fourth concerns attribution of culpable responsibility. STC 76/1990 does not support treating all four statements as facts enjoying the same evidentiary presumption. The Court expressly confined the relevant probative effect to facts directly verified by officials, excluding legal classifications and evaluative opinions.

169.3. The relationship with Article 77.5 of Law 39/2015

Article 77.5 of Law 39/2015 provides that documents formalised by officials possessing the status of authorities, recording facts verified by them and satisfying the applicable legal requirements, have evidentiary value without prejudice to evidence submitted by interested parties.

The statutory wording must be read carefully. It does not establish that every statement appearing in an official report is conclusive. Nor does it eliminate the right to submit contradictory evidence. The Constitution and the applicable procedural law require the Administration to distinguish evidentiary findings from conclusions concerning legal responsibility.

169.4. The presumption of innocence is not reversed

STC 76/1990 also clarifies that the evidentiary value of inspection records does not automatically reverse the burden of proof in sanctioning proceedings. The Administration must establish the facts supporting the infringement and the

required basis of culpability. An operator may challenge the official evidence. However, the opportunity to challenge that evidence is not equivalent to an obligation to prove innocence. This distinction prevents the transformation of an official inspection report into an irrebuttable administrative accusation.

169.5. The correct doctrinal conclusion

The judgment supports three propositions:

- Inspection reports may constitute admissible evidence.
- Their evidentiary significance is not absolute and is subject to assessment alongside other evidence.
- Legal classifications and evaluative opinions do not acquire automatic factual certainty merely because they appear in an official report.

The judgment does not establish that inspection reports are inherently unreliable or that they cannot support sanctions. Indeed, the Court accepted that appropriately assessed official records may provide sufficient evidence in administrative sanctioning proceedings. This qualification is essential to an accurate presentation of the doctrine.

170. STC 76/1990 and the constitutional rejection of objective sanctioning liability

170.1. The culpability principle

STC 76/1990 also addresses the constitutional guarantees governing administrative sanctions. The Court recognises that the presumption of innocence extends to punitive administrative proceedings. The Administration must establish both the relevant factual conduct and the basis for attributing culpable responsibility. This is particularly important where food safety incidents occur without evidence of deliberate misconduct.

170.2. The limits of the principle

The judgment does not mean that an operator escapes responsibility whenever it lacked an intention to cause harm. Negligence may satisfy the culpability requirement where the applicable statutory conditions are met. Nor does the principle eliminate legally imposed duties of organisation, supervision and prevention. The appropriate question is whether the evidence supports responsibility under the governing legal framework.

170.3. Corporate responsibility

Food businesses frequently operate through legal persons. The attribution of responsibility to a company requires attention to organisational duties and the conduct legally attributable to the entity. However, the constitutional prohibition of purely objective punitive liability remains relevant. The fact that an adverse result occurred does not dispense with the legal analysis required for a sanction.

170.4. Application to a food safety incident

Suppose a manufacturer detects microbiological contamination despite maintaining an apparently appropriate food safety management system. The discovery may justify immediate protective measures. It may require withdrawal, investigation or corrective action. However, a sanctioning decision must establish the applicable infringement and the legally required culpability. The existence of contamination is relevant evidence. It is not necessarily a complete demonstration of punishable responsibility.

Doctrinal status: *The constitutional culpability principle is established. Its application to a particular food safety incident requires analysis of the applicable sectoral legislation and the facts.*

171. STC 22/1984: Administrative enforcement and the inviolability of the home

171.1. Identification of the judgment

Spanish Constitutional Court · STC 22/1984 · 17 February 1984

STC 22/1984 concerns the relationship between administrative execution and the constitutional protection of the home. The underlying dispute arose from administrative action involving entry into residential premises. The judgment is important because it rejects the assumption that administrative enforceability, by itself, authorises entry into constitutionally protected premises.

171.2. Article 18.2 of the Constitution

Article 18.2 protects the inviolability of the home. The constitutional rule establishes that entry or search ordinarily requires the consent of the holder or judicial authorisation, subject to the constitutionally recognised exception of *flagrante delicto*. The Court's reasoning demonstrates that administrative powers of execution remain subject to constitutional rights. A legally enforceable administrative decision does not, merely by existing, eliminate the requirements governing entry into a protected home.

171.3. Relevance to food inspection

Food inspection frequently requires access to industrial premises. However, the constitutional treatment of premises depends upon their nature and the activities carried out there. A production hall open to routine regulatory inspection does not necessarily enjoy the same constitutional protection as a dwelling. Conversely, certain areas used by legal persons may fall within constitutional protection where the relevant criteria are satisfied.

The distinction requires examination of subsequent jurisprudence and the particular characteristics of the premises. STC 22/1984 should therefore not be cited as establishing that every food factory requires prior judicial authorisation

before an inspector may enter. That would be an unjustified extension of the judgment.

171.4. The limits of administrative self-execution

The judgment establishes a broader constitutional principle. Administrative powers of execution cannot override constitutionally protected spaces merely because the Administration considers its intervention necessary. Where judicial authorisation is required, the authority must satisfy the applicable conditions. Where entry is lawfully permitted without such authorisation, the official must still act within the statutory powers governing the inspection.

171.5. Practical application

Suppose a food manufacturer operates a facility containing a production area, administrative offices and a private residential section. The legal treatment of access may differ among these spaces. The authority cannot assume that the entire property possesses one uniform constitutional status. Equally, the operator cannot automatically classify all commercial premises as a protected domicile merely to prevent lawful inspection. The analysis must consider the nature and function of each area.

172. STC 137/1985 and STC 69/1999: The constitutional protection of corporate premises

172.1. STC 137/1985: Legal persons may hold the right to inviolability of domicile

STC 137/1985 · 17 October 1985 · ECLI:ES:TC: 1985:137

This judgment concerned judicial authorisation for entry into premises belonging to a commercial company in the context of tax collection proceedings. The Constitutional Court recognised that the protection established by Article 18.2 is not categorically limited to natural persons. Legal persons may also benefit from the constitutional guarantee where the nature of the right and the circumstances

permit. Importantly, the Court dismissed the particular application for constitutional protection because judicial authorisation had been granted.

The judgment therefore cannot be presented as establishing that the challenged entry was unconstitutional.

172.2. STC 69/1999: The protected corporate sphere is narrower

STC 69/1999 · 26 April 1999

STC 69/1999 further clarified the constitutional protection of premises belonging to legal persons. The Court explained that the protection of corporate premises does not possess precisely the same content or intensity as the protection of a natural person's home. It identified particular relevance in spaces constituting centres of direction or places where documents and other materials concerning the internal life of the company are kept from third-party access.

172.3. Application to food manufacturing facilities

A food manufacturing establishment may contain several functionally distinct areas. A production hall may be subject to ordinary official inspection powers. A restricted corporate office may raise different constitutional questions. An archive containing internal management documents may require examination of the circumstances under which access is sought. A laboratory containing proprietary information may involve confidentiality obligations, even where it does not constitute a constitutionally protected domicile.

These distinctions must not be collapsed. The constitutional status of a particular area depends upon its function and the applicable jurisprudential criteria.

172.4. A critical distinction: Domicile protection versus trade secret protection

An area containing commercially confidential information does not automatically become constitutionally protected premises merely because the information is valuable. Article 18.2 and trade secret legislation protect different

legal interests. The same inspection may engage both regimes, but the conditions governing each must be examined separately.

Doctrinal conclusion: *Corporate domicile protection is established constitutional doctrine. Its application to particular food production, administrative or research areas requires a fact-specific assessment.*

173. STC 54/2015: The validity of consent to administrative entry

173.1. Identification of the judgment

Spanish Constitutional Court · STC 54/2015 · 16 March 2015

This judgment arose from a tax inspection involving entry into corporate premises and access to computer equipment. The Constitutional Court found a violation of the company's right to inviolability of domicile because the consent relied upon did not constitute an effective constitutional justification for the intrusion in the circumstances of the case.

173.2. Consent is a substantive constitutional question

The judgment illustrates that consent cannot always be established merely by demonstrating that an inspector was physically permitted to enter. The circumstances in which consent was obtained may be decisive. Relevant questions may include who granted consent, whether that person possessed appropriate authority and whether the consent was legally effective. However, STC 54/2015 should not be interpreted as establishing an identical advance-information requirement for every entry into every type of commercial premises.

Its holding must be understood within the circumstances of the protected premises and inspection involved.

173.3. Implications for food inspectors

A food inspector may have statutory authority to access premises for official controls. In situations and when access concerns constitutionally protected areas, the authority must consider the applicable constitutional requirements. Where entry is based upon consent, its legal validity may become significant. Where consent is absent and judicial authorisation is legally required, the authority must follow the appropriate procedure. These questions are distinct from the operator's statutory obligation to cooperate with lawful inspections.

173.4. Practical evidentiary considerations

A dispute concerning consent may require examination of the inspection report, communications preceding entry, the identity and authority of the person granting access, and the precise scope of the inspection. The existence of a signed document may be relevant. However, the document must be assessed within the applicable constitutional and factual context.

174. Supreme Court jurisprudence on judicial authorisation for administrative entry

174.1. The role of the Supreme Court

The Spanish Supreme Court has developed important jurisprudence concerning judicial authorisation for entry into constitutionally protected premises, particularly in tax inspection cases. The jurisprudence addresses the relationship between administrative inspection powers and judicial protection of the domicile. An important distinction must be preserved. The fact that a Supreme Court judgment concerns tax inspection does not make every operational requirement automatically applicable to food safety inspection.

Nevertheless, the constitutional principles governing protected premises may have broader relevance.

174.2. The necessity of judicial scrutiny

Judicial authorisation is not intended to operate as a purely mechanical confirmation of an administrative request. The competent court must examine the legally relevant conditions for entry. These may include the statutory basis, necessity and proportionality of the intervention. The precise requirements depend upon the applicable legislation and the circumstances.

174.3. STS 2222/2020: The procedural significance of preparatory entry measures

The Supreme Court's judgment of 7 July 2020, ECLI:ES:TS:2020:2222, addressed questions concerning preparatory entry and inspection activities in the context of tax proceedings. The judgment's specific holding concerns the treatment of those activities under the tax procedural framework. It should not be presented as a direct determination of food inspectors' entry powers. Its comparative significance lies in demonstrating that the procedural character and timing of inspection activity may have legally important consequences.

174.4. A limitation on doctrinal transfer

Tax authorities and food safety authorities possess different statutory powers. Food inspectors may operate under Regulation (EU) 2017/625 and applicable national and regional legislation. Consequently, an argument based upon tax inspection jurisprudence must explain why the constitutional reasoning is transferable. The analysis should identify which part of the judicial decision concerns a general constitutional guarantee and which part depends upon tax-specific legislation.

175. Technical discretion and the scope of judicial control

175.1. The legal problem

Food safety authorities frequently exercise technical judgment. They may assess microbiological evidence, evaluate manufacturing controls or determine whether

a particular process creates an unacceptable risk. Such decisions require specialist knowledge. However, technical expertise does not eliminate judicial control.

175.2. What courts may examine

Depending upon the proceedings and applicable legal framework, judicial scrutiny may concern:

- The competence of the authority.
- The applicable statutory requirement.
- The accuracy and sufficiency of relevant facts.
- The methodology supporting technical conclusions.
- The reasoning of the decision.
- The proportionality of the measure.
- Compliance with procedural guarantees.

This does not mean that a court must independently reproduce every scientific experiment underlying a regulatory assessment. The appropriate intensity of review depends upon the nature of the issue and the available evidence.

175.3. The limits of administrative expertise

An authority cannot establish the legality of a measure solely by describing its conclusion as technical. Where a legal question concerns the meaning of a regulation, the Administration's professional expertise does not make its interpretation unreviewable. Similarly, where a scientific conclusion is disputed, the authority may need to explain the evidentiary foundation for its position.

175.4. A necessary evidentiary qualification

Scientific disagreement does not automatically demonstrate administrative arbitrariness. Two qualified experts may reach different conclusions from incomplete evidence. The court must evaluate the legally relevant standards and the evidence available. The mere existence of an alternative expert opinion does not necessarily invalidate the authority's assessment. The decisive issue is whether the challenged decision remains legally and evidentially defensible.

176. Presumption of innocence, proof of facts and proof of culpability

The jurisprudence examined above supports a particularly important distinction between three separate questions.

First: What occurred? **Second:** Did the conduct breach a binding legal requirement? And **Third:** Is the alleged offender legally responsible for a sanctionable infringement?

These questions may overlap, but they are not identical.

176.1. Establishing the facts

The Administration may rely upon inspection reports, laboratory findings, records and other legally admissible evidence. The evidence must be assessed under the applicable procedural rules. An official document may possess significant evidentiary value. However, its conclusions are not necessarily conclusive.

176.2. Establishing the infringement

Once the facts have been established, the authority must identify the relevant legal obligation. A finding of technical inadequacy does not automatically identify a statutory infringement. The decision must explain how the established conduct satisfies the applicable legal classification.

176.3. Establishing culpability

In sanctioning proceedings, the authority must also establish the legally required basis for attributing responsibility. The nature of that responsibility depends upon the applicable legislation and the circumstances. Preventive action and punishment must remain distinct.

176.4. A practical example

An inspector observes that a food manufacturer has failed to record a critical monitoring parameter. The missing record may constitute an established fact. Whether that omission infringes a legal obligation depends upon the applicable requirements and the operator's control system. Whether a sanction is justified depends upon the statutory infringement and the legally required culpability. The Administration should not collapse these stages into a single conclusion.

177. Judicial doctrine and the limits of precautionary intervention

177.1. The precautionary principle does not replace legal authority

Food safety enforcement may involve uncertainty concerning the existence or magnitude of a risk. Article 7 of Regulation (EC) No 178/2002 provides a framework for precautionary measures under specified conditions. However, the principle must be applied within the relevant statutory framework. The existence of uncertainty does not create an unrestricted power to prohibit any unfamiliar process.

177.2. Protective measures are not sanctions

A product may be immobilised because the available evidence supports a legally justified protective intervention. That measure does not necessarily establish that the operator committed a sanctionable infringement. A subsequent sanction requires its own legal and evidentiary foundation.

177.3. Proportionality remains relevant

Protective measures must comply with applicable proportionality requirements. The authority should consider the nature of the suspected risk, the available evidence and the effectiveness of possible interventions. However, proportionality does not require a regulator to tolerate an unacceptable food safety risk merely to avoid commercial harm.

177.4. The need for sector-specific jurisprudence

The constitutional principles developed in general administrative cases provide an important foundation. Nevertheless, a definitive food safety monograph should supplement them with decisions concerning product withdrawal, immobilisation, microbiological findings, official sampling and other sector-specific interventions. Without that additional jurisprudence, claims concerning the precise judicial treatment of such measures should remain qualified.

178. Original doctrinal contribution: The Judicial Authority and Doctrinal Transferability Test

The present research proposes the **Judicial Authority and Doctrinal Transferability Test (JADTT)**. Its purpose is to prevent inaccurate reliance upon judicial decisions originating in different regulatory fields. The framework is an original research proposal and not an established judicial test.

Stage	Required inquiry
1. Identification	Is the judgment precisely identified by court, date and reference?
2. Facts	What material circumstances gave rise to the dispute?
3. Legal issue	What question was the court required to decide?
4. Holding	What did the court actually determine?
5. Normative foundation	Which constitutional or statutory provisions governed the decision?
6. Generality	Is the relevant reasoning constitutional, statutory or fact-specific?
7. Transferability	Can the reasoning properly be applied to food safety enforcement?
8. Subsequent development	Has later legislation or jurisprudence qualified the proposition?
9. Evidentiary relevance	What evidence would be necessary to apply the doctrine to a new dispute?
10. Qualification	Is the resulting proposition binding doctrine, analogy or original argument?

178.1. Application to STC 76/1990

The judgment concerns tax inspection and administrative sanctioning. Its constitutional analysis of the presumption of innocence has broad relevance. Its

treatment of official inspection records is particularly instructive. However, the specific statutory framework was tax legislation. Accordingly, application to food safety requires consideration of Article 77.5 of Law 39/2015 and the relevant food control legislation.

178.2. Application to STC 22/1984

The judgment concerns administrative entry into a protected home. Its constitutional reasoning is relevant where food inspection implicates Article 18.2. However, it does not establish that every industrial premises constitutes a protected domicile. Subsequent jurisprudence concerning legal persons and corporate premises must also be considered.

178.3. Application to STC 54/2015

The judgment concerns the validity of consent to entry into corporate premises. Its reasoning may be relevant where a food inspector relies upon consent to access constitutionally protected areas. However, the legal validity of consent must be assessed in the circumstances of the particular inspection.

178.4. The methodological contribution

The JADTT establishes a disciplined sequence for using case law. It requires the researcher to distinguish the court's actual decision from broader doctrinal conclusions. This reduces the risk of presenting persuasive analogies as binding authority. It also strengthens the credibility of original legal research by making the limits of each argument explicit.

179. A consolidated jurisprudential matrix for food safety disputes

Judicial authority	Established proposition	Food safety relevance	Transferability
STC 76/1990	Official inspection records may be evidence but do not possess irrebuttable factual authority	Evidentiary assessment of inspection reports	Strong, subject to applicable legislation

Judicial authority	Established proposition	Food safety relevance	Transferability
STC 76/1990	Presumption of innocence applies to administrative sanctions	Proof of infringement and culpability	Governing constitutional principle
STC 22/1984	Administrative execution does not automatically override protected domicile rights	Entry into constitutionally protected premises	Constitutional principle, fact-dependent
STC 137/1985	Legal persons may enjoy protection of the inviolability of domicile	Corporate premises	Direct constitutional relevance
STC 69/1999	Corporate domicile protection has a particular scope and intensity	Offices, management centres and reserved corporate spaces	Direct constitutional relevance
STC 54/2015	Consent relied upon to justify entry must be constitutionally effective	Consensual access to protected corporate areas	Strong analogy, fact-dependent
STS 2222/2020	Preparatory inspection activity may have specific procedural consequences	Timing and legal character of inspection steps	Limited; tax-specific holding

This matrix does not imply that all the judgments directly concern food safety inspections. Its purpose is to identify the extent to which their reasoning may legitimately inform the legal assessment of official food controls.

180. Conclusions of the first instalment of Part II

The judicial decisions examined in this instalment establish several important limits upon administrative inspection and sanctioning. First, official inspection reports may constitute admissible evidence, but their evidentiary value is not absolute. Second, the constitutional presumption of innocence applies to administrative sanctions and prevents the Administration from dispensing with proof of the relevant facts and culpability. Third, administrative enforcement powers remain subject to constitutional protection of the domicile.

Fourth, legal persons may benefit from that protection, although its scope and intensity differ from those applicable to natural persons. Fifth, the validity of consent to entry may require substantive constitutional examination. Finally, the application of jurisprudence from other regulatory fields requires careful

distinction between general constitutional principles and sector-specific statutory holdings.

The research therefore reaches a methodological conclusion of particular importance: *A defensible challenge to official food control activity must be founded not merely upon broad constitutional language, but upon a precise relationship between the applicable legislation, the established facts, the relevant judicial doctrine and the administrative consequence being contested*.

This conclusion reinforces the integrated model developed in Part I. It also identifies a necessary direction for subsequent research: systematic examination of judgments dealing specifically with food safety enforcement, laboratory evidence, product restrictions and administrative sanctions.

Verified primary judicial and statutory sources

1. STC 76/1990, 26 April 1990 — Presumption of innocence, culpability and the evidentiary status of inspection records.
2. STC 22/1984, 17 February 1984 — Administrative execution and the inviolability of domicile.
3. STC 137/1985, 17 October 1985 — Domicile protection of legal persons.
4. STC 69/1999, 26 April 1999 — Scope of constitutional protection for corporate premises.
5. STC 54/2015, 16 March 2015 — Effective consent to administrative entry.
6. Supreme Court, STS 2222/2020, 7 July 2020, ECLI:ES:TS:2020:2222 — Discussed in the Supreme Court's published cassation jurisprudence compilation.
7. Law 39/2015 — Article 77.5 and the procedural rules governing evidence.
8. Spanish Constitution — Articles 9.3, 18.2, 24, 103 and 106.
9. Regulation (EU) 2017/625 — Official control powers, sampling, enforcement and rights of appeal.

CHAPTER 16

181. Judicial Review of Food Safety Measures: Product Immobilisation, Withdrawal, Closure, Sampling Disputes and the Evidentiary Threshold for Administrative Intervention

Spanish Supreme Court and High Court jurisprudence on precautionary powers, traceability, scientific evidence, proportionality, compensation and effective judicial protection.

Abstract

Official food controls frequently require competent authorities to intervene before every factual or scientific uncertainty has been resolved. Product immobilisation, withdrawal, seizure, destruction and temporary suspension of activities may be necessary to prevent risks to public health.

These measures nevertheless raise fundamental questions concerning statutory authority, evidentiary sufficiency, proportionality, procedural protection and compensation.

The present instalment examines Spanish judicial decisions directly concerning food products and related agri-food enforcement. Particular attention is devoted to the Spanish Supreme Court's jurisprudence arising from the 2001 olive-pomace oil alert, the Galician High Court's examination of precautionary immobilisation of seafood, and judicial treatment of contradictory laboratory analysis.

These decisions reveal a more complex picture than the proposition that every unlawful administrative intervention necessarily generates compensation, or that preventive measures require the same degree of proof as administrative sanctions. The study also examines the interaction between Regulation (EU) 2017/625 and Royal Decree 562/2025, including the modern Spanish framework for second expert opinions and second official analyses.

An original **Food Control Judicial Review and Evidentiary Threshold Model (FC-JRET)** is proposed to distinguish the legal thresholds applicable to inspection, suspicion, precautionary intervention, established non-compliance and punitive responsibility. The central thesis is that the legality of preventive food safety intervention depends upon the existence of an adequate legal and factual foundation at the relevant time, whereas punitive responsibility and compensation require additional, distinct legal assessments.

***Keywords**: Food safety; Spanish Supreme Court; precautionary measures; immobilisation; food withdrawal; traceability; olive-pomace oil; judicial review; second expert opinion; laboratory evidence; proportionality; public liability.*

181.1. The central judicial problem: Must the Administration wait for conclusive proof?

A fundamental distinction governs the law of official food controls. The Administration may need to act before the existence of a food safety hazard has been established with the degree of certainty ordinarily required for punitive proceedings. A suspected contamination incident may justify temporary restrictions while the competent authority investigates. However, this does not mean that suspicion authorises unrestricted intervention.

The authority must possess a legally sufficient basis for its action and comply with the applicable requirements of necessity, proportionality and review.

Three separate questions arise:

1. Was the initial intervention legally justified by the information available when it was adopted?
2. Did the Administration reassess the intervention appropriately as new evidence became available?
3. If the measure was unlawful or caused economic damage, do the conditions for annulment or compensation exist?

The questions are related but not interchangeable. An initial immobilisation may be justified even if subsequent testing establishes that the product was safe.

Conversely, an initially justified measure may become disproportionate if maintained after the grounds supporting it have disappeared. The judicial decisions examined below demonstrate the importance of these distinctions.

182. The 2001 olive-pomace oil alert: A foundational Spanish food safety dispute

182.1. The factual background

In July 2001, Spanish health authorities initiated an alert concerning olive-pomace oil products following concerns about polycyclic aromatic hydrocarbons, including benzo[a]pyrene. The administrative intervention affected the marketing and immobilisation of products within the sector. The dispute generated extensive litigation concerning the legality of the original intervention and the possibility of compensation for economic losses.

This litigation is particularly important because it produced decisions addressing different legal questions arising from substantially related circumstances. The cases demonstrate why annulment, public liability and scientific risk assessment must be analysed separately.

182.2. The Supreme Court judgment of 27 June 2007

Supreme Court · Third Chamber · 27 June 2007 · Cassation appeal 10820/2004

The Supreme Court considered an appeal arising from the administrative decision of 3 July 2001 concerning olive-pomace oil. The underlying judgment of the Madrid High Court had annulled the challenged administrative decision. The Supreme Court's decision maintained that annulment. The dispute concerned the legality of the administrative action and its statutory and procedural foundation. It is therefore a directly relevant food safety precedent, rather than merely an analogy from another regulatory field.

182.3. The significance of the annulment

The judgment demonstrates that the invocation of public health does not place administrative intervention beyond judicial review. An authority may pursue a legitimate protective objective while still adopting an act that fails to satisfy the applicable legal requirements. However, the decision should not be interpreted as establishing that every intervention during the olive-pomace oil alert was necessarily unjustified on scientific grounds. Nor does annulment automatically resolve the separate question of compensation.

Those issues were addressed in subsequent litigation.

183. The Supreme Court's 2011 jurisprudence: Annulment does not automatically generate compensation

183.1. Identification of the judgment

Supreme Court · Third Chamber, Section Six · 16 September 2011 · Cassation appeal 714/2007

This judgment addressed public liability arising from the precautionary measures adopted during the olive-pomace oil alert. It reviewed earlier Supreme Court decisions concerning similar compensation claims. The Court distinguished the annulment of the administrative intervention from the separate legal requirements governing public liability. The judgment concluded that the relevant economic losses did not establish compensable unlawful injury under the circumstances considered.

183.2. The legally decisive distinction

The Supreme Court expressly acknowledged the existence of the earlier judgment annulling the administrative decision. Nevertheless, it considered that the economic consequences of the protective intervention could fall within the losses that affected operators had a legal duty to bear. This distinction is consistent with the statutory principle, now expressed in Article 32.1 of Law 40/2015, that

annulment of an administrative act does not itself establish entitlement to compensation.

The analysis therefore requires more than proof that the challenged decision was unlawful.

183.3. The role of scientific and technological knowledge

The litigation involved the presence of benzo[a]pyrene and the technological possibilities available to reduce contamination. The Supreme Court considered the relevant duties of producers and the state of available technology. This aspect is particularly significant. The Court did not treat the economic consequences of intervention in isolation from the regulatory responsibilities of the operators. The assessment concerned the legal character of the damage in the circumstances of the case.

183.4. Implications for innovative food manufacturers

The precedent cannot be used to argue that every manufacturer must bear every loss arising from an unlawful food safety measure. Equally, it cannot support the opposite proposition that annulment automatically entitles the operator to compensation. The outcome depends upon the applicable legal framework, the circumstances giving rise to intervention and the requirements of public liability.

Established holding: In the olive-pomace oil litigation examined, the Supreme Court rejected compensation notwithstanding the earlier annulment of the relevant administrative decision.

Doctrinal implication: Judicial annulment and compensable injury are analytically distinct.

Limit of transferability: The conclusion must not be generalised to every food safety restriction without examining the relevant facts.

184. STSJ Galicia 291/2020: The judicial importance of traceability and progressive release

184.1. Identification of the judgment

High Court of Justice of Galicia · Contentious-Administrative Chamber, Section Two · Judgment 291/2020 · 23 June 2020 · Appeal 4003/2019 · ECLI:ES:TSJGAL:2020:2785

This judgment provides a particularly valuable example of judicial review of precautionary measures affecting food products. The dispute arose from an operation involving fishery products and frozen Norway lobster. The competent Galician authority had adopted measures involving seizure and immobilisation of substantial quantities of seafood. The operator challenged the measures, arguing, among other matters, that they lacked adequate justification and caused serious economic harm.

The proceedings involved approximately 39,693 kg of frozen Norway lobster initially subject to immobilisation, together with other identified products.

184.2. The legal framework

The dispute was governed principally by the relevant Galician fisheries legislation, particularly Article 156 of Law 11/2008. That provision authorised specified precautionary measures under statutory conditions. The case therefore concerned a fisheries enforcement regime with consequences for food products, rather than an ordinary hygiene inspection governed exclusively by general food safety legislation. This distinction matters when transferring the judgment's reasoning to other sectors.

184.3. The initial evidentiary problem

The authority identified deficiencies concerning the traceability of certain products. The operator argued that the merchandise was traceable and that the restrictions were unjustified. However, the judgment recorded that relevant

documentation was not available at the time of the initial intervention. Some documentation was produced subsequently. The court considered the information available when the measures were adopted and the subsequent administrative response to new evidence.

184.4. Progressive release of immobilised merchandise

A particularly important feature of the case was the progressive lifting of restrictions as documentation establishing traceability became available. The court regarded this process as evidence that the measures had been confined, in objective and temporal terms, to what was considered necessary. The judgment did not require the Administration to maintain the original immobilisation unchanged after the evidentiary situation evolved. Nor did it regard the subsequent release of merchandise as proof that the initial measure had been unlawful.

184.5. The court's decision

The High Court dismissed the operator's appeal. It considered the measures adequately reasoned and supported by the relevant factual and legal circumstances. It also distinguished the precautionary measures from the eventual determination of sanctioning responsibility. The judgment therefore supports the proposition that a temporary restriction may be justified by an established documentary deficiency even before the underlying infringement has been finally determined.

184.6. An important limit on the holding

The decision does not establish that every traceability deficiency justifies immobilisation of an entire inventory. The legality of the measure depends upon the applicable powers, the evidence and the proportionality assessment. Nor does it establish that the Administration may maintain restrictions indefinitely after receiving adequate documentation. Indeed, the progressive release of merchandise formed an important part of the court's reasoning.

184.7. Original doctrinal implication: Dynamic proportionality

The case supports a broader analytical proposition. Proportionality should not be evaluated exclusively at the moment a measure is adopted. Where relevant circumstances change, the continuing justification for the measure may require reassessment. This research describes that requirement as dynamic proportionality. The expression is used here as an analytical formulation; it is not presented as the formal name of a judicial test established by STSJ Galicia 291/2020. The practical implication is substantial.

A measure that was initially justified may require modification when the operator produces reliable new evidence.

185. A second lesson from STSJ Galicia 291/2020: Precautionary measures are not sanctions

The judgment expressly distinguished the legal nature of precautionary intervention from the eventual imposition of sanctions. The operator argued that certain measures lacked the statutory foundation required for sanctions. The court examined the specific legal basis for precautionary measures and rejected the conflation of the two categories.

185.1. Different purposes

A precautionary measure seeks to protect the relevant public interest or preserve the effectiveness of proceedings. A sanction responds to an infringement under the applicable punitive regime. The measures may arise from the same facts but perform different legal functions.

185.2. Different evidentiary thresholds

The authority may adopt a precautionary measure before the infringement has been finally established. However, it must possess a sufficient legal and factual basis for intervention. The eventual sanction requires satisfaction of the separate requirements governing punitive responsibility.

185.3. Different judicial questions

When reviewing a precautionary measure, the court examines whether the statutory conditions for that measure were satisfied. It does not necessarily determine whether the operator ultimately committed the alleged infringement. This distinction prevents the judicial review of interim intervention from becoming a premature adjudication of the entire sanctioning case.

185.4. Relevance to food safety enforcement

The same distinction is essential where a competent authority immobilises a food product pending analytical verification. The legality of the initial restriction and the eventual imposition of a penalty require separate examination. An operator may successfully contest a sanction without necessarily establishing that the initial protective intervention was unlawful. Conversely, a defective precautionary measure may be challengeable independently of the final sanctioning outcome.

186. STSJ Madrid 492/2018: Contradictory laboratory analysis and procedural rights

186.1. Identification of the judgment

High Court of Justice of Madrid · Contentious-Administrative Chamber, Section Ten · Judgment 492/2018 · 23 July 2018 · Appeal 53/2018

This case concerned a dispute involving DEOLEO, S.A. and analytical procedures applicable to olive oil. The litigation examined the legal requirements governing an analysis intended to resolve differences between earlier analytical results. The court considered the relationship between the applicable European analytical rules and the former Spanish procedures under Royal Decree 1945/1983.

186.2. The procedural issue

The operator challenged aspects of the analytical procedure, including whether the company should have been notified or summoned to participate in the

decisive analysis. The court examined whether the applicable legislation imposed such a requirement. The relevant analysis depended upon the specific European regulation governing olive oil analytical methods and the Spanish procedural rules then applicable.

186.3. The doctrinal significance

The judgment illustrates that procedural rights concerning laboratory analysis must be derived from the applicable legal framework. A general appeal to the right of defence does not automatically establish that every analytical operation must take place in the physical presence of the operator. Conversely, where legislation provides a specific right to documentary review or further analysis, the authority must respect that right. The decisive question is the legal content of the applicable procedural guarantee.

186.4. The temporal limitation

The case was decided under a framework that predates Royal Decree 562/2025. It must therefore be treated as historical jurisprudence. Its interpretation of former analytical procedures cannot automatically be applied to official food controls governed by the current Spanish framework. This is especially important because the 2025 reform substantially changed the relationship between official sampling, second expert opinions and further analysis.

187. The 2025 reform: Royal Decree 562/2025 and the modern right to a second expert opinion

187.1. A major change in Spanish official controls

Royal Decree 562/2025 established a new framework complementing Regulation (EU) 2017/625. The consolidated text updated on 30 September 2026 includes detailed provisions concerning sampling, expert review and second analyses. For official food controls falling within its scope, this framework must be examined rather than assuming the continued application of the traditional analytical procedure under Royal Decree 1945/1983.

187.2. Article 29: The right to request a second expert opinion

Article 29 provides for the exercise of the operator's right to a second expert opinion following an unfavourable analytical, testing or diagnostic result. The request must ordinarily be submitted within 10 working days from the day following notification of that result. The procedure may involve documentary review, a second analysis where available under the statutory conditions, or both.

187.3. Article 30: Documentary expert review

Article 30 establishes the framework for documentary review by an appropriately qualified expert. This is not merely a request for the original laboratory to repeat its conclusion. The purpose is to permit an independent technical assessment of the sampling, analysis, testing or diagnostic process under the legally established conditions. The review may concern methodology, documentation, technical validity and other matters within the statutory scope.

187.4. Article 31: Second official analysis

Where the statutory conditions permit a second analysis, the procedure involves an official laboratory satisfying the applicable requirements. Article 31.4 provides that the result of the second analysis, when performed under that provision, prevails over the first. This is a legally significant rule. However, it does not mean that every privately commissioned analysis automatically overrides an official result. The distinction between a statutory second analysis and an independent private expert report must be preserved.

187.5. Technical feasibility

The right to further analysis operates within scientific and practical limits. Certain samples may be unsuitable for repeated testing because of perishability, insufficient material or the distribution of the relevant hazard. Microbiological contamination may be heterogeneous. A negative result from a second sample does not always establish that the first positive result was scientifically erroneous.

The legal framework must therefore be interpreted together with the relevant analytical science.

187.6. The right to expert review does not automatically suspend protective action

Article 35.4 of Regulation (EU) 2017/625 expressly preserves the obligation of competent authorities to act promptly to eliminate or contain relevant risks. Consequently, requesting a second expert opinion does not automatically authorise the operator to market immobilised goods. The right to contradiction and the duty to protect public health operate simultaneously.

188. Scientific uncertainty and the legal significance of conflicting analytical results

188.1. A conflict of results is not necessarily proof of laboratory error

Suppose an official laboratory identifies a pathogen in a food sample. A subsequent analysis produces a negative result. Several explanations may be possible.

The samples may not be identical.

The hazard may be unevenly distributed. The product may have changed between analyses. Different methods may possess different performance characteristics. An analytical error may also have occurred. The legal significance of the discrepancy therefore requires technical examination.

188.2. Measurement uncertainty

Quantitative analytical methods may involve measurement uncertainty. The treatment of uncertainty depends upon the applicable analytical rules, decision criteria and legal limits. A numerical result should not automatically be treated as legally conclusive without considering the relevant method and applicable decision rules. However, measurement uncertainty cannot be invoked abstractly

to disregard every unfavorable result. The operator must identify the specific technical issue and its relevance to the legal conclusion.

188.3. Qualitative microbiological findings

Qualitative tests present different problems. A pathogen may be detected in one analytical portion and not another. This may reflect heterogeneous distribution rather than analytical contradiction. Consequently, the legal significance of a second result depends upon the sampling design, test method and applicable microbiological criterion.

188.4. The importance of the sampled lot

The legal consequences of an analytical finding depend partly upon the relationship between the sample and the relevant production lot. A sample may establish non-compliance in the sampled unit. Whether the result supports restriction of a larger lot depends upon the applicable sampling plan, regulatory criteria and evidence concerning representativeness. The authority should avoid treating the boundaries of the relevant lot as self-evident where they are technically disputed.

189. Product withdrawal, recall and immobilisation: Three different legal functions

189.1. Withdrawal

Withdrawal generally concerns preventing a product from continuing through the supply chain. It may be undertaken voluntarily by the operator or required by the competent authority. Article 19 of Regulation (EC) No 178/2002 establishes important obligations concerning withdrawal where the statutory conditions are met.

189.2. Recall

Recall concerns action directed towards products that may already have reached consumers. It may involve informing consumers and recovering products where the relevant conditions apply. Withdrawal and recall should not be treated as synonymous. Their operational and legal implications differ.

189.3. Immobilisation

Immobilisation restricts movement or disposal of goods while the relevant legal conditions remain satisfied. It may preserve the status of products pending investigation or further decision-making. The scope and duration of immobilisation require legal justification.

189.4. Destruction

Destruction is a more definitive intervention. It may eliminate the possibility of later commercial recovery. Accordingly, the legal basis, necessity and evidentiary foundation require particular attention. However, destruction may be justified where the applicable legislation authorises it and the relevant circumstances warrant that measure.

189.5. The danger of conceptual confusion

The fact that all four interventions concern food products does not make their legal conditions identical. An authority may possess sufficient grounds for temporary immobilisation without yet possessing a basis for destruction. Similarly, an operator may be required to withdraw products even where no punitive sanction is justified. The correct legal analysis must identify the purpose and statutory foundation of each measure.

190. The evidentiary threshold for preventive intervention

190.1. Suspicion is not equivalent to established non-compliance

Article 137 of Regulation (EU) 2017/625 addresses suspected non-compliance and requires competent authorities to investigate appropriately. Article 138 addresses action where non-compliance has been established. The provisions recognise different stages of regulatory intervention. However, they should not be interpreted as establishing a single numerical or probabilistic threshold of proof applicable to every food safety decision.

The legally sufficient evidentiary foundation depends upon the particular power exercised, the suspected risk, the governing legislation and the measure's consequences.

190.2. A differentiated evidentiary approach

The research proposes distinguishing five stages:

Stage	Legal question	Evidentiary requirement
Inspection	Is there lawful authority to conduct the control?	Applicable inspection powers and selection criteria
Investigation	Are there grounds requiring verification?	Legally relevant suspicion or information
Precautionary intervention	Is temporary restriction justified?	Sufficient factual and legal basis for the specific measure
Established non-compliance	Has the relevant obligation been breached?	Evidence satisfying the applicable substantive and procedural requirements
Sanction	Is the person culpably responsible for an infringement?	Proof satisfying sanctioning guarantees, including the presumption of innocence

This table is an analytical model rather than a codification of judicially established standards.

190.3. Why a single evidentiary threshold would be inappropriate

If preventive measures required the same proof as final sanctions, authorities might be unable to intervene promptly against serious risks. Conversely, if sanctions required no more than preliminary suspicion, punitive guarantees would be undermined. The legal system must therefore distinguish the purposes and conditions of different forms of intervention.

190.4. Judicial review of the initial decision

A court reviewing precautionary intervention should examine the information reasonably available when the decision was adopted. Later evidence may be relevant, but it does not automatically determine whether the original measure was justified. The Galician seafood judgment illustrates this distinction.

190.5. Judicial review of continued restrictions

The continued maintenance of a measure presents a separate question. As new evidence becomes available, the factual justification may change. The authority may need to reconsider the scope or duration of the restriction. The progressive release of merchandise in STSJ Galicia 291/2020 provides a concrete example of such reassessment.

191. Original doctrinal contribution: The Food Control Judicial Review and Evidentiary Threshold Model

The present research proposes the Food Control Judicial Review and Evidentiary Threshold Model (FC-JRET). Its purpose is to distinguish the legal requirements applicable to different stages of official food control intervention. The model is an original academic proposal, not an established judicial test.

191.1. Six dimensions of judicial assessment

FC-JRET · Six-dimensional assessment

1. Statutory authority

Identify the legal power authorising the specific measure.

2. Evidentiary foundation

Establish the facts and scientific information supporting intervention.

3. Regulatory purpose

Distinguish investigation, precaution, correction and punishment.

4. Proportionality

Assess the measure's suitability, necessity and legally relevant consequences.

5. Temporal reassessment

Determine whether new evidence requires modification or termination.

6. Effective review

Identify the available administrative, judicial and compensatory remedies.

191.2. The model's central distinction

The model separates the justification for initial intervention from the justification for maintaining that intervention. This is particularly important in food safety disputes involving evolving scientific evidence. An initial restriction may be legally justified by a credible suspicion. However, the authority must not assume that the original justification remains sufficient regardless of subsequent developments.

191.3. Relationship with the jurisprudence

The olive-pomace oil cases demonstrate the separation between annulment and compensation. The Galician seafood judgment demonstrates the significance of traceability evidence and progressive reassessment. The Madrid analytical dispute demonstrates the importance of identifying the procedural law applicable at the

relevant time. Royal Decree 562/2025 supplies a modern statutory framework for second expert opinions and analyses. Together, these materials support a differentiated approach to official control disputes.

They do not establish FC-JRET as a formally recognised judicial doctrine.

192. Applied industrial scenarios

Scenario A. A positive microbiological result in a ready-to-eat product

An official laboratory detects a pathogen. The competent authority immobilises the affected lot. The operator requests a second expert opinion and provides additional validation data. The legality of the initial immobilisation depends upon the applicable requirements and information available at that time. The second expert opinion may be relevant to subsequent decisions. However, its request does not automatically suspend protective measures. A sanction would require separate analysis of the relevant infringement and responsibility.

Scenario B. A traceability deficiency involving imported ingredients

A manufacturer cannot immediately produce complete documentation concerning several imported ingredients lots. The authority restricts the affected goods. The operator subsequently provides documentation establishing traceability for some lots. The Galician judgment suggests the importance of assessing whether the restrictions should be adjusted as the evidentiary situation changes. However, the result depends upon the applicable statutory powers and the sufficiency of the new documentation.

Scenario C. A novel preservation technology

An inspector considers a manufacturing process unfamiliar and potentially unsafe. The operator provides technical validation studies. The authority must determine whether the process satisfies the applicable legal requirements. Novelty alone does not establish non-compliance. However, the operator remains

responsible for demonstrating compliance with relevant obligations. Where credible risk persists, proportionate protective action may be justified.

Scenario D. Destruction of a disputed consignment

An authority proposes destruction of products following an unfavourable laboratory result. The operator disputes the sampling methodology and requests expert review. The legal assessment must examine whether destruction is authorised and justified, whether less definitive measures are legally appropriate and whether the applicable procedural safeguards have been respected. The availability of a second expert opinion does not automatically prohibit urgent action.

Nevertheless, the irreversible character of destruction may be particularly relevant to the proportionality assessment.

193. Conclusions of the second instalment of Part II

The Spanish jurisprudence examined in this instalment demonstrates that food safety enforcement cannot be reduced to a binary distinction between lawful and unlawful inspection activity. The legal system recognises preventive intervention under conditions different from those governing punitive sanctions. The Supreme Court's olive-pomace oil litigation establishes that annulment of an administrative measure does not automatically create entitlement to compensation.

The Galician High Court's seafood judgment demonstrates that traceability deficiencies may justify precautionary restrictions and that subsequent production of documentation may support progressive release. The Madrid analytical dispute illustrates the importance of applying the correct procedural framework to laboratory evidence. Royal Decree 562/2025 provides modern statutory guarantees concerning second expert opinions and second official analyses.

Together, these sources support a central conclusion:

The legality of food safety intervention must be assessed by reference to the authority's statutory powers, the evidence available at the relevant time, the measure's protective or punitive purpose, its proportionality and the continuing duty to reassess restrictions as the factual situation evolves.

A second conclusion is equally important. Judicial annulment, compensation, protective intervention and punitive responsibility are separate legal questions. None should be treated as the automatic consequence of another.

Judicial decisions and principal legislation

Authority	Decision or provision	Principal relevance
Supreme Court	27 June 2007, cassation 10820/2004	Judicial annulment arising from the olive-pomace oil alert
Supreme Court	16 September 2011, cassation 714/2007	Public liability and the distinction between annulment and compensable injury
TSJ Galicia	Judgment 291/2020, 23 June 2020, ECLI:ES: TSJGAL:2020:2785	Precautionary immobilisation, traceability and progressive release
TSJ Madrid	Judgment 492/2018, 23 July 2018	Historical analytical contradiction procedures
European Union	Regulation (EU) 2017/625, Articles 35 and 137–138	Expert review, suspicion and established non-compliance
Spain	Royal Decree 562/2025, Articles 29–31	Second expert opinion and second official analysis
Spain	Law 40/2015, Article 32	Conditions of public liability

Selected sources

Supreme Court, 27 June 2007 — Olive-pomace oil alert.

Supreme Court, 16 September 2011 — Public liability.

TSJ Galicia, Judgment 291/2020 — Precautionary seafood immobilisation.

TSJ Madrid, Judgment 492/2018 — Olive oil analytical procedures.

Royal Decree 562/2025 — Consolidated Spanish official controls framework.

Regulation (EU) 2017/625 — Official controls.

CHAPTER 17

194. Judicial Doctrine on Food Safety Sanctions: Typicity, Culpability, Analytical Evidence, Procedural Expiry and the Limits of Punitive Enforcement

The constitutional limits of administrative punishment in the food sector: statutory classification, corporate responsibility, evidentiary sufficiency, procedural guarantees and judicial review.

Abstract

Administrative sanctions constitute one of the most intrusive instruments available to food safety authorities. Unlike preventive measures, whose primary purpose is to avert or contain risk, sanctions express a legally regulated judgment that an infringement has occurred and that responsibility may be attributed to the alleged offender.

This distinction is central to the constitutional guarantees applicable to punitive administrative proceedings. The present instalment examines the Spanish legal framework governing food safety sanctions through the jurisprudential principles of legality, tipicidad, culpability, presumption of innocence, proportionality and procedural certainty. It analyses the relationship between the Spanish Constitution, Laws 39/2015 and 40/2015, Law 17/2011 on Food Safety and Nutrition, and the sanctioning powers recognised under Regulation (EU) 2017/625.

Special attention is devoted to the distinction between technical non-conformity and legally classified infringement, the evidentiary value of inspection reports, the attribution of responsibility to legal persons, the significance of procedural expiry and the limits of punitive enforcement based upon scientific uncertainty.

The study also separates food hygiene and public health sanctions from the distinct sanctioning regime governing commercial relationships in the food supply chain. An original Food Sanction Legality and Evidentiary Assessment Model (FS-LEAM) is proposed to organise the judicial examination of administrative sanctions.

The central thesis is that the legitimacy of a food safety sanction depends not merely upon identifying an undesirable industrial condition, but upon proving conduct that satisfies a legally defined infringement, establishing the required culpability and respecting the procedural guarantees governing punitive administrative action.

Keywords: Food safety sanctions; Spanish administrative law; tipicidad; culpability; presumption of innocence; inspection reports; analytical evidence; procedural expiry; corporate liability; judicial review; proportionality.

194.1. The constitutional distinction between protection and punishment

Food safety enforcement may involve several forms of administrative intervention. An inspector may require information, collect samples or document deficiencies. A competent authority may order corrective action, immobilise goods or restrict an activity. Where the relevant statutory conditions are satisfied, the Administration may also impose sanctions. These interventions may arise from the same factual circumstances, but their legal nature differs. A preventive measure seeks to address a risk or preserve a legally protected interest.

A sanction responds to conduct classified as an administrative infringement. The distinction has significant constitutional consequences. Article 25.1 of the Spanish Constitution establishes the principle of legality in punitive matters. Article 24 provides guarantees, including the presumption of innocence, that constitutional jurisprudence has extended to administrative sanctioning proceedings with the adaptations appropriate to their nature.

The Administration cannot avoid these guarantees by describing a punitive intervention as merely corrective. Conversely, not every burdensome

administrative measure is necessarily a sanction. The correct classification depends upon its statutory foundation, purpose and legal characteristics.

195. The principle of legality and the requirement of statutory authority

195.1. Article 25.1 of the Spanish Constitution

Article 25.1 provides that no person may be convicted or sanctioned for acts or omissions that did not constitute a criminal offence, misdemeanour or administrative infringement under the legislation in force when they occurred. The principle applies to administrative sanctions. Its principal function is to prevent punishment without a prior legal foundation. In the food sector, this means that an authority must identify the legal provision establishing the infringement and the applicable sanctioning framework.

195.2. Article 25 of Law 40/2015

Article 25 of Law 40/2015 governs the principle of legality in administrative sanctioning. The exercise of sanctioning powers requires express recognition by a law and must comply with the legally established procedure. The existence of a general inspection power does not automatically establish an unlimited sanctioning power. The Administration must distinguish its authority to inspect from its authority to punish.

195.3. The role of European Union legislation

European Union food law establishes extensive obligations concerning food safety, hygiene, traceability and official controls. Regulation (EU) 2017/625 requires Member States to establish effective, proportionate and dissuasive penalties for infringements within its scope. However, the existence of a Union obligation does not dispense with the need to identify the applicable domestic sanctioning provision where national law establishes the infringement and penalty.

The legal analysis must therefore connect the substantive obligation with the relevant sanctioning framework.

195.4. The limits of administrative guidance

Inspection manuals, technical recommendations and voluntary certification standards may assist in understanding good practice. They do not automatically create sanctionable obligations. A manufacturer cannot lawfully be sanctioned merely for failing to follow a preferred recommendation unless the relevant conduct also satisfies a binding legal requirement and a legally defined infringement. This distinction is especially important in technologically innovative manufacturing processes.

196. Typicity: From technical deficiency to legally defined infringement

196.1. Article 27 of Law 40/2015

Article 27 establishes the principle of tipicidad. Only infringements classified as such by law may constitute administrative offences, subject to the statutory framework governing regulatory development. The Administration must therefore identify the conduct described by the relevant infringement provision. A general assertion that an industrial process is inadequate is not sufficient.

196.2. The problem of open-textured food safety obligations

Food legislation frequently establishes outcome-based duties. For example, operators may be required to implement appropriate hygiene procedures, maintain traceability or ensure that food placed on the market is safe. These obligations may require technical interpretation. However, the use of broad statutory concepts does not eliminate the requirement to identify the specific conduct constituting an infringement. The authority must explain how the established facts satisfy the relevant legal classification.

196.3. An example involving alternative preservation technology

A manufacturer uses a validated preservation process that differs from the method preferred by an inspector. The inspector considers the method unfamiliar. That circumstance alone does not establish an infringement. The authority must identify the applicable legal obligation and demonstrate the relevant non-compliance. Conversely, a manufacturer cannot establish compliance merely by asserting that its technology is innovative. The process must satisfy the applicable legal requirements.

196.4. The limits of analogy

Article 27.4 of Law 40/2015 prohibits analogical application of provisions defining infringements and sanctions. This is particularly important where an authority attempts to classify an unfamiliar process under a provision addressing materially different conduct. The prohibition of punitive analogy does not prevent ordinary legal interpretation. However, interpretation must remain within the legally permissible meaning of the provision.

197. Culpability: The limits of objective responsibility in food safety sanctions

197.1. Article 28 of Law 40/2015

Article 28 establishes the principle of responsibility in administrative sanctioning. Natural and legal persons, together with other entities expressly covered by the provision, may be sanctioned where they are responsible for an infringement through intent or fault.

This wording is significant.

The statute does not authorise the imposition of punitive responsibility solely because an undesirable outcome occurred. The Administration must establish the legally relevant basis for attributing the infringement to the alleged offender.

197.2. STC 76/1990: A governing constitutional principle

The Constitutional Court's judgment STC 76/1990, of 26 April 1990, provides an important constitutional foundation. The Court held that the presumption of innocence applies to administrative sanctioning and rejected both purely objective punitive responsibility and reversal of the burden of proving the facts supporting the sanction. The judgment arose in taxation, not food safety. Its constitutional principles nevertheless extend to administrative punishment more generally.

The correct conclusion is not that food businesses can avoid sanctions by asserting good faith. Rather, the Administration must establish responsibility in accordance with the applicable legal provisions.

197.3. Negligence does not require an intention to cause harm

The culpability principle must not be confused with a requirement to prove deliberate misconduct in every case. A food business may incur responsibility through negligence where the statutory conditions are satisfied. For example, a manufacturer may fail to implement mandatory monitoring procedures despite having the organisational capacity and legal obligation to do so. The absence of an intention to endanger consumers does not necessarily exclude responsibility.

The relevant inquiry concerns the applicable duty, the conduct, its attribution and the legally required degree of fault.

197.4. The position of legal persons

Corporate responsibility presents particular difficulties. A company acts through directors, employees, organisational structures and operating procedures. An infringement may arise from inadequate supervision, deficient systems or conduct attributable to the entity under the applicable legal framework. However, the fact that a company owns a facility does not eliminate the need to identify the basis for its responsibility.

The Administration should distinguish corporate organisational fault from unsupported assumptions that every employee error automatically proves culpability at every corporate level.

197.5. The limits of compliance certifications

ISO 9001, IFS Food and other private certification systems may provide relevant evidence concerning organisational controls. They do not automatically establish compliance with every statutory obligation. Nor do they create immunity from sanctions. Conversely, failure to obtain a voluntary private certification does not automatically constitute an administrative infringement. The authority must identify the applicable legal obligation and the evidence of its breach.

198. Evidentiary sufficiency: Inspection reports, laboratory findings and expert disagreement

198.1. Article 77.5 of Law 39/2015

Article 77.5 establishes evidentiary value for documents formalised by officials possessing the relevant status and recording facts verified by them, subject to the applicable legal requirements. This provision does not establish an irrebuttable presumption. It expressly preserves the possibility of contrary evidence.

198.2. The Constitutional Court's distinction

STC 76/1990 explains that the evidentiary value of official inspection records extends to facts directly verified by the official, not automatically to legal classifications, value judgments or opinions. This distinction is particularly important where inspection reports combine observations with technical interpretations. Consider an inspector who records that a product was stored at a specified temperature. That observation may possess evidentiary value.

However, a conclusion that the temperature necessarily rendered the product unsafe may require additional technical assessment. A further conclusion that the operator committed a serious sanctionable infringement requires legal

classification and proof of the relevant responsibility. These propositions cannot be treated as evidentially identical.

198.3. Laboratory evidence

An official laboratory result may constitute important evidence. However, its legal significance depends upon the applicable analytical method, sampling procedure, decision criteria and statutory requirements. The Administration must distinguish the scientific finding from the legal consequence attributed to it. A detected substance may be relevant to food safety. Whether its presence establishes an infringement depends upon the applicable legislation and the circumstances.

198.4. Contradictory expert evidence

An operator may submit an independent expert report challenging the official analysis. The authority must assess legally relevant evidence under the applicable procedural rules. However, the existence of a contradictory report does not automatically invalidate the official result. The dispute may concern sampling representativeness, analytical uncertainty, laboratory methodology or interpretation of the relevant legal limit. Each question requires its own analysis.

198.5. The contemporary statutory framework

Regulation (EU) 2017/625 and Royal Decree 562/2025 establish specific safeguards concerning official sampling and second expert opinions. These procedures must be distinguished from ordinary private expert reports. The existence of a statutory right to a second expert opinion does not mean that any later private analysis automatically replaces an official result. The evidentiary effect of the second analysis depends upon the precise statutory procedure followed.

199. Procedural guarantees in sanctioning proceedings

199.1. Article 53 of Law 39/2015

Article 53 establishes rights of interested parties in administrative proceedings. Its provisions include access to the file, opportunities to submit allegations and evidence, and other procedural guarantees. In sanctioning proceedings, additional rights apply. These include the right to be informed of the facts attributed to the alleged offender, the infringements they may constitute and the possible sanctions.

199.2. Separation of instruction and resolution

Article 63.1 requires sanctioning proceedings to be initiated ex officio and establishes separation between the investigation and sanctioning phases, assigning them to different bodies. This institutional distinction seeks to reduce the risk that the same decision-making process becomes both accusation and final adjudication without adequate procedural safeguards. However, administrative separation should not be equated with the constitutional independence required of judicial courts.

199.3. The initiation agreement

Article 64 regulates the initiation of sanctioning proceedings. The initiation agreement must identify the relevant elements required by the statute, including the alleged facts and their possible classification. The initial classification may be provisional. However, the alleged offender must receive sufficient information to exercise the rights of defence.

199.4. Evidence and the proposed resolution

Articles 76–78 govern allegations and evidence. Article 89 addresses the proposed resolution. The proposal must identify the facts considered proven, their legal classification, the alleged infringement, the responsible person and the proposed sanction. It must also address the evaluation of relevant evidence.

199.5. The final sanctioning resolution

Article 90 requires the sanctioning resolution to include an assessment of the evidence, identification of the relevant facts and responsibility, and the infringement and sanction imposed—or a declaration that no infringement or responsibility exists. The decision cannot lawfully substitute an unsupported conclusion for the required factual and legal reasoning.

200. Procedural expiry: Caducity is not prescription

200.1. The conceptual distinction

Spanish administrative law distinguishes caducidad of proceedings from prescripción of infringements and sanctions. The concepts address different legal questions. Caducity concerns the consequences of failing to complete a proceeding within the applicable maximum period. Prescription concerns the extinction of the Administration's power to pursue an infringement or enforce a sanction after the legally established period. A proceeding may expire while the infringement remains actionable.

Conversely, the infringement may become time-barred, preventing lawful continuation through a new proceeding.

200.2. Article 25 of Law 39/2015

Article 25 governs the consequences of failure to issue and notify an express decision within the maximum period in proceedings initiated ex officio. In proceedings in which the Administration exercises sanctioning or other intervention powers capable of producing unfavourable effects, expiry generally entails caducity under the statutory conditions. However, the calculation requires attention to the applicable procedural period, legally permitted suspensions and extensions, and the date of notification.

200.3. Article 95: The effect of caducity

Article 95 establishes that caducity does not, by itself, produce prescription of the Administration's actions. Nevertheless, expired proceedings do not interrupt the prescription period in the manner contemplated by the provision. A new proceeding may be possible where the infringement has not prescribed and the applicable conditions are satisfied.

200.4. Why expiry matters for food businesses

Food safety sanctioning proceedings may involve extensive analytical investigations, technical reports and communications between authorities. These circumstances do not automatically suspend the statutory deadline. The authority must identify the specific legal provision permitting suspension or extension. Administrative complexity alone is not a general authorisation to disregard procedural time limits.

200.5. A judicial review checklist

In an appeal concerning caducity, the relevant chronology should identify:

Event	Legal significance
Initiation of proceedings	Starting point for the applicable calculation
Notification of initiation	Relevant to procedural guarantees and chronology
Suspension decisions	Must possess a legally recognised basis
Resumption	Determines the continuation of the calculation
Extensions	Require compliance with applicable statutory conditions
Final resolution	Must satisfy the relevant decision requirements
Notification of resolution	Critical to determining timely completion

The calculation should not be performed by assuming that every delay is attributable to the operator or that every request for additional evidence suspends the deadline.

201. Prescription of food safety infringements and sanctions

201.1. Article 30 of Law 40/2015

Article 30 establishes the general framework for prescription of administrative infringements and sanctions. Where specific legislation establishes applicable periods, those provisions must be examined. The general periods in Article 30 operate within the statutory conditions governing their application.

201.2. Commencement and interruption

The calculation may depend upon whether the infringement is instantaneous, continuous or continuing. The statute also regulates interruption through initiation of sanctioning proceedings with the knowledge of the interested party and the consequences of procedural inactivity. These distinctions can be decisive. For example, a single defective labelling event may raise different temporal questions from a continuing failure to maintain legally required records.

201.3. The danger of retrospective reclassification

An authority should not characterise a completed infringement as continuing merely to avoid prescription. The classification must follow the relevant legal provision and the actual conduct. Similarly, a series of distinct events should not automatically be treated as a single continuous infringement. The analysis must examine the statutory elements and the facts.

201.4. Caducity and prescription together

Where an initial proceeding has expired, the Administration may seek to initiate a new proceeding. However, it must determine whether the alleged infringement remains actionable. The operator should therefore examine both caducity and prescription. One may provide a defence even where the other does not.

202. Proportionality and the graduation of sanctions

202.1. Article 29 of Law 40/2015

Article 29 requires sanctions to satisfy proportionality. Relevant factors include the degree of culpability or intentionality, continuity or persistence of the conduct, the nature of the harm and legally established reincidence. The provision also seeks to prevent unlawful conduct from becoming economically more advantageous than compliance. However, this objective does not authorise arbitrary sanction amounts. The Administration must remain within the statutory framework.

202.2. The statutory classification of food safety infringements

Law 17/2011 establishes categories of infringements and sanctions concerning food safety and nutrition. Article 50 identifies relevant categories of conduct. Article 51 distinguishes minor, serious and very serious infringements.

Article 52 governs sanctions.

Article 53 addresses additional consequences within its statutory scope. The competent authority must identify the applicable provisions and consider any relevant sectoral or autonomous-community legislation.

202.3. The significance of risk

Food safety sanctions may legitimately take account of risk to public health. However, risk should not be invoked as an undefined aggravating factor. The decision must identify the factual circumstances supporting the assessment and the statutory relevance of those circumstances. A hypothetical risk cannot automatically be treated as an established serious injury. Conversely, the absence of actual consumer injury does not necessarily exclude a serious infringement where the legislation protects against risk itself.

202.4. Reincidence

Reincidence must satisfy the statutory conditions. A previous inspection warning is not necessarily equivalent to a final sanction establishing an infringement. The authority must identify the relevant prior decision and explain why the legal requirements for reincidence are met.

203. Non bis in idem and overlapping sanctioning regimes

203.1. Article 31 of Law 40/2015

Article 31 prohibits multiple sanctions for the same facts where the legally relevant identity of subject, facts and protected legal foundation exists. The principle is commonly described as non bis in idem. Its application requires more than demonstrating that two proceedings concern the same industrial incident. The legal interests protected and the statutory classifications must also be examined.

203.2. Food safety and consumer protection

A labelling incident may potentially engage food safety legislation and consumer protection law. Whether multiple sanctions are permissible depends upon the applicable legal framework and the identity requirements governing non bis in idem. The existence of different administrative authorities does not automatically justify multiple punishment. Equally, the involvement of the same product does not automatically establish that two legally distinct infringements constitute prohibited duplication.

203.3. Criminal proceedings

Article 47 of Law 17/2011 contains specific provisions concerning the relationship between administrative sanctioning and criminal proceedings. Where criminal proceedings concern the same facts, the statute establishes consequences for the administrative proceedings and the treatment of facts established by final judicial decisions. The precise application requires examination of the statutory conditions.

203.4. Preventive measures are not automatically sanctions

The principle does not mean that the Administration must choose between immobilising unsafe goods and imposing a lawful sanction. A genuinely protective measure may coexist with punitive proceedings. However, the legal nature of the measure must be assessed substantively. An authority cannot evade punitive guarantees merely by assigning a preventive label to a measure that is, in substance, punitive.

204. Food safety sanctions versus food supply-chain commercial sanctions

A particularly important distinction concerns the scope of Law 12/2013 on measures to improve the functioning of the food supply chain. That legislation regulates commercial relationships and contractual practices within the food chain. It is not interchangeable with food hygiene or public health legislation.

204.1. Different protected interests

Food safety sanctions primarily address compliance with obligations concerning safety, hygiene and related regulatory requirements. Food supply-chain commercial sanctions may concern contractual duties, payment practices and other obligations established by the relevant commercial regulatory framework. Although both regimes affect food businesses, their legal foundations differ.

204.2. Different competent authorities

The authorities responsible for enforcement may differ. The relevant jurisdictional and procedural arrangements must therefore be identified in each case.

204.3. Different factual elements

A dispute concerning the absence of a mandatory written food supply contract does not establish a food hygiene infringement. Similarly, a microbiological non-

compliance finding does not automatically establish a breach of commercial contracting legislation.

204.4. Methodological caution concerning 2026 case law

Recent judicial decisions concerning the food supply chain may be highly relevant to administrative sanctioning principles. However, they should not be presented as direct food safety precedents unless they actually concern food safety obligations. For the definitive monograph, each judgment should be identified by its official reference, date, court and precise holding. Unverified descriptions of recent decisions should not be used as authority.

205. Original doctrinal contribution: The Food Sanction Legality and Evidentiary Assessment Model

The research proposes the Food Sanction Legality and Evidentiary Assessment Model (FS-LEAM). Its purpose is to provide a structured method for examining the validity of administrative sanctions imposed upon food business operators. The model is an original analytical proposal, not a judicially established test.

FS-LEAM · Eight-stage legality assessment

1

Competence

Was the sanction imposed by the legally competent authority?

2

Legal classification

Does a valid legal provision define the alleged infringement?

3

Established facts

Are the material facts supported by legally sufficient evidence?

4

Culpability

Is the required basis of responsibility established?

5

Procedural guarantees

Were the applicable rights of defence respected?

6

Temporal validity

Were the proceedings completed within the applicable periods, and has the infringement prescribed?

7

Proportionality

Was the sanction classified and graduated lawfully?

8

Non-duplication

Does the decision respect the prohibition of prohibited double punishment?

205.1. The model's principal contribution

The model prevents the Administration's reasoning from collapsing several legally distinct questions into one conclusion. A technical deficiency may be established. However, the authority must still identify the infringement, attribute responsibility and determine the lawful sanction.

205.2. The importance of sequencing

The sequence matters.

A sanction should not be justified primarily through its proportionality if the conduct was never legally classified as an infringement. Similarly, a technically persuasive laboratory result cannot cure the absence of statutory competence.

205.3. The limits of the model

FS-LEAM does not replace the applicable legislation. Nor does it establish that every procedural defect necessarily produces the same consequence. The legal effects of procedural irregularities depend upon the relevant statutory rules and judicial doctrine. The framework is intended to improve analytical clarity.

206. Applied industrial scenarios

Scenario A. An inspector rejects an alternative hygiene process

A manufacturer employs a validated sanitation method. The inspector considers the process inadequate because it differs from a familiar procedure. The authority initiates sanctioning proceedings. The legal analysis must determine whether the applicable legislation requires a specific method or permits alternative means of achieving compliance. If the law permits alternatives, the Administration must establish the relevant non-compliance rather than relying solely upon unfamiliarity.

The operator must nevertheless provide evidence demonstrating that the process satisfies the applicable requirements.

Scenario B. An unfavourable laboratory result

An official laboratory identifies a substance exceeding an applicable limit. The manufacturer challenges the sampling procedure and submits an independent analytical report. The authority must assess the evidence under the applicable legal framework. A sanction requires proof of the relevant infringement and culpability. The operator's technical challenge must be evaluated, but it does not automatically invalidate the official finding.

Scenario C. A sanctioning proceeding exceeds its deadline

The Administration initiates proceedings but fails to issue and notify the resolution within the legally applicable period. No valid suspension or extension accounts for the delay.

The proceeding may have expired.

However, the operator must separately examine whether the infringement has prescribed. The Administration may, under the applicable conditions, be able to initiate a new proceeding.

Scenario D. A manufacturer receives two sanctions for one incident

An authority imposes a food safety sanction. Another authority subsequently sanctions conduct arising from the same event. The operator invokes non bis in idem. The analysis must identify the subjects, facts and protected legal foundations. The fact that both sanctions concern the same product is not, by itself, conclusive.

Scenario E. A company holds recognised private certifications

A manufacturer maintains ISO and food safety certification systems. An inspection identifies a statutory deficiency. The company argues that certification establishes compliance. Certification may provide relevant evidence. However, it does not automatically displace binding food safety requirements. The

Administration must still establish the infringement and the legally required responsibility.

207. Conclusions of the third instalment of Part II

Spanish administrative sanctioning law establishes a demanding legal framework for punitive intervention. The Administration must identify the applicable statutory power, establish the legally classified infringement, prove the relevant facts and culpability, respect procedural guarantees and impose a proportionate sanction. The evidentiary value of inspection reports does not eliminate the presumption of innocence. Technical findings must be distinguished from legal classifications. Procedural caducity must be distinguished from prescription.

Preventive measures must be distinguished from sanctions. And food safety enforcement must not be confused with the separate commercial regulation of food supply-chain relationships.

The central conclusion is:

A food safety sanction is not justified merely because an inspector identifies an undesirable condition. It is justified only where the Administration establishes conduct satisfying a legally defined infringement, attributes responsibility in accordance with the culpability principle and respects the substantive and procedural guarantees governing administrative punishment.

The proposed FS-LEAM framework provides a structured method for evaluating those requirements. However, it remains an academic analytical proposal rather than a formally established judicial doctrine.

Primary legal and judicial references

1. Spanish Constitution — Articles 24 and 25.
2. Law 40/2015 — Articles 25–31 governing administrative sanctioning.
3. Law 39/2015 — Articles 25, 53, 63–64, 76–78, 89–90 and 95.
4. Law 17/2011 on Food Safety and Nutrition — Articles 47–53.

5. STC 76/1990, 26 April 1990 — Presumption of innocence, culpability and the evidentiary status of inspection records.
6. Regulation (EU) 2017/625 — Official controls, sampling, enforcement and penalties.
7. Royal Decree 562/2025 — Current Spanish provisions concerning official sampling and second expert opinions.
8. Law 12/2013 on the Food Supply Chain — Commercial food-chain obligations and their separate sanctioning framework.

CHAPTER 18

208. Administrative Silence, Inactivity and Procedural Delay in Food Safety Enforcement: Judicial Remedies Against Regulatory Paralysis

The legal consequences of administrative inaction, prolonged product immobilisation, delayed authorisations, failure to reconsider precautionary measures and non-execution of binding decisions.

Abstract

Administrative inactivity constitutes a particularly complex form of regulatory intervention. Unlike an express prohibition, an administrative failure to act may have no immediately identifiable decision, no articulated reasoning and no clearly defined endpoint. Nevertheless, its economic consequences for a food business may be equivalent to, or more severe than, those of a formal restrictive measure.

A manufacturer awaiting an administrative decision may be unable to market a product. A consignment may remain immobilised while the authority delays reviewing new analytical evidence. An establishment may be unable to resume production because the Administration fails to implement a binding decision. An application may remain unresolved despite the expiry of the statutory period.

Spanish administrative law addresses these situations through several distinct mechanisms: the duty to issue express decisions, administrative silence, caducity, judicial review of inactivity, judicial protection against *vía de hecho*, interim measures and public liability. These mechanisms are not interchangeable.

Administrative silence does not automatically authorise the marketing of food subject to mandatory safety requirements. The expiry of a sanctioning proceeding does not necessarily extinguish the underlying substantive obligations. And the continued effects of an initially lawful precautionary measure require examination under the legislation governing that measure.

This instalment develops a systematic distinction between procedural delay, legally defined administrative silence, failure to perform a concrete administrative obligation and non-execution of binding judicial decisions. It also proposes an

original **Regulatory Inactivity and Judicial Protection Assessment Framework (RIJPAF)** for evaluating the legal and economic consequences of regulatory paralysis.

The central thesis is that **administrative inaction must not become an informal mechanism for imposing indefinite restrictions that the competent authority could not lawfully maintain through a reasoned and reviewable decision**.

Keywords: Administrative silence; administrative inactivity; food safety enforcement; judicial review; procedural delay; product immobilisation; precautionary measures; Spanish administrative law; interim relief; public liability; regulatory paralysis.

208.1. Introduction: When administrative inaction becomes regulatory intervention

Administrative law traditionally focuses upon decisions. An authority grants or refuses an authorisation.

An inspector issues a requirement.

A competent body orders immobilisation. A sanctioning authority imposes a penalty. These decisions possess an identifiable legal form and may be challenged through the applicable procedures. Administrative inactivity presents a different problem. The authority may simply fail to decide. It may postpone a technical assessment.

It may leave a request unanswered.

It may fail to reconsider a restriction after receiving new evidence. Or it may decline to implement the practical consequences of a binding administrative or judicial decision. The operator may then experience substantial economic consequences without receiving a new formal act explaining why those consequences must continue. This creates an asymmetry between regulatory power and procedural protection. A written restrictive decision ordinarily identifies an administrative act capable of challenge.

A prolonged absence of decision may force the operator first to establish which legal mechanism governs the authority's omission. The problem becomes particularly acute in food manufacturing because time may directly affect the value and safety of the products concerned.

Perishable goods deteriorate.

Production schedules are disrupted. Supply contracts may become impossible to perform. Laboratory results may lose practical relevance as goods approach the end of their commercial life. However, these consequences do not automatically establish administrative unlawfulness. The legal analysis must identify the precise duty allegedly breached, the applicable deadline and the legal consequences of the omission.

209. Four legally distinct forms of regulatory paralysis

The expression *administrative inactivity* is often used imprecisely. For legal analysis, at least four categories must be distinguished.

Category	Defining feature	Principal legal framework
Failure to decide	An initiated administrative procedure remains unresolved	Law 39/2015, Articles 21–25
Failure to perform	The Administration omits a concrete obligation already legally established	Law 29/1998, Article 29
Failure to execute	A binding administrative or judicial decision is not implemented	Applicable execution rules; Law 29/1998, Articles 103–112
Material action without lawful procedure	The Administration acts outside the legally required administrative basis or procedure	*Vía de hecho* and Law 29/1998, Article 30

These categories may overlap factually. Nevertheless, their legal requirements and remedies differ.

209.1. Failure to decide

A manufacturer applies for an authorisation and the Administration fails to issue a decision within the statutory period. The relevant questions concern the duty to decide, the maximum period and the legal effects of silence.

209.2. Failure to perform

An authority is subject to a concrete obligation to perform a specified administrative act but does not do so. The relevant question is whether the omission satisfies the requirements for judicial review of administrative inactivity.

209.3. Failure to execute

A court annuls a restriction and orders particular consequences. The Administration fails to comply. The primary legal framework concerns execution of the judgment.

209.4. Material action without lawful procedure

An authority physically prevents access to goods or premises without an adequate administrative basis. Depending upon the circumstances, the conduct may raise questions concerning *vía de hecho*. However, the mere existence of a procedural irregularity does not automatically establish that every administrative action constitutes *vía de hecho*. The classification must be justified under the applicable judicial doctrine.

210. The statutory duty to issue an express decision

210.1. Article 21 of Law 39/2015

Article 21 establishes the general duty of public administrations to issue and notify an express decision in administrative proceedings, subject to the exceptions established by law. The duty applies even where the statutory period has expired.

This is fundamental.

Administrative silence is not a general permission for authorities to avoid deciding. It is a legal mechanism determining the consequences of failure to issue a timely decision. The underlying duty to resolve ordinarily remains.

210.2. Maximum decision periods

The maximum period depends upon the legislation governing the procedure. Where the applicable provisions do not establish a specific period, Article 21 generally establishes a three-month period. The general framework also limits the maximum period that regulations may establish, subject to statutory or European Union exceptions. However, it would be incorrect to assume that every food safety procedure must be resolved within three months.

Authorisations, registrations, sanctioning proceedings and other procedures may be governed by different deadlines. The first task is therefore to identify the precise administrative procedure.

210.3. Suspension of the decision period

Article 22 regulates circumstances in which the maximum period may be suspended. These include certain requests for documents, mandatory reports and other legally specified situations. Suspension is not automatic merely because the authority considers the file technically complex. The statutory conditions must be satisfied.

210.4. Extension of the maximum period

Article 23 permits exceptional extension under specified conditions. The extension must be reasoned and comply with the statutory limits. Administrative workload alone does not create an unlimited right to postpone a decision.

210.5. The evidentiary importance of the administrative chronology

A legally sound assessment of delay requires a complete chronology. The date of filing, confirmation of receipt, requests for additional information, suspension decisions, resumption and notification must be identified. Without that chronology, assertions that the Administration has exceeded the statutory period may be premature.

211. Positive and negative administrative silence

211.1. Article 24 of Law 39/2015

Article 24 establishes the general regime of administrative silence in proceedings initiated at the request of an interested party.

As a general rule, expiry of the maximum period without notification of an express decision may produce positive silence, subject to exceptions established by applicable law, European Union law or international law, as well as the specific exceptions contained in Article 24 itself.

The rule must be applied to the particular procedure. It does not establish a universal right to obtain every requested administrative authorisation through silence.

211.2. Positive silence

Where positive silence lawfully applies, the resulting presumed act has the legal consequences established by the statute. The Administration's subsequent express decision is constrained by that positive result under Article 24.3. However,

positive silence cannot lawfully confer rights contrary to essential legal requirements in circumstances governed by the relevant invalidity rules. Article 47.1(f) of Law 39/2015 is particularly relevant where rights or powers are acquired without satisfying essential requirements.

The relationship between positive silence and invalidity must be examined carefully.

211.3. Negative silence

Negative silence generally permits the interested party to pursue the applicable administrative or judicial remedy. It does not ordinarily constitute a substantive finding that the application was legally unfounded. Nor does it release the Administration from its duty to decide. The resulting procedural position differs from that created by positive silence.

211.4. Food safety authorisations

A manufacturer seeking approval of a product, ingredient, establishment or regulated activity must identify the specific authorisation regime. Some approvals are governed by directly applicable European Union legislation. Others depend upon national or autonomous-community procedures. Where express authorisation is legally required, the operator must not assume that the mere passage of time permits marketing. The consequences of silence must be established from the applicable legal framework.

211.5. Registration versus authorisation

A further distinction concerns registration. Some registration systems serve primarily informational or control functions. Others may be connected to substantive conditions for lawful operation. The legal effects of delay therefore depend upon the nature of the registration and the relevant legislation. The terms *registration*, *notification* and *authorisation* should not be treated as interchangeable.

212. Procedures initiated ex officio: Article 25 of Law 39/2015

Article 25 governs the consequences of failure to issue and notify an express decision in proceedings initiated ex officio. The statute distinguishes proceedings

capable of producing favourable legal situations from sanctioning or other intervention proceedings capable of producing adverse effects.

212.1. Proceedings capable of producing favourable effects

Where the applicable conditions are satisfied, interested parties who have appeared may treat their claims as rejected by silence. This is different from the general positive-silence rule applicable to many proceedings initiated at an interested party's request.

212.2. Sanctioning and adverse intervention proceedings

Article 25.1(b) provides for caducity in sanctioning proceedings and, generally, other ex officio intervention proceedings capable of producing adverse effects, under the statutory conditions. The Administration must then address the procedural consequences established by law. However, caducity of proceedings must not be confused with automatic extinction of every underlying substantive obligation.

212.3. The effect of delay attributable to the interested party

Article 25.2 addresses interruption of the calculation where the proceedings have been paralysed for reasons attributable to the interested party. The Administration must establish the relevant circumstances. A mere allegation that the operator failed to cooperate does not automatically establish every condition required for interruption.

212.4. The relationship with precautionary measures

A precautionary measure may have been adopted within proceedings that subsequently expire. The continuing legal basis of the measure must then be examined under the applicable procedural and sectoral legislation. The Administration cannot simply assume that an expired proceeding indefinitely preserves every restrictive measure adopted during its course. Conversely, the existence of an independent statutory power to protect public health may justify further intervention where the legal conditions remain satisfied.

The legal consequences depend upon the specific measure and governing provisions.

213. Judicial review of administrative inactivity: Article 29 of Law 29/1998

Article 29 of the Law regulating contentious-administrative jurisdiction establishes a specific remedy against certain forms of administrative inactivity. Its scope is narrower than the ordinary-language meaning of administrative delay.

213.1. Article 29.1: Failure to perform a concrete obligation

Article 29.1 applies where the Administration is obliged to perform a concrete service or act in favour of one or more determined persons under a directly operative general provision, administrative act, contract or agreement. The interested party may demand performance. If the Administration fails to comply or reach an agreement within three months of the demand, the legally entitled person may bring a contentious-administrative action. This procedure requires a sufficiently concrete obligation.

It does not provide a universal judicial mechanism for compelling the Administration to perform every activity that a claimant considers desirable.

213.2. Article 29.2: Failure to execute final administrative acts

Article 29.2 addresses the Administration's failure to execute its own final acts. Affected persons may request execution. If execution does not occur within one month, the statute provides for judicial review through the specified procedure. This mechanism differs from Article 29.1. It concerns an existing final administrative act rather than the original establishment of an obligation.

213.3. Article 32: Judicial relief

Article 32 permits the claimant, in the relevant Article 29 proceedings, to seek an order requiring the Administration to fulfil its obligations in the specific terms in which those obligations are legally established. This is significant because the remedy is directed towards actual performance. However, the court cannot simply substitute its preferred regulatory policy for discretionary administrative judgment where the statutory conditions for the inactivity remedy are absent.

214. A significant 2026 Supreme Court judgment: The strict limits of Article 29.1

214.1. Identification

Spanish Supreme Court · Contentious-Administrative Chamber, Section Four · Judgment 915/2026 · 15 July 2026 · Cassation appeal 5797/2023

The Supreme Court's judgment of 15 July 2026 provides particularly relevant contemporary clarification of the requirements governing administrative inactivity under Article 29.1 of Law 29/1998. The Court reaffirmed that this remedy requires an obligation to perform a concrete act or service in favour of determined persons. It also emphasised that the obligation must not depend upon an outstanding margin of administrative appreciation or discretionary determination.

The judgment distinguishes actionable inactivity from general administrative slowness or ineffectiveness.

214.2. The legally decisive requirement

The claimant must identify an obligation possessing sufficiently defined content. A general statutory responsibility to protect public health does not, without more, establish a concrete obligation to perform a particular act in favour of a specific manufacturer. Similarly, a broad obligation to supervise food businesses does not necessarily allow an operator to compel a particular inspection outcome through Article 29.1.

The existence of administrative responsibilities is not equivalent to the existence of an individually enforceable concrete prestation.

214.3. The distinction between a duty to decide and a duty to grant

Suppose a manufacturer applies for a regulatory authorisation. The Administration fails to decide. There may be a legally enforceable duty to resolve the application. However, the authority may retain discretion or technical assessment responsibilities concerning whether the authorisation should be granted. The manufacturer cannot automatically transform the duty to decide into a duty to grant the authorisation through Article 29.1.

The appropriate route may involve the statutory silence regime and judicial review of the resulting express or presumed decision.

214.4. Why this judgment matters to food businesses

The judgment prevents a serious procedural error. An operator may experience substantial harm from administrative delay yet choose the wrong judicial mechanism. If the claimed obligation requires further administrative assessment, Article 29.1 may be unavailable. The claimant must identify whether the case concerns a concrete prestation, an unresolved application, a final administrative act awaiting execution or an unlawful material intervention.

214.5. Relationship with earlier jurisprudence

The 2026 judgment reaffirms established doctrine, including reasoning reflected in STS 187/2019 of 18 February 2019, cassation appeal 3509/2017. It therefore should not be presented as creating an entirely new judicial remedy. Its significance lies in confirming the narrow scope of the existing remedy.

214.6. A necessary limitation

The judgment did not concern an ordinary food safety authorisation or product immobilisation. Its relevance to food enforcement arises from its interpretation of Article 29.1, a general procedural provision. The application to particular food safety disputes remains dependent upon the statutory obligation asserted.

215. The Supreme Court's 2025 jurisprudence: Administrative inactivity is not a universal remedy for regulatory delay

215.1. Judgment 559/2025

Spanish Supreme Court · Contentious-Administrative Chamber, Section Four · Judgment 559/2025 · 13 May 2025 · Cassation appeal 620/2024

The Supreme Court again examined the limits of judicial proceedings against administrative inactivity. The judgment discusses the distinction between concrete obligations susceptible to enforcement under Article 29 and situations requiring administrative decisions involving judgment or appreciation. The Court reaffirmed that Article 29.1 is not an appropriate procedural route for every failure to issue an administrative act.

215.2. The distinction between legal entitlement and regulatory expectation

A manufacturer may have a legitimate commercial interest in obtaining rapid administrative action. However, a commercial expectation does not automatically establish an enforceable right to a particular administrative prestation. The operator must identify the legal source and content of the claimed obligation. This does not mean that delay is necessarily lawful. It means that the remedy must correspond to the legal nature of the omission.

215.3. The role of negative silence

Where the Administration fails to decide an application requiring substantive assessment, negative silence may provide the procedural mechanism allowing judicial review. The court can then examine the legality of the administrative position under the relevant framework. The operator should not attempt to bypass that framework by describing every unresolved application as material inactivity under Article 29.

215.4. The importance of the remedy sought

A claimant may seek an order requiring the Administration to issue a decision. Alternatively, the claimant may seek recognition of a substantive entitlement. These are different forms of relief. The legal basis and available judicial powers must be examined separately. The distinction is especially relevant where the requested authorisation requires scientific assessment.

216. Failure to execute final administrative acts

216.1. Article 29.2 of Law 29/1998

Article 29.2 provides a specific route where the Administration fails to execute its final administrative acts. The relevant act must be identified. The claimant must determine what execution requires and whether the Administration has failed to perform it.

216.2. A food safety example

Suppose a competent authority adopts a final administrative decision lifting a product immobilisation. The operator requests implementation. However, the relevant administrative body fails to release the goods or communicate the

decision to the warehouse responsible for custody. The legal analysis may concern failure to execute a final administrative act. Article 29.2 may be relevant if its conditions are satisfied.

216.3. The limits of the remedy

The operator must distinguish a final act requiring execution from a preliminary technical opinion or informal communication. A laboratory report indicating compliance does not necessarily constitute a final administrative decision lifting a restriction. Similarly, an internal recommendation to reconsider a measure may not establish a concrete execution obligation.

216.4. The one-month period

Article 29.2 establishes a one-month period following the request for execution before the judicial remedy becomes available under that provision. This differs from the three-month period under Article 29.1. The distinction is procedurally significant.

216.5. The Supreme Court's 2024 clarification

The Supreme Court's judgment of 16 December 2024, cassation appeal 7770/2022, ECLI:ES:TS:2024:6187, examined whether particular administrative instructions or measures established sufficiently concrete obligations for purposes of Article 29.2. The Court rejected an overly broad understanding of inactivity where the relevant instruments did not establish the concrete performance claimed. The decision arose from litigation concerning measures affecting care homes during the COVID-19 crisis.

Its relevance to food safety is analogical, concerning the legal requirements for enforcing administrative obligations.

217. Administrative *vía de hecho*: When material intervention lacks an adequate legal basis

217.1. The legal concept

Vía de hecho concerns certain forms of material administrative action undertaken without the legally required foundation or in circumstances satisfying the relevant judicial doctrine. It is distinct from ordinary administrative error. Not every

defective decision or procedural irregularity transforms subsequent administrative action into *vía de hecho*. The classification requires careful analysis.

217.2. Article 30 of Law 29/1998

Article 30 permits an interested party to demand cessation of material action constituting *vía de hecho*. If the demand is not made, or is not satisfied within the statutory period, the interested party may bring the corresponding contentious-administrative action. The statute establishes a ten-day period following the cessation demand. The judicial filing periods are governed by Article 46.3 and are especially short.

217.3. Food product immobilisation without formal legal support

Consider a warehouse holding food products. An inspector verbally directs the warehouse not to release the merchandise. No written decision is subsequently provided, and the authority fails to identify the legal basis or duration of the restriction. The circumstances may justify examining whether the intervention constitutes unlawful material action. However, the absence of an immediately available written document does not automatically establish *vía de hecho*.

The law permits certain urgent administrative actions, and the legal significance of oral orders depends upon the applicable procedural and sectoral framework. The operator must identify the actual administrative conduct and determine whether it satisfies the judicial requirements of *vía de hecho*.

217.4. Article 32.2: Available relief

Where the action is legally characterised as *vía de hecho*, Article 32.2 permits the claimant to seek a declaration of unlawfulness, cessation of the conduct and other appropriate measures, including restoration and compensation where legally justified. The remedy is potentially important because it addresses material interference rather than requiring the operator to identify a conventional final administrative act.

217.5. The practical importance of evidence

Evidence may include written communications, warehouse instructions, official records, witness statements and contemporaneous documentation showing that the operator was prevented from exercising control over its goods. The evidence must distinguish administrative conduct from actions independently undertaken

by private parties. An operator cannot automatically attribute every commercial restriction imposed by a warehouse or customer to the Administration.

218. Prolonged immobilisation: The problem of continuing justification

218.1. Initial legality and subsequent legality

An immobilisation may be justified when adopted. However, its continued maintenance raises a separate legal question. The authority must act within the statutory conditions governing the measure. Where the factual basis changes, the continued restriction may require reassessment.

218.2. Article 137 of Regulation (EU) 2017/625

Article 137 requires competent authorities to investigate suspected non-compliance. Where necessary, official detention of goods may form part of the investigation. The provision also emphasises action directed towards eliminating or containing relevant risks. The existence of investigative powers does not mean that every immobilisation may remain in force indefinitely.

218.3. Article 138: Established non-compliance

Where non-compliance is established, Article 138 requires competent authorities to adopt appropriate measures. These may include restrictions, withdrawal or other interventions within the statutory framework. The authority must consider the nature of the non-compliance and the operator's compliance history where the Regulation requires.

218.4. Delay in laboratory analysis

Suppose goods are immobilised pending official laboratory results. The laboratory experiences significant delays. The operator faces increasing storage costs and deterioration of the merchandise. The delay does not automatically invalidate the initial measure. However, the authority may need to examine whether the continued restriction remains legally justified, whether alternative evidence is available and whether proportionate measures can protect public health while reducing unnecessary damage.

The assessment depends upon the nature of the suspected hazard and the applicable law.

218.5. The significance of new evidence

An operator may provide traceability documentation, independent analytical findings or technical validation data. The authority must assess their legal and scientific relevance. However, the submission of new evidence does not automatically compel release. The question is whether the information alters the factual or legal basis supporting the restriction.

218.6. The relationship with the Galician seafood judgment

STSJ Galicia 291/2020, examined in the preceding instalment, provides a useful example. The authority progressively released merchandise as traceability documentation became available. The court considered that conduct relevant to the proportionality of the intervention. The case supports the analytical importance of reassessment, although it does not establish a universal release deadline applicable to every food safety immobilisation.

219. Interim judicial protection against regulatory paralysis

219.1. Articles 129–136 of Law 29/1998

The contentious-administrative jurisdiction provides mechanisms for interim judicial protection. Article 129 establishes the general possibility of requesting precautionary measures. Article 130 addresses the conditions governing their adoption, including the risk that execution of the challenged act or application of the contested provision could deprive the appeal of its legitimate purpose. The court must also consider the potential effects upon general or third-party interests.

219.2. Urgent protection under Article 135

Article 135 establishes a mechanism for particularly urgent situations. The court may adopt or refuse measures through an expedited procedure, subject to the statutory requirements and subsequent procedural safeguards. This mechanism may be particularly relevant where perishable goods or irreversible industrial consequences are involved. However, urgency must be demonstrated. A manufacturer's assertion that the measure is commercially inconvenient does not automatically establish the conditions for exceptional judicial intervention.

219.3. Article 136: Inactivity and *vía de hecho*

Article 136 contains specific provisions concerning interim measures in proceedings against administrative inactivity and *vía de hecho*. Its operation differs from the ordinary regime and must be examined according to the type of action brought. The availability of relief does not eliminate the need to establish the underlying procedural conditions.

219.4. The public health balance

Food safety litigation frequently requires courts to balance economic harm against potential risks to consumers. The existence of substantial commercial damage does not automatically justify suspending a measure intended to prevent serious health risks. Conversely, the mere invocation of public health does not exempt the authority from providing an adequate factual and legal basis for the restriction. The court must examine the relevant circumstances.

219.5. The importance of technical evidence

An application for interim relief may require evidence concerning product stability, analytical findings, the scope of the affected lot, alternative containment measures and the economic consequences of continued restriction. Unsupported estimates of losses may weaken the application. Similarly, general assertions that a product is safe may be insufficient where the authority possesses credible contrary evidence. The evidentiary burden must be addressed in the procedural context of the interim application.

220. Public liability for regulatory delay

220.1. The constitutional and statutory foundation

Article 106.2 of the Spanish Constitution establishes the constitutional foundation of public liability under the conditions determined by law. Articles 32–34 of Law 40/2015 regulate the substantive framework. Law 39/2015 governs the relevant administrative procedure. The existence of administrative delay does not automatically establish entitlement to compensation.

220.2. The requirement of compensable damage

The claimant must establish damage satisfying the statutory requirements. The damage must be effective, economically assessable and individualised in the legally

relevant sense. The claimant must also establish the required causal relationship and the absence of a legal duty to bear the damage.

220.3. Delay and causation

Suppose an authority unlawfully delays a decision. During that period, the manufacturer loses a supply contract. The existence of delay and contract loss does not automatically establish causation. The analysis must determine whether the contract would probably have been performed if the Administration had acted lawfully and on time. Other possible causes may include market changes, manufacturing deficiencies, supplier failures or contractual conditions.

220.4. Actual loss and lost profit

A compensation claim may involve storage expenses, deterioration, additional financing costs or lost profits. Each category requires appropriate evidence. Lost profits must not be treated as speculative projections detached from commercial reality. Relevant material may include contracts, historical sales, production records, cost structures and evidence concerning the probability of performance.

220.5. The significance of mitigation

An operator may be expected to take reasonable steps to limit avoidable losses, subject to the applicable legal framework. However, mitigation does not require the operator to violate food safety restrictions. The analysis should distinguish lawful commercial alternatives from measures that would compromise regulatory compliance.

220.6. The limits of compensation

Monetary compensation may not fully restore lost market opportunities, commercial reputation or customer relationships. This reinforces the importance of timely administrative and judicial review. Nevertheless, compensation remains subject to the statutory requirements and cannot be assumed merely because a business has suffered economic inconvenience.

221. European Union law and the limits of administrative silence

221.1. National procedural autonomy

European Union law frequently leaves procedural implementation to Member States. However, national procedures must comply with applicable Union

requirements, including the principles of equivalence and effectiveness. Where Union legislation establishes a specific authorisation or approval regime, national administrative silence rules cannot be applied in a manner inconsistent with that regime.

221.2. Directly applicable food safety requirements

Regulation (EC) No 178/2002 establishes general obligations concerning food safety and the responsibilities of food business operators. The absence of an administrative response does not eliminate those obligations. An operator cannot rely upon silence to justify placing unsafe food on the market.

221.3. Approval regimes

Some food products or ingredients require authorisation under specific Union legislation. Examples include certain novel foods, food additives and other regulated categories. The legal consequences of administrative delay depend upon the relevant authorisation procedure. It would be incorrect to assume that Spanish positive silence automatically replaces an express Union authorisation.

221.4. The duty of effective administration

Union law recognises principles concerning effective judicial protection and lawful administrative implementation. However, Article 41 of the Charter of Fundamental Rights, concerning good administration, is addressed in its terms to Union institutions, bodies, offices and agencies. Its direct scope should not be inaccurately extended to every national administrative authority. National authorities implementing Union law remain subject to applicable Union general principles and Charter requirements within the scope established by Article 51.

The distinction is important for doctrinal precision.

222. Original doctrinal contribution: The Regulatory Inactivity and Judicial Protection Assessment Framework

The present research proposes the **Regulatory Inactivity and Judicial Protection Assessment Framework (RIJPAF)**. Its purpose is to distinguish different forms of regulatory paralysis and identify the corresponding legal questions. The framework is an original academic proposal, not an established judicial test.

222.1. Eight-stage assessment

Stage	Legal question
1. Classification	Does the case concern failure to decide, failure to perform, failure to execute or unlawful material action?
2. Source of obligation	What legal provision, act or decision establishes the Administration's duty?
3. Content of obligation	Is the required conduct concrete or does it involve further administrative assessment?
4. Temporal requirements	What deadline applies, and have lawful suspensions or extensions occurred?
5. Continuing restrictions	Does any precautionary measure retain an adequate legal and factual basis?
6. Procedural route	Is the appropriate remedy silence review, Article 29, *vía de hecho* or execution proceedings?
7. Interim protection	Are urgent judicial measures legally available and justified?
8. Compensation	Is there legally compensable damage causally attributable to the omission?

222.2. The model's principal contribution

The framework rejects the assumption that all administrative delay is legally equivalent. An unresolved application differs from failure to execute a final administrative act. A delayed laboratory report differs from material seizure without lawful support. Non-execution of a judgment differs from administrative silence. The remedy must correspond to the legal character of the omission.

222.3. A further distinction: Delay versus continuing intervention

A prolonged immobilisation may involve two simultaneous legal problems. The authority may have delayed completing its investigation. At the same time, it may be maintaining a restriction whose factual justification requires reassessment. The operator should therefore examine both the procedural delay and the continuing legality of the restrictive measure.

222.4. The limits of the model

RIJPAF does not create new rights or judicial remedies. It organises the analysis of existing law. Its practical usefulness would require validation through systematic study of administrative files and judicial decisions.

223. Applied industrial scenarios

Scenario A. A delayed food establishment authorisation

A manufacturer submits an application under a legally applicable authorisation regime. The Administration fails to decide within the maximum period. The operator must identify whether the procedure is subject to positive or negative silence and whether specific Union or national rules require express authorisation. The operator should not assume that delay alone permits commencement of the regulated activity. Where the law provides for negative silence, the relevant appeal route may become available.

Scenario B. Immobilised perishable ingredients

A consignment is immobilised pending laboratory analysis. The authority does not provide a timely update. The goods approach the end of their commercial shelf life. The operator should distinguish the legality of the original measure from the legality of maintaining it. Relevant evidence includes the initial grounds for immobilisation, laboratory chronology, product stability, subsequent findings and the availability of alternative protective measures. Urgent judicial relief may be relevant where the statutory conditions are satisfied.

Scenario C. Failure to implement a final release decision

The competent authority issues a final administrative decision lifting an immobilisation. The warehouse nevertheless continues to retain the goods because the Administration has not implemented the decision. Article 29.2 of Law 29/1998 may be relevant where the statutory conditions are satisfied. The operator must identify the final act and the concrete performance required.

Scenario D. An inspector's informal prohibition

An inspector orally instructs a manufacturer to cease using a production line.

No written decision is provided.

The operator requests clarification of the legal basis. The legal analysis must determine whether the instruction was lawfully issued under an applicable power and whether the subsequent conduct satisfies the conditions for challenge as an administrative act or *vía de hecho*. The absence of written documentation is relevant but not necessarily conclusive.

Scenario E. Delayed recognition of analytical compliance

A second official analysis produces a result favourable to the operator under the applicable statutory procedure. The authority nevertheless delays reconsidering the restriction. The operator must examine the legal consequences of the second analysis, the authority's duty to reassess the measure and the appropriate procedural remedy. The result of the second analysis must be considered within the precise statutory framework governing its evidentiary effect.

224. Conclusions of the fourth instalment of Part II

Administrative inactivity is not a single legal phenomenon. Spanish law distinguishes failure to decide, failure to perform concrete obligations, failure to execute final administrative acts and material action constituting *vía de hecho*. Each category possesses distinct procedural requirements. Articles 21–25 of Law 39/2015 establish the principal framework concerning the duty to decide and administrative silence. Articles 29–32 of Law 29/1998 provide specific judicial mechanisms addressing inactivity and unlawful material intervention.

The Supreme Court's jurisprudence, including its decisions of 13 May 2025 and 15 July 2026, confirms that Article 29.1 is a narrowly defined remedy requiring a concrete obligation in favour of determined persons. It cannot be used as a universal mechanism for compelling administrative activity involving unresolved discretion or technical assessment. In food safety enforcement, a further distinction is essential. An initially justified precautionary measure may require reassessment as the factual situation evolves.

Administrative delay does not automatically invalidate the measure, but neither does initial legality justify its indefinite maintenance. Finally, compensation requires proof of legally compensable damage and the relevant causal relationship.

The principal conclusion is:

The Administration's power to intervene in food safety matters includes a corresponding obligation to act within the applicable procedural framework. Administrative silence, institutional delay or failure to reconsider restrictions cannot lawfully substitute for the reasoned exercise of statutory powers.

The RIJPAF framework provides a structured method for identifying the legal nature of regulatory paralysis and selecting the appropriate remedy.

Primary legislation and judicial references

1. Law 39/2015 on Common Administrative Procedure — Articles 21–25, 47 and 95.
2. Law 29/1998 regulating contentious-administrative jurisdiction — Articles 29–32, 46 and 129–136.
3. Law 40/2015 — Articles 32–34 on public liability.
4. Supreme Court, Judgment 915/2026, 15 July 2026, cassation 5797/2023 — Requirements for judicial review of administrative inactivity.
5. Supreme Court, Judgment 559/2025, 13 May 2025, cassation 620/2024 — Scope of Article 29.1.
6. Supreme Court, Official Jurisprudence Chronicle 2024–2025 — Discussion of STS 16 December 2024, ECLI:ES:TS:2024:6187.
7. Regulation (EU) 2017/625 — Articles 7 and 137–138.
8. Regulation (EC) No 178/2002 — General food safety obligations.
9. Royal Decree 562/2025 — Spanish official control procedures and expert review.

CHAPTER 19

225. State Liability for Unlawful Food Safety Enforcement: Compensable Damage, Causation, Lost Profits, Reputational Injury and the Economic Consequences of Regulatory Error

From the annulment of regulatory measures to the judicial proof of economic loss: Spanish public liability doctrine, industrial causation, financial evidence and the limits of compensation.

Abstract

Official food controls may cause substantial economic damage even where their purpose is the legitimate protection of public health. Product immobilisation, compulsory withdrawal, destruction, suspension of manufacturing operations and delays in administrative decision-making can affect inventories, production capacity, commercial contracts, working capital and market reputation.

Spanish law does not establish that every loss caused by regulatory intervention must be compensated. Nor does the subsequent annulment of an administrative measure automatically establish public liability.

The constitutional and statutory framework requires the claimant to demonstrate legally compensable damage, an adequate causal relationship with administrative activity and the absence of a legal duty to bear the injury, subject to the applicable exclusions and procedural requirements.

This instalment examines those conditions through the constitutional foundation of public liability, Articles 32–34 of Law 40/2015, the administrative claims procedure established by Law 39/2015 and the judicial review framework under Law 29/1998. Particular attention is devoted to the Spanish Supreme Court's olive-pomace oil litigation, which demonstrates the distinction between annulment of food safety measures and compensable injury.

The article develops a detailed economic methodology for distinguishing actual losses, lost profits, inventory impairment, additional financing costs and reputational damage. It also introduces an original **Regulatory Damage,**

Causation and Compensation Assessment Framework (RDCCAF) for evaluating claims arising from official food controls.

The central thesis is that **the economic consequences of regulatory intervention must be assessed through a disciplined legal and evidentiary methodology that distinguishes lawful protective burdens from compensable administrative injury and demonstrated commercial losses from speculative expectations**.

Keywords: Public liability; food safety enforcement; administrative annulment; causation; lost profits; inventory destruction; regulatory delay; reputational damage; Spanish Supreme Court; compensation; economic evidence.

225.1. Introduction: The economic asymmetry of official food controls

Food safety enforcement may affect an industrial operation within hours. A manufacturing line may be stopped.

A warehouse may be sealed.

A consignment may be immobilised.

A product may be withdrawn from distribution. An authority may require destruction of goods that cannot be recovered. The economic consequences may extend beyond the immediate value of the affected merchandise. Production interruption can generate fixed-cost absorption problems. Delayed deliveries may produce contractual penalties. Customers may seek alternative suppliers. Financing requirements may increase. Commercial confidence may deteriorate. Nevertheless, the existence of economic harm does not automatically establish public liability.

The Administration may lawfully impose restrictions that cause substantial losses where intervention is necessary and authorised to protect public health. Conversely, a legally defective measure may generate compensable injury where the applicable requirements are satisfied. The legal problem is therefore not whether regulatory intervention caused commercial inconvenience. It is whether the resulting damage constitutes a legally compensable injury attributable to the Administration.

This requires separating several distinct questions:

- Was the administrative conduct lawful?

- Did the claimant suffer actual damage?
- Was that damage legally compensable?
- Did the administrative conduct cause the damage?
- Can the amount be established with sufficient reliability?
- Were there independent causes or reasonable opportunities to reduce the loss?

The questions must be answered separately.

226. The constitutional foundation: Article 106.2 of the Spanish Constitution

Article 106.2 of the Constitution establishes the constitutional foundation of public liability. It recognises the right of individuals, under the terms established by law, to compensation for injury suffered in their property or rights as a consequence of the functioning of public services, except in cases of force majeure. The provision must be read together with the statutory framework. It does not create an unrestricted entitlement to compensation for every adverse consequence of public administration.

226.1. Objective liability does not mean automatic liability

Spanish public liability is frequently described as objective. However, this characterisation must not be misunderstood. It does not mean that every loss caused by administrative activity is compensable. The claimant must establish the requirements governing injury, causation and the absence of a legal duty to bear the damage. The objective character of the regime does not eliminate those elements.

226.2. Lawful and unlawful administrative activity

Public liability may arise in circumstances involving lawful or unlawful administrative functioning. However, the legal analysis differs according to the circumstances. A lawful protective measure may impose losses that the operator has a legal duty to bear. An unlawful measure may strengthen the claimant's position concerning the absence of such a duty, but does not automatically establish every element of compensation.

226.3. The role of public health

The importance of public health may justify significant regulatory intervention. However, public health is not a general immunity from liability. Where the Administration causes compensable damage under the statutory conditions, the protective purpose of its action does not automatically exclude responsibility. The relevant question is whether the legal requirements for compensation are satisfied.

227. Article 32 of Law 40/2015: The substantive structure of public liability

227.1. General requirements

Article 32 establishes the general principles governing public liability. It recognises compensation for injury caused by the normal or abnormal functioning of public services, subject to the statutory requirements and exclusions. The damage must be effective, economically assessable and individualised in relation to a person or group. The statute also addresses circumstances in which the claimant has a legal duty to bear the damage.

227.2. The legal duty to bear the injury

The concept of *antijuridicidad del daño* is central. The relevant question is not simply whether the Administration acted unlawfully. It is whether the claimant had a legal duty to bear the particular injury. This distinction is especially important in regulated industries. Food manufacturers operate under extensive statutory obligations. Compliance with those obligations may require expenditure, production interruption or withdrawal of unsafe products. Such consequences do not automatically constitute compensable damage.

227.3. Annulment does not automatically establish compensation

Article 32.1 expressly provides that annulment of administrative acts or provisions, whether through administrative or judicial proceedings, does not by itself give rise to a right to compensation. This rule is fundamental to the present research. A manufacturer may successfully challenge an immobilisation order. However, compensation still requires proof of the remaining statutory elements.

227.4. Force majeure and the state of scientific knowledge

Article 34.1 excludes compensation for certain damage arising from circumstances that could not have been foreseen or avoided according to the state of scientific or technical knowledge existing when the damage occurred, subject to the statutory framework. This provision requires careful interpretation. It should not be used as a general defence whenever an authority invokes scientific uncertainty. The relevant statutory conditions must be established.

228. The olive-pomace oil litigation: A decisive distinction between annulment and compensation

228.1. The factual context

The Spanish olive-pomace oil alert of July 2001 generated extensive litigation concerning restrictions adopted after concerns arose about contamination by polycyclic aromatic hydrocarbons, particularly benzo[a]pyrene. The administrative measures affected the commercialisation and immobilisation of olive-pomace oil. The sector subsequently pursued judicial challenges and claims for compensation. The litigation is particularly important because it produced decisions addressing different aspects of administrative legality and public liability.

228.2. The Supreme Court judgment of 27 June 2007

In its judgment of 27 June 2007, cassation appeal 10820/2004, the Supreme Court confirmed the annulment of the administrative decision of 3 July 2001. The decision therefore established a defect in the legality of the challenged administrative intervention. However, the judgment did not automatically determine the outcome of every subsequent compensation claim.

228.3. STS 6028/2011: The compensation question

Supreme Court · Third Chamber, Section Six · 16 September 2011 · ECLI:ES:TS:2011:6028 · Cassation appeal 714/2007

In this judgment, the Supreme Court rejected a compensation claim arising from the immobilisation of olive-pomace oil. The Court expressly acknowledged the earlier annulment. Nevertheless, it concluded that the relevant economic losses did not establish compensable unlawful injury under the circumstances. The

Court considered the producers' obligations concerning the reduction of benzopyrene and the technical means available at the relevant time.

228.4. The importance of the operator's regulatory duties

The judgment did not treat the losses as compensable merely because the challenged administrative decision had been annulled. Instead, the Court examined whether the affected operators had a legal duty to bear the consequences of the protective intervention. The decision therefore demonstrates that public liability cannot be assessed without considering the regulatory responsibilities of the claimant.

228.5. The distinction between administrative invalidity and antijuridical injury

The following propositions must be kept separate. An administrative act may be annulled because it was not adopted in accordance with the law. The operator may have suffered economic losses. Nevertheless, those losses may not satisfy the statutory requirements for compensation. The converse is also possible: liability may arise from administrative functioning that is not characterised simply as an unlawful act, provided the statutory conditions are satisfied.

228.6. The limits of the precedent

The olive-pomace oil litigation does not establish that manufacturers must bear every loss caused by food safety enforcement. Nor does it establish that administrative annulment is irrelevant to compensation. The judgment must be understood in the context of the specific products, regulatory duties, scientific circumstances and evidence examined.

Established holding: The Supreme Court rejected compensation in the particular olive-pomace oil case despite the earlier annulment.

General statutory principle: Annulment alone does not establish entitlement to compensation. **Original doctrinal implication:** Public liability analysis should distinguish the legality of intervention from the legal character of each category of resulting economic damage.

229. The requirement of effective and individualised damage

229.1. Effective damage

A compensation claim requires actual damage. A hypothetical commercial opportunity that never possessed a demonstrable probability of materialisation may be insufficient. This does not mean that lost profits are categorically excluded. It means that the claimed loss must be established through appropriate evidence.

229.2. Economically assessable damage

The damage must be capable of economic assessment. In industrial food manufacturing, this may include identifiable inventory losses, additional storage expenses, wasted production inputs and other documented costs. However, the calculation must avoid duplication. For example, an inventory loss should not be counted once as destroyed stock and again as the full revenue that the same stock would have generated without deducting relevant costs.

229.3. Individualisation

The injury must be individualised in relation to the claimant or an identifiable group. A general market decline affecting an entire sector does not automatically establish compensable injury attributable to a particular administrative act. The claimant must demonstrate the legally relevant relationship between the administrative conduct and its own loss.

229.4. Documentary evidence

Relevant evidence may include purchase invoices, inventory records, warehouse reports, production orders, commercial contracts, transport documentation, financial statements and accounting records. The evidence should establish not only the amount claimed but also the circumstances in which the loss occurred.

230. Causation: The central evidentiary problem

230.1. The causal relationship

A claimant must establish that the administrative functioning caused the alleged injury in the legally relevant sense. Temporal succession is insufficient. The fact that a loss occurred after an inspection does not automatically demonstrate that the inspection caused it.

230.2. Multiple contributing causes

Food manufacturing losses may arise from several factors. An administrative restriction may coincide with reduced market demand, manufacturing deficiencies, supplier delays or contractual disputes. The analysis must distinguish the contribution of each relevant cause. Where the evidence supports only partial attribution to administrative conduct, the compensable amount may differ from the operator's total accounting loss.

230.3. The counterfactual question

A useful economic method asks:

What would probably have happened if the Administration had acted lawfully?
This counterfactual scenario must be grounded in evidence. It should not assume perfect production, unlimited demand or the absence of ordinary commercial risks.

230.4. The significance of contemporaneous records

Evidence created at the time of the events may be particularly valuable. Production schedules, customer orders and inventory records prepared before the dispute can help establish what was realistically expected. Documents created exclusively after litigation begins may still be relevant, but their assumptions require careful examination.

230.5. Independent expert analysis

Complex claims may require forensic accounting or economic expert evidence. The expert should explain the methodology, source data, assumptions and sensitivity of the calculation. A persuasive report must permit the court to understand how the claimed figure was derived.

231. Actual losses: Inventory, storage and industrial interruption

231.1. Inventory impairment

Product immobilisation may result in deterioration or loss of commercial value. The economic assessment should identify the affected lots, their condition, acquisition or production costs and any recoverable value. The existence of an administrative restriction does not automatically establish that the entire inventory became worthless.

231.2. Destruction

Where products are destroyed, the claimant may seek to establish the economic value lost. However, the calculation must consider whether the goods were legally marketable, whether they possessed residual value and whether the destruction was attributable to compensable administrative conduct. A product that could not lawfully have been marketed does not automatically support a claim for the profits of its hypothetical sale.

231.3. Storage costs

Additional warehousing, refrigeration, insurance and handling costs may constitute identifiable losses. The claimant should distinguish ordinary operating costs from additional expenditure caused by the disputed intervention.

231.4. Production interruption

A manufacturing stoppage may produce costs associated with idle capacity, labour, utilities and equipment. However, fixed costs require careful treatment. A cost that the business would have incurred regardless of the restriction should not automatically be counted as an additional expense. Its relevance may instead arise through lost contribution margin or demonstrable wasted capacity.

231.5. Restart costs

Restarting production may involve sanitation, recalibration, validation, additional testing and other expenditure. These costs may be relevant where they are demonstrably attributable to the intervention and satisfy the statutory requirements. The claimant must avoid including ordinary maintenance or planned operational expenditure unrelated to the disputed measure.

232. Lost profits: From commercial expectation to evidentiary proof

232.1. The concept of *lucro cesante*

Lost profits concern gains that the claimant would probably have obtained but for the legally relevant damaging event. They differ from actual expenditure or direct asset loss. The assessment is necessarily counterfactual. However, it must remain evidence-based.

232.2. Revenue is not profit

A frequent methodological error is to equate lost sales with lost profits. Suppose a manufacturer loses an order worth €200,000. The economic loss is not automatically €200,000. The business may have avoided raw material expenditure, packaging, freight, commissions or other variable costs. The relevant calculation must identify the profit or contribution that would probably have been earned.

232.3. Contribution margin

For short-term production interruption, contribution margin may provide a useful analytical starting point.

A simplified model is:

However, this calculation is not automatically equivalent to legally compensable lost profit. Additional adjustments may be required for displaced sales, substitute production, capacity constraints, taxes, recoverable costs and other relevant factors.

232.4. Existing contracts

Signed customer orders may provide strong evidence of expected sales. However, their legal and commercial conditions must be examined. A contract may permit cancellation. Delivery may depend upon regulatory approval. The customer may possess alternative termination rights. The operator must demonstrate the realistic probability of performance.

232.5. Historical sales

Historical sales data may assist where the claimant lacks specific contracts. However, the analysis should consider seasonality, market trends, production capacity and changes in customer demand. A simple extrapolation from the highest-performing month may exaggerate the likely outcome.

232.6. New products

Lost profits involving products not yet commercially established are particularly difficult to prove. Projected sales may depend upon untested assumptions. A business plan may demonstrate commercial intention but not necessarily establish that the projected profits would have materialised. The assessment should distinguish credible commercial evidence from speculative forecasts.

233. A worked industrial example: Quantifying the effects of a production stoppage

The following example is hypothetical. It is intended to illustrate economic methodology and does not represent a judicially accepted calculation or a real compensation award. A food ingredient manufacturer experiences a 20-day production interruption. The company had confirmed orders that could not be fulfilled.

Hypothetical financial assessment

Confirmed orders affected	**€240,000**
Avoided variable costs	−€156,000
Lost contribution margin	€84,000
Additional storage expenses	€9,500
Documented restart costs	€12,000
Recoverable substitute sales	−€18,000
Illustrative net economic impact	€87,500

Illustrative accounting calculation only. The figures assume that the €18,000 substitute-sales adjustment represents net recovered contribution, not gross revenue.

233.1. Why the calculation is only a starting point

The figure of €87,500 is not automatically compensable. The claimant must establish that the interruption was attributable to the Administration and that the resulting damage satisfies the statutory requirements. The calculation must also be checked for omitted costs, double counting and relevant commercial contingencies.

233.2. Sensitivity analysis

The claimed amount may depend upon the probability that the affected orders would have been fulfilled. If some orders were conditional or likely to be cancelled independently, the expected loss may be lower. A forensic economic report should explain the assumptions rather than present a single figure as mathematically inevitable.

233.3. The distinction between economic and legal valuation

Economic experts can estimate financial consequences. They do not determine whether the damage is legally compensable. That assessment belongs to the competent administrative or judicial authority applying the relevant law.

234. Reputational injury and the loss of commercial confidence

234.1. The reputational consequences of food safety intervention

A food safety alert may affect the market reputation of a manufacturer.

Customers may suspend orders.

Distributors may demand additional guarantees.

Retailers may withdraw products.

The company may experience adverse publicity. These consequences can be economically significant. However, reputational damage is particularly difficult to quantify.

234.2. The distinction between reputational harm and commercial loss

Reputational injury may manifest through identifiable economic consequences. Examples include cancelled contracts, reduced sales, additional marketing expenditure or loss of customer relationships. These consequences may be more readily assessed than an abstract claim that the company's image has deteriorated. Nevertheless, the legal framework may recognise different forms of damage where the applicable requirements are satisfied.

234.3. Causation and independent publicity

A manufacturer may experience reputational harm because an authority publicly identifies a food safety concern. However, the resulting publicity may also arise from independent reporting, customer decisions or actual product deficiencies. The claimant must identify the administrative conduct allegedly causing the damage. It must then establish the relevant causal relationship.

234.4. Truthful regulatory communication

Authorities may possess statutory duties concerning transparency and public health information. The fact that an accurate and legally authorised warning damages commercial reputation does not automatically make the resulting injury

compensable. Conversely, materially inaccurate or unlawful administrative communications may raise different questions. The legal assessment depends upon the circumstances.

234.5. A proposed evidentiary approach

Reputational damage claims should identify the alleged harmful communication, the relevant audience, the chronology of commercial consequences and the available evidence of causation. Relevant evidence may include customer correspondence, sales trends, distribution agreements and market analysis. The methodology should avoid attributing every subsequent decline in revenue to the administrative intervention.

235. The duty to mitigate avoidable losses

235.1. The general problem

A claimant may suffer damage that could have been reduced through reasonable commercial action. The assessment of compensation may therefore require examination of whether the claimant took appropriate steps to limit avoidable loss. However, the relevant legal consequences must be grounded in the applicable law and judicial doctrine.

235.2. Lawful mitigation

Possible measures may include redirecting unaffected production, preserving goods under appropriate conditions, negotiating delivery extensions or identifying alternative lawful markets. These measures may reduce the economic consequences of intervention.

235.3. The limits of mitigation

The operator cannot be expected to disregard a lawful immobilisation order. Nor should mitigation be equated with an obligation to undertake commercially irrational or technically unsafe measures. The assessment must consider what was reasonably available in the circumstances.

235.4. The importance of documentation

A manufacturer should preserve evidence of mitigation efforts. Relevant records may include communications with customers, alternative production plans, warehouse arrangements and attempts to recover commercial value. Such

evidence may assist in establishing that the claimed losses were not unnecessarily increased.

236. Procedural requirements for public liability claims

236.1. Article 67 of Law 39/2015

Article 67 governs the initiation of public liability proceedings at the request of an interested party. As a general rule, the right to claim prescribes one year after the event or act giving rise to compensation, or after its harmful effect becomes apparent. The statute contains specific rules concerning personal injury and claims associated with annulment of administrative acts or provisions.

Where compensation is claimed following annulment, the relevant one-year period is governed by the statutory rule referring to notification of the administrative resolution or final judgment. The applicable starting point must be determined carefully.

236.2. Required contents of the claim

The claimant must identify the alleged injuries, the presumed causal relationship with administrative functioning and, where possible, the economic assessment of the damage. The claim should also identify when the injury occurred. Supporting documentation and proposed evidence should be included.

236.3. The service report

Article 81.1 requires a report from the service whose functioning allegedly caused the compensable injury. The statute establishes a maximum period of ten days for that report. The requirement provides an institutional opportunity to examine the administrative conduct giving rise to the claim.

236.4. Advisory opinions

Article 81.2 establishes circumstances in which an opinion from the Council of State or the corresponding autonomous-community advisory body is mandatory. The provision refers, among other cases, to claims of €50,000 or more, or the amount established by applicable autonomous-community legislation. The precise threshold must therefore be checked for the competent administration.

236.5. The final resolution

Article 91 requires the resolution to address the existence or absence of causation and, where appropriate, the assessment, amount and form of compensation.

This requirement is significant.

A rejection should not simply state that the Administration acted in pursuit of public health. It must address the legally relevant requirements of the claim.

236.6. Administrative silence

Article 91.3 provides that, where six months elapse without the required resolution or agreement, the claim may be understood as rejected. The applicable judicial remedy may then be pursued under the relevant conditions. This negative-silence mechanism does not eliminate the Administration's duty to resolve.

237. Judicial review of compensation decisions

237.1. The contentious-administrative jurisdiction

Public liability decisions may be challenged before the competent contentious-administrative court under the applicable procedural rules. The court may examine the legal requirements of liability, the evidence of damage, causation and the amount claimed.

237.2. The importance of the administrative file

The administrative file may contain the original inspection records, laboratory findings, internal reports, decisions and communications relevant to the alleged injury. A complete file is therefore essential. Where documents are missing or incomplete, the claimant may need to use the procedural mechanisms available to obtain or challenge the evidence.

237.3. Expert evidence

Complex claims may require technical and economic experts. A food safety expert may address whether the underlying intervention was scientifically justified. An economic expert may quantify the consequences. The two disciplines should not be conflated. A scientifically defective intervention does not automatically establish a particular amount of financial loss. Similarly, a detailed financial calculation does not establish that the administrative conduct was unlawful or that the damage was legally compensable.

237.4. The judicial assessment

The court must evaluate the evidence under the applicable procedural standards. It may accept, reject or modify the claimed valuation depending upon the record. The claimant should therefore avoid treating a privately commissioned expert report as conclusive merely because it contains detailed calculations.

238. Original doctrinal contribution: The Regulatory Damage, Causation and Compensation Assessment Framework

The research proposes the **Regulatory Damage, Causation and Compensation Assessment Framework (RDCCAF)**. The framework is an original academic proposal and not an established judicial test. Its purpose is to organise the legal and economic assessment of compensation claims arising from official food controls.

238.1. Eight-stage assessment

Stage	Required inquiry
1. Administrative conduct	What action or omission allegedly caused the injury?
2. Legal character	Was the conduct lawful, unlawful or otherwise relevant under the liability regime?
3. Damage identification	What actual injuries did the operator suffer?
4. Antijuridicity	Did the operator have a legal duty to bear those injuries?
5. Causation	What evidence connects the administrative conduct to each loss?
6. Economic valuation	How should each category of loss be quantified?
7. Adjustments	Are there independent causes, recoveries or avoidable losses?
8. Procedural validity	Was the claim brought through the correct procedure and within the applicable period?

238.2. The model's central contribution

The framework requires each category of loss to be examined separately. A claimant should not present one aggregate figure without explaining its components. For example, destroyed inventory, lost contribution margin and additional storage costs may require different evidence and valuation methods.

238.3. The antijuridicity stage

The framework places particular emphasis upon the legal duty to bear the injury. This reflects the importance of the Supreme Court's olive-pomace oil jurisprudence. A manufacturer may demonstrate that losses occurred without establishing that those losses are compensable.

238.4. The causation stage

Each claimed loss should be linked to the relevant administrative conduct. The analysis should consider alternative explanations. This reduces the risk of attributing ordinary commercial difficulties to regulatory intervention.

238.5. The valuation stage

Economic estimates should be based upon verifiable records and transparent assumptions. Where uncertainty remains, the expert should explain its effect upon the result.

238.6. The limits of the model

RDCCAF does not create new legal rights. It does not replace statutory requirements or judicial doctrine. It is intended to provide a disciplined analytical method capable of supporting legal research, administrative claims and expert assessment.

239. Applied industrial scenarios

Scenario A. Unlawful immobilisation of a food ingredient

A competent authority immobilises an ingredient consignment. The measure is subsequently annulled. The manufacturer claims storage costs, deterioration and lost profits. The legal analysis must distinguish annulment from compensation. The claimant must establish actual damage, causation and the absence of a legal duty to bear the injury.

Scenario B. Destruction of goods following an erroneous analytical finding

An official laboratory reports non-compliance.

The authority orders destruction.

A later legally relevant analytical review establishes that the original finding was erroneous. The operator may have grounds to examine public liability. However,

the claim requires analysis of the applicable powers, procedural compliance, causation and valuation. The existence of analytical error does not automatically determine the amount of compensation.

Scenario C. Production stoppage following an inspection

An inspector orders suspension of a manufacturing line. The restriction is later found to lack an adequate legal foundation. The manufacturer claims lost production revenue. The economic assessment must identify the contribution that would probably have been earned, rather than simply treating all foregone sales as profit.

Scenario D. Reputational harm following public communication

An authority publicly identifies a manufacturer as presenting a food safety concern. The communication is subsequently found to contain material inaccuracies. The company experiences cancelled contracts and declining sales. The claim must establish the relevant administrative conduct, the nature of the inaccuracies, causation and the economic consequences.

Scenario E. Delay in lifting a precautionary measure

An initially justified immobilisation remains in place after the authority receives evidence materially changing the factual basis for restriction. The manufacturer suffers additional storage costs and product deterioration. The legal analysis should distinguish the original intervention from the continued maintenance of the measure. Compensation, if available, may concern losses attributable to the legally relevant period of unjustified continuation rather than the entire duration of immobilisation.

240. Conclusions of the fifth instalment of Part II

Public liability for food safety enforcement requires a disciplined distinction between administrative illegality and compensable injury. The Constitution establishes the foundation of public liability. Law 40/2015 identifies the substantive requirements. Law 39/2015 governs the administrative claims procedure. The Supreme Court's olive-pomace oil jurisprudence demonstrates that annulment of a regulatory measure does not automatically establish entitlement to compensation.

The claimant must demonstrate effective, economically assessable and individualised damage, the required causal relationship and the absence of a legal duty to bear the injury. In industrial food manufacturing, the economic assessment may involve inventory losses, storage expenses, production interruption, lost profits and reputational consequences. Each category requires appropriate evidence. Revenue should not be confused with profit. Hypothetical opportunities should not be presented as established losses.

And ordinary commercial risks should not automatically be attributed to administrative intervention.

The central conclusion is:

Compensation for regulatory error requires more than proof that an administrative measure was annulled or that a food business suffered economic losses. It requires a legally grounded demonstration that identifiable administrative functioning caused specific damage which the operator had no legal duty to bear, supported by reliable economic evidence.

The proposed RDCCAF framework provides an integrated method for conducting that assessment.

Primary legislation and judicial references

1. Spanish Constitution — Article 106.2.
2. Law 40/2015 — Articles 32–34.
3. Law 39/2015 — Articles 65, 67, 81, 91 and 92.
4. Supreme Court, 16 September 2011, ECLI:ES:TS:2011:6028 — Olive-pomace oil immobilisation and public liability.
5. Full judgment and related case-law references — STS 16 September 2011.
6. Law 29/1998 — Judicial review of administrative liability decisions.
7. Regulation (EU) 2017/625 — Official controls and enforcement.
8. Regulation (EC) No 178/2002 — General food safety obligations.

CHAPTER 20

241. Regulatory Harassment, Repeated Inspections, Retaliatory Enforcement and Misuse of Public Powers

Judicial proof, institutional accountability, selective enforcement and the constitutional limits of administrative discretion in the Spanish food industry.

Abstract

Official food inspections are indispensable instruments for protecting public health, verifying regulatory compliance and maintaining confidence in the food supply chain. Their legitimacy, however, depends not only upon the existence of statutory powers but also upon the purposes for which those powers are exercised.

An inspection may be formally authorised yet raise serious legal concerns where its selection, frequency, scope or consequences are influenced by improper considerations. Repeated inspections may be entirely legitimate when justified by risk, compliance history or new information. Conversely, an objectively unjustified pattern of intervention may warrant investigation where evidence suggests retaliation, discriminatory treatment or the pursuit of purposes unrelated to food safety.

Spanish administrative law provides several relevant mechanisms: the constitutional prohibition of arbitrariness, the principles of objectivity and impartiality, the prohibition of *desviación de poder*, the rules governing abstention and recusal, judicial review of administrative decisions, public liability and disciplinary accountability.

Nevertheless, the legal categories must remain distinct. Administrative irregularity is not necessarily harassment. Unequal inspection frequency does not automatically establish discrimination. Annulment does not prove criminal misconduct. And a hostile relationship between an operator and an inspector does not, without more, establish misuse of public powers.

This instalment examines those distinctions and develops an evidentiary methodology for assessing potentially abusive enforcement patterns. It proposes

an original **Regulatory Enforcement Integrity and Retaliation Assessment Framework (REIRAF)**, integrating inspection chronology, risk justification, comparative treatment, documentary evidence, institutional safeguards and available remedies.

The central thesis is that **the lawful exercise of official inspection powers requires not merely formal competence but a demonstrable connection between regulatory intervention and the public purposes for which those powers were conferred**.

Keywords: Regulatory harassment; repeated inspections; administrative retaliation; *desviación de poder*; arbitrariness; selective enforcement; food safety; inspection planning; judicial review; institutional accountability; circumstantial evidence.

241.1. The problem of enforcement legitimacy

Food safety authorities possess extensive powers to inspect establishments, examine documentation, collect samples, verify traceability and investigate suspected non-compliance. These powers necessarily involve discretion. Authorities must decide which establishments to inspect, how frequently to inspect them, what evidence to examine and whether identified deficiencies justify further action. Discretion is unavoidable because regulatory resources are finite and food safety risks differ among operators.

However, discretion must not be confused with unrestricted personal choice. An inspection power is conferred for a legally defined public purpose. It cannot legitimately be used as an instrument of personal retaliation, commercial favouritism or institutional pressure unrelated to that purpose. The central difficulty is evidentiary. An operator may experience repeated inspections as hostile or disproportionate. Yet repeated inspection is not, by itself, proof of improper conduct.

The authority may possess legitimate reasons for intensified supervision. The legal analysis must therefore distinguish subjective perceptions from objectively demonstrable irregularities. The relevant question is not simply whether an operator feels targeted. It is whether the available evidence supports a legally significant departure from the purposes, criteria and procedural requirements governing official controls.

242. Constitutional foundations: Arbitrariness, objectivity and equality

242.1. Article 9.3: The prohibition of arbitrariness

Article 9.3 of the Spanish Constitution guarantees, among other principles, the prohibition of arbitrariness by public authorities. This principle does not eliminate administrative discretion. Rather, it requires the exercise of public powers to remain within legally permissible bounds. A discretionary decision may be unlawful where it lacks an adequate factual foundation, disregards legally relevant criteria or pursues an improper purpose.

However, an operator's disagreement with an inspection decision does not automatically establish arbitrariness.

242.2. Article 103.1: Objective service of the general interest

Article 103.1 provides that public administration serves the general interest objectively and acts in accordance with principles including effectiveness, hierarchy, decentralisation, coordination and full submission to law. Objectivity is particularly important in inspection activity. Inspectors must apply the relevant legal requirements independently of personal relationships, commercial pressures or hostility towards regulated operators.

The constitutional requirement concerns the institutional exercise of public authority, not merely the subjective attitude of individual officials.

242.3. Article 14: Equality before the law

Article 14 establishes equality before the law and prohibits discrimination on constitutionally relevant grounds. Claims of unequal regulatory treatment require careful analysis. Different inspection frequencies may be justified by differences in risk, activity, compliance history or other legally relevant factors. The principle of equality does not require identical treatment of operators whose circumstances materially differ.

Conversely, materially comparable operators should not be subjected to unjustified differences in treatment where the applicable constitutional requirements are satisfied.

242.4. Article 24: Effective judicial protection

Article 24 guarantees effective judicial protection. Its relevance arises when an operator challenges inspection-related decisions or alleges that the Administration has acted unlawfully. However, Article 24 does not convert every disagreement with an inspector into a constitutional violation. The precise procedural guarantees depend upon the nature of the administrative action and subsequent proceedings.

242.5. Article 106.1: Judicial control of administrative action

Article 106.1 provides that courts control regulatory power, the legality of administrative action and its submission to the purposes justifying it. The final element is particularly important. Judicial review concerns not only whether the Administration possessed a formal power, but also whether it exercised that power consistently with its legally assigned purpose.

243. The European Union framework: Risk-based inspection as a legal constraint

243.1. Article 9 of Regulation (EU) 2017/625

Article 9 requires competent authorities to conduct official controls regularly, on a risk basis and at appropriate frequencies.

The Regulation identifies factors relevant to inspection planning, including:

- Risks associated with products, processes and activities.
- Information suggesting potential consumer deception.
- Previous official control results and the operator's compliance history.
- The reliability and results of the operator's own controls, including relevant third-party assurance systems.
- Other information indicating possible non-compliance.

These factors provide a structured legal basis for differentiating inspection frequency. They do not establish a universal numerical limit on how often a particular establishment may be inspected.

243.2. Increased inspection frequency may be legitimate

A manufacturer with repeated serious non-compliances may require intensified supervision. An establishment handling high-risk ready-to-eat products may be inspected more frequently than a facility producing lower-risk shelf-stable ingredients. A credible complaint, emerging hazard or suspected fraudulent practice may justify additional controls. The mere existence of repeated inspections therefore does not establish harassment.

243.3. Risk-based supervision is not an exemption from inspection

A company with a strong compliance record may reasonably expect that record to be considered under Article 9. However, favourable previous inspections do not confer immunity from future controls. Likewise, ISO 9001 or private food safety certification may be relevant to the assessment but does not prevent the competent authority from conducting independent official controls.

243.4. Article 5: Impartiality and conflicts of interest

Article 5 requires competent authorities to maintain arrangements ensuring the impartiality, quality and consistency of official controls. It also requires procedures ensuring that staff conducting controls are free from conflicts of interest. These obligations are institutionally significant. They provide a legal foundation for questioning whether a control system adequately addresses potential conflicts, although a breach must be established through relevant facts.

243.5. Article 13: Documentary accountability

Article 13 requires written records of official controls, including their purpose, methods, outcomes and, where appropriate, required actions. The Regulation also provides operators with access to copies under specified conditions. These records can be particularly important when assessing a sequence of inspections. They may establish whether the scope of repeated controls was consistent, whether earlier deficiencies were resolved and whether later interventions relied upon new information.

243.6. The limits of statistical comparison

An operator cannot establish retaliation simply by demonstrating that it received more inspections than the regional average. A meaningful comparison must account for differences in risk classification, production activity, compliance

history and other legally relevant factors. An apparently exceptional inspection frequency may be justified. Conversely, a frequency that appears statistically ordinary may still conceal improper conduct if particular decisions were influenced by unlawful considerations.

The correct assessment therefore combines quantitative evidence with the legal and factual circumstances.

244. *Desviación de poder*: Misuse of powers under Spanish administrative law

244.1. Article 70.2 of Law 29/1998

Article 70.2 expressly recognises *desviación de poder* as a ground for upholding a contentious-administrative challenge. It defines the concept as the exercise of administrative powers for purposes other than those established by the legal system. The provision is especially relevant to allegations that inspection powers have been used to pursue personal or institutional objectives unrelated to food safety.

244.2. The importance of administrative purpose

The concept concerns the purpose for which a power is exercised. An authority may possess formal competence. It may follow certain procedural requirements. Yet its action may still be unlawful if the power is exercised for an improper purpose. This distinguishes *desviación de poder* from defects concerning competence or procedure.

244.3. Improper purpose does not necessarily require personal enrichment

A misuse of powers may arise from objectives unrelated to those legally assigned to the authority. The concept is not confined to corruption or financial gain. Nevertheless, allegations of improper purpose require an adequate evidentiary foundation. A court should not infer misuse merely because an administrative decision was adverse to the operator.

244.4. Mixed motives

A difficult question arises where legitimate regulatory concerns coexist with evidence of personal hostility. The presence of a legitimate food safety issue does not necessarily eliminate the relevance of improper considerations. However, the

claimant must establish the legal significance of the alleged improper purpose in the particular decision. It would be excessive to conclude that every decision made by an official who dislikes an operator is automatically invalid.

The assessment concerns the exercise of public power, not the mere existence of interpersonal disagreement.

244.5. The distinction between error and misuse

An inspector may misunderstand a technical requirement. The resulting decision may be legally defective. That does not automatically demonstrate *desviación de poder*. Misuse of powers concerns improper purpose. An error of law may occur without any such purpose. The distinction is important because different allegations require different evidence.

245. The evidentiary problem: How can improper purpose be established?

245.1. Direct evidence

Direct evidence may include communications or instructions demonstrating that inspection powers were used for an improper objective. Such evidence may be decisive where authentic, legally obtained and relevant. However, direct evidence of administrative motive is often unavailable.

245.2. Circumstantial evidence

Improper purpose may need to be examined through a combination of circumstances. Potentially relevant evidence includes the timing of inspections, changes in enforcement intensity, departures from ordinary planning criteria, contradictory explanations and documented communications. Nevertheless, temporal proximity or unusual frequency does not automatically establish retaliation. The evidence must support a rational inference.

245.3. The chronology of enforcement

Suppose an operator challenges an administrative decision. Shortly afterwards, the establishment receives several additional inspections. The chronology may justify closer examination. However, the inspections may also have been triggered by newly identified risks or previously scheduled controls. The claimant must examine the available explanations.

245.4. Comparative evidence

Comparison with similarly situated operators may help identify unusual treatment. But comparators must be selected carefully. A manufacturer producing microbiologically sensitive ready-to-eat products cannot automatically be compared with a low-risk dry-ingredient warehouse. Relevant differences may justify different inspection frequencies.

245.5. Documentary inconsistencies

An inspection record may identify one reason for intervention while subsequent administrative communications offer a different explanation. Such inconsistencies may be relevant. However, they must be assessed in context. The emergence of new information may legitimately alter an authority's reasoning. The evidentiary question is whether the explanation is credible and legally relevant.

245.6. The standard of proof

A challenge based upon *desviación de poder* must satisfy the applicable rules governing evidence and judicial assessment. There is no justification for treating the claimant's suspicion as proof. Equally, the absence of a written admission of improper motive does not necessarily render the allegation incapable of proof. The judicial assessment must consider the totality of legally admissible evidence.

246. Abstention and recusal: Institutional safeguards against conflicts of interest

246.1. Article 23 of Law 40/2015

Article 23 establishes circumstances in which authorities and public employees must abstain from participating in administrative proceedings. These include legally specified situations involving personal interests, relationships, prior involvement and other circumstances capable of compromising impartiality. The provision is relevant where an inspector or decision-maker possesses a legally significant personal connection to the operator or dispute.

246.2. Article 24: Recusal

Article 24 permits interested parties to seek recusal where an applicable ground exists. The request must identify the circumstances supporting the allegation.

Recusal is not a general mechanism allowing an operator to select the inspector it prefers. Nor is disagreement with an inspector's technical conclusions, by itself, a statutory ground for recusal.

246.3. The consequences of failure to abstain

Article 23.4 establishes that participation by a person who should have abstained does not necessarily imply invalidity of the acts in which that person intervened.

This qualification is important.

A conflict of interest may require institutional correction or accountability without automatically invalidating every resulting administrative decision. The effect upon validity requires separate examination.

246.4. An industrial example

Suppose an inspector possesses a direct financial interest in a competing business. That circumstance may raise a legally significant conflict-of-interest question. The operator should document the factual basis and invoke the appropriate procedure. However, an allegation based solely upon speculation about personal relationships would be insufficient.

246.5. Institutional independence versus personal neutrality

The legal system requires impartial performance of official duties. It does not require inspectors to be indifferent to non-compliance. An inspector may firmly enforce food safety requirements without thereby demonstrating hostility or bias. The decisive question is whether the official acts within the legally assigned functions and free from disqualifying interests.

247. Administrative motivation and the evidentiary trace of enforcement decisions

247.1. Article 35 of Law 39/2015

Article 35 requires specified administrative acts to be reasoned, including acts limiting rights or legitimate interests, provisional measures and decisions departing from previously followed criteria. The obligation to give reasons is particularly important where an authority adopts a burdensome intervention. It permits the operator to understand the legal and factual basis of the decision and facilitates judicial review.

247.2. Inspection planning and individual decisions

Not every internal inspection-planning decision necessarily requires the same form of motivation as a formal immobilisation order. The applicable requirements depend upon the nature of the act. However, inspection records and relevant administrative documentation may provide evidence concerning the reasons for intervention.

247.3. Departures from previous treatment

Suppose an authority has repeatedly accepted a particular compliance arrangement. It subsequently adopts a different interpretation. The authority may be entitled—or required—to change its position where the law or evidence warrants it. However, Article 35.1(c) makes departures from previously followed criteria relevant to the duty to give reasons. The operator's legitimate expectations may also require consideration under the applicable legal principles.

247.4. Inconsistent technical criteria

Different inspectors may express different views concerning the same process. This does not automatically establish arbitrariness. Technical disagreement may be genuine. However, persistent inconsistency may justify examining whether the authority has adequate procedures for ensuring the quality and consistency required by Regulation (EU) 2017/625.

247.5. A distinction between consistency and immutability

Regulatory consistency does not mean that an authority must preserve an erroneous interpretation indefinitely. The Administration may correct previous mistakes. The requirement is that changes comply with the law and are adequately justified where the applicable rules require.

248. Repeated inspections and cumulative regulatory burden

248.1. The economic significance of inspection frequency

Repeated inspections may consume managerial time, disrupt production and require extensive documentation. These burdens may be substantial, especially for smaller food manufacturers. However, the existence of cost does not automatically establish unlawfulness. Official controls necessarily impose compliance burdens.

248.2. Recital 34 of Regulation (EU) 2017/625

The Regulation recognises that official controls may burden operators and calls for their organisation in a manner that limits that burden to what is necessary for effective controls. This provides an important interpretative principle. It does not establish a general right to refuse inspections because they are inconvenient.

248.3. Duplicative controls

A manufacturer may be inspected by different authorities exercising overlapping but legally distinct competences. The duplication may appear inefficient. However, the legal assessment must identify the powers and purposes of each authority. Multiple inspections are not automatically unlawful simply because they concern the same establishment.

248.4. The cumulative-effects problem

A series of individually lawful inspections may nevertheless create questions concerning institutional planning and proportionality. For example, repeated demands for identical documents without a relevant change in circumstances may warrant examination. Yet cumulative burden alone does not establish improper motive. The legal inquiry must connect the burden to the applicable statutory requirements and evidence.

248.5. The need for longitudinal analysis

A single inspection report may not reveal an unusual enforcement pattern. A longitudinal record may be more informative. The relevant data include dates, reasons for inspection, identified deficiencies, corrective actions and subsequent outcomes. Such records permit a more disciplined assessment of whether intensified supervision was risk-based or otherwise justified.

249. The relationship between administrative misuse and disciplinary accountability

249.1. Separate legal regimes

An administrative act may be unlawful without the official responsible necessarily committing a disciplinary infringement. Disciplinary responsibility requires satisfaction of the applicable statutory conditions. Similarly, an official may

breach professional duties even where the resulting administrative act is not annulled. The questions must be examined separately.

249.2. The public employee's duties

The consolidated Basic Statute of Public Employees, approved by Royal Legislative Decree 5/2015, establishes principles and duties concerning professional conduct. These include objectivity, integrity, neutrality, responsibility and impartiality. The applicable disciplinary regime must be identified according to the official's employment status and the competent administration.

249.3. Institutional supervision

A complaint alleging improper inspection conduct may justify internal review. However, the submission of a complaint does not establish that misconduct occurred. The competent authority must examine the facts and apply the relevant procedural guarantees.

249.4. The distinction between administrative correction and punishment

An institution may improve inspection procedures, reassign responsibilities or clarify technical criteria without necessarily imposing disciplinary sanctions. Such corrective measures may be appropriate even where the evidence does not establish culpable misconduct. The legal system should distinguish organisational improvement from individual punishment.

250. Criminal responsibility: Why regulatory harassment is not automatically a criminal offence

250.1. The principle of criminal legality

Criminal responsibility requires conduct satisfying the elements of a legally defined offence. The fact that administrative conduct appears abusive does not automatically establish criminal liability.

250.2. Administrative prevarication

Article 404 of the Spanish Criminal Code addresses specified arbitrary resolutions issued by authorities or public officials with knowledge of their injustice. The offence requires more than an incorrect legal interpretation. Its statutory and

jurisprudential elements must be established. An inspector's technical mistake does not automatically constitute criminal prevarication.

250.3. Documentary falsification

Article 390 concerns specified forms of falsification of official documents. A factual disagreement concerning an inspection report is not necessarily documentary falsification. The legal analysis must distinguish error, inaccurate assessment and deliberate falsification satisfying the statutory elements.

250.4. Coercion and other offences

Certain conduct may raise questions under other criminal provisions. However, lawful exercise of regulatory powers must not be confused with criminal coercion. The relevant offence requires its own elements and proof.

250.5. The evidentiary threshold

Criminal allegations require particular care. A pattern of inspections may justify administrative scrutiny without providing sufficient grounds to assert that an official committed a crime. The legal analysis should avoid converting suspicion into a definitive accusation.

250.6. The appropriate sequence

Where an operator alleges improper enforcement, the initial analytical task is to establish what occurred. The second is to determine which administrative duties or powers were engaged. Only then should the evidence be assessed against the elements of any potentially relevant disciplinary or criminal provision. This sequence helps prevent overclassification.

251. Original doctrinal contribution: The Regulatory Enforcement Integrity and Retaliation Assessment Framework

The present research proposes the **Regulatory Enforcement Integrity and Retaliation Assessment Framework (REIRAF)**. Its purpose is to provide a structured method for evaluating potentially abusive patterns of official food control activity. REIRAF is an original academic proposal. It is not an established judicial test.

251.1. Nine dimensions of assessment

Dimension	Principal question
1. Legal competence	Did the authority possess the relevant inspection powers?
2. Regulatory purpose	Was the intervention connected to the purposes assigned by law?
3. Risk justification	Was the frequency and scope of controls supported by relevant risk factors?
4. Procedural regularity	Were applicable documentation and procedural requirements respected?
5. Impartiality	Were legally significant conflicts of interest present?
6. Comparative treatment	Were materially comparable operators treated differently without adequate justification?
7. Temporal pattern	Does the chronology reveal relevant changes following disputes or complaints?
8. Evidentiary coherence	Are the authority's explanations consistent with the documentary record?
9. Remedies and accountability	Which administrative, judicial or institutional responses are legally available?

251.2. The distinction between anomalies and proof

REIRAF distinguishes indicators requiring examination from evidence sufficient to establish a legal conclusion. An unusual inspection frequency is an indicator. A documented conflict of interest may be evidence of a particular legal defect. An express instruction to use inspection powers for retaliation may provide evidence of improper purpose. These circumstances possess different evidentiary significance.

251.3. A proposed three-stage assessment

Stage I — Screening

Identify objective anomalies in inspection frequency, scope, timing, documentation or treatment.

Stage II — Verification

Examine risk classifications, inspection records, administrative explanations, comparator data and relevant communications.

Stage III — Legal qualification

Determine whether the established facts support a particular legal defect, including procedural invalidity, misuse of powers, conflict of interest or another legally defined consequence.

251.4. The model's principal contribution

The framework prevents the analytical collapse of three different propositions:

An operator has been inspected frequently. The inspection pattern is objectively unusual. The pattern establishes unlawful retaliation. The first proposition may be readily documented. The second requires contextual comparison. The third requires legally sufficient evidence of improper conduct or purpose.

251.5. The importance of alternative explanations

REIRAF requires examination of legitimate regulatory explanations. These may include new risk information, changes in production, previous deficiencies or coordinated inspection programmes. An assessment that ignores plausible alternative explanations is methodologically weak.

251.6. The limits of the framework

REIRAF cannot determine guilt or administrative invalidity automatically. Its purpose is to improve the organisation and evaluation of evidence. Judicial conclusions remain dependent upon the applicable legal rules and facts.

252. Applied industrial scenarios

Scenario A. Repeated inspections following an administrative appeal

A manufacturer challenges a previous inspection decision. Over the following months, the establishment receives several additional inspections.

The operator alleges retaliation.

The relevant evidence includes the inspection chronology, reasons recorded for each visit, changes in risk classification, previous non-compliances and any communications concerning the appeal. Temporal proximity may justify investigation. It does not, by itself, prove retaliatory purpose.

Scenario B. Selective enforcement of a technical requirement

An authority requires one manufacturer to adopt a specific hygiene method while accepting different methods at comparable establishments. The manufacturer alleges unequal treatment. The assessment must determine whether the establishments are materially comparable and whether the applicable legislation permits alternative methods. Differences in risk or process validation may justify different requirements. An unexplained departure from relevant criteria may warrant closer judicial examination.

Scenario C. An inspector with a potential conflict of interest

An inspector has a documented personal or financial connection to a competitor. The operator questions impartiality. The relevant statutory grounds for abstention or recusal must be examined. The existence of a conflict may justify institutional action. However, the validity of the resulting administrative acts requires separate legal analysis.

Scenario D. Repeated requests for identical documentation

A food manufacturer provides requested traceability records. Different inspection teams repeatedly demand the same material without identifying new concerns. The operator experiences substantial administrative burden. The analysis should examine whether the requests are justified by distinct statutory functions, new information or legitimate verification needs. Unnecessary duplication may raise questions concerning administrative efficiency and proportionality. However, duplication alone does not establish harassment.

Scenario E. Alleged retaliation through public communication

Following a dispute with an operator, an official communicates adverse information about the company to third parties. The operator alleges that the communication was intended to damage its reputation. The assessment must identify the information disclosed, its accuracy, the legal basis for disclosure and the applicable confidentiality obligations. Improper motive cannot be inferred solely from the fact that the information was commercially damaging.

253. Conclusions of the sixth instalment of Part II

The constitutional and statutory legitimacy of official food controls depends upon more than the formal existence of inspection powers. Those powers must

be exercised for their legally assigned purposes. Regulation (EU) 2017/625 requires risk-based official controls and institutional arrangements safeguarding impartiality and consistency. Spanish constitutional law prohibits arbitrariness and requires objective service of the general interest.

Article 70.2 of Law 29/1998 expressly recognises misuse of administrative powers as a ground of judicial challenge. Nevertheless, allegations of regulatory harassment require disciplined evidentiary analysis. Repeated inspections may be justified. Unequal treatment may reflect relevant differences in risk. Technical disagreement does not automatically demonstrate hostility. And an unlawful administrative decision does not necessarily establish disciplinary or criminal responsibility.

The research therefore reaches a central conclusion:

The distinction between legitimate regulatory intensity and unlawful administrative retaliation cannot be established by inspection frequency alone. It requires examination of statutory purpose, risk justification, procedural regularity, comparative treatment and the totality of relevant evidence.

The proposed REIRAF framework provides a structured methodology for conducting that examination. Its contribution lies in distinguishing indicators of potential misuse from legally sufficient proof of an infringement.

Primary legal sources and research references

1. Spanish Constitution — Articles 9.3, 14, 24, 103 and 106.
2. Regulation (EU) 2017/625 — Articles 5, 9 and 13; Recitals 32–35.
3. Law 29/1998 regulating contentious-administrative jurisdiction — Articles 25, 31–32, 70–71 and 129–136.
4. Law 40/2015 — Articles 3, 23–24 and 32–36.
5. Law 39/2015 — Articles 34–35, 47–48 and applicable procedural guarantees.
6. Royal Legislative Decree 5/2015 — Basic Statute of Public Employees — Articles 52–54 and 93–98.
7. Organic Law 10/1995 — Spanish Criminal Code — Articles 404 and 390.

Jurisprudential limitation

The statutory definition of *desviación de poder* and the European requirements concerning impartiality and risk-based controls are directly established legal rules. However, this instalment does not attribute a specific factual holding concerning retaliatory food inspections to the Spanish Supreme Court without a verified judgment.

CHAPTER 21

254. Trade Secrets, Confidential Business Information and the Limits of Official Inspection Powers

Judicial protection of industrial know-how, regulatory access to proprietary documentation, professional secrecy and the constitutional boundaries of information gathering in food manufacturing.

Abstract

Official food controls depend upon access to information. Competent authorities must be able to verify product safety, manufacturing processes, traceability, hygiene systems and compliance with applicable legal requirements. These functions may require examination of documents containing commercially sensitive information.

At the same time, food manufacturers depend upon the protection of proprietary formulations, process parameters, manufacturing methods, technical data and confidential business relationships. Unauthorised disclosure may destroy the competitive value of information developed through substantial investment in research and industrial innovation.

The relationship between regulatory access and industrial confidentiality is therefore not a simple opposition between public health and private commercial interests.

European Union law recognises both the powers necessary for effective official controls and obligations protecting confidential information. Directive (EU) 2016/943 establishes a harmonised framework for the protection of trade secrets, while expressly preserving lawful acquisition and disclosure in circumstances required or permitted by law. Spanish Law 1/2019 implements that framework and establishes civil remedies against unlawful acquisition, use and disclosure.

The present instalment examines the interaction between these instruments, Regulation (EU) 2017/625, constitutional protection of corporate premises, data protection rules and administrative confidentiality obligations. Particular

attention is devoted to the distinction between lawful regulatory access, excessive information demands, unauthorised disclosure and subsequent commercial exploitation of confidential information.

The study proposes an original Regulatory Access and Trade Secret Protection Framework (RATSPF) to organise the legal assessment of information requests during official food inspections. The central thesis is that the protection of trade secrets does not create immunity from lawful food safety inspection, but lawful inspection powers do not confer unrestricted rights to disclose, disseminate or commercially exploit confidential industrial information.

Keywords: Trade secrets; food safety inspection; industrial know-how; confidential business information; Regulation (EU) 2017/625; Directive (EU) 2016/943; Spanish Law 1/2019; corporate confidentiality; professional secrecy; regulatory proportionality.

254.1. The regulatory paradox of industrial transparency

Food safety regulation requires transparency towards competent authorities. Manufacturers must be able to demonstrate compliance with legally applicable requirements. This may involve providing information concerning ingredients, manufacturing controls, hazard analysis, traceability and process validation. However, some of the same information may constitute valuable proprietary knowledge.

A manufacturer's competitive advantage may depend upon a particular combination of ingredients, a validated processing method or confidential industrial parameters. Disclosure of such information to competitors could permit imitation without the investment required to develop the technology. The legal challenge is therefore to reconcile two legitimate interests. The first is effective public supervision of food safety. The second is the protection of confidential industrial information against unlawful acquisition, use or disclosure.

Neither interest automatically eliminates the other. An operator cannot refuse every lawful inspection request by invoking commercial confidentiality. Conversely, an inspector cannot assume that obtaining information for regulatory purposes authorises its unrestricted circulation. The analysis must distinguish the legal basis for obtaining information from the legal conditions governing its subsequent handling.

255. The legal concept of a trade secret

Directive (EU) 2016/943 and Article 1 of Spanish Law 1/2019 establish three cumulative characteristics of protected trade secrets.

Information must:

1. Be secret, in the sense that it is not generally known or readily accessible to persons within the relevant circles.
2. Possess commercial value because it is secret.
3. Have been subject to reasonable steps, under the circumstances, to keep it secret.

These requirements are substantive. A document does not automatically become a legally protected trade secret merely because its owner marks it Confidential. Equally, the absence of a particular label does not necessarily exclude protection where the statutory requirements are otherwise satisfied.

255.1. Secrecy

Information may remain secret even where certain employees, contractors or regulatory authorities legitimately know it. Secrecy does not require that only one individual possess the information. The relevant question is whether it is generally known or readily accessible within the appropriate professional circles.

255.2. Commercial value

The information must possess commercial value because it is secret. This may arise from its usefulness in reducing manufacturing costs, improving performance, achieving reproducibility or enabling a competitive industrial process. The value need not necessarily be demonstrated through a separate market transaction involving the secret itself.

255.3. Reasonable protective measures

Protection also depends upon reasonable steps to preserve secrecy. Relevant measures may include access restrictions, confidentiality agreements, document controls, contractual obligations and information security arrangements. What is reasonable depends upon the circumstances. A multinational manufacturer and a small research enterprise may employ different protective systems without necessarily producing different legal conclusions.

255.4. Examples in food biotechnology

Potentially protectable information may include proprietary manufacturing methods, confidential process settings, non-public validation protocols, specialised ingredient combinations and commercially valuable industrial data. However, protection must be assessed individually. Publicly disclosed information, general scientific principles and information readily ascertainable through lawful means do not automatically qualify as trade secrets.

256. Article 15 of Regulation (EU) 2017/625: The duty to cooperate with official controls

256.1. The statutory foundation of access

Article 15 requires operators to provide competent authorities with access, to the extent necessary for official controls or other official activities, to relevant equipment, premises, information and documents. The provision is central to the relationship between inspection powers and industrial confidentiality. It establishes that commercially sensitive information is not categorically exempt from regulatory examination.

Where information is necessary to verify compliance and the request falls within the authority's lawful powers, an operator cannot simply refuse cooperation because the material contains proprietary know-how. However, Article 15 expressly connects access to the necessity of performing official control functions.

256.2. Access is not ownership

Regulatory access to a document does not transfer ownership of the underlying intellectual property. An inspector examining a proprietary manufacturing protocol does not thereby acquire the right to use the protocol commercially. Nor does the authority automatically acquire a licence to reproduce the technology for purposes unrelated to its statutory functions.

This distinction is essential.

Lawful access, lawful retention, lawful disclosure and lawful commercial use are separate legal questions.

256.3. Necessity and scope

The scope of an information request should be connected to the regulatory question being investigated. For example, an authority examining the safety of a processing step may legitimately require evidence concerning the effectiveness of the process. Depending upon the applicable requirements, that may involve examination of validation studies, critical control parameters or other confidential technical information. However, the authority should be able to identify why the requested information is relevant to the official control.

The necessity qualification does not create an automatic right for the operator to decide unilaterally what information the authority may inspect. Disputes must be resolved under the applicable administrative and judicial framework.

256.4. Technical verification without unnecessary dissemination

A manufacturer may propose controlled access arrangements, such as restricted review by authorised officials, confidential annexes or secure documentary transmission. Such arrangements can reduce unnecessary exposure. Nevertheless, they are not an unconditional substitute for the information the authority is legally entitled to obtain. A proposal to disclose only a summary may be insufficient where the full underlying information is necessary to verify compliance.

The appropriate solution must reconcile the legal duty to cooperate with the authority's confidentiality obligations.

257. Article 8 of Regulation (EU) 2017/625: Professional secrecy as a regulatory obligation

Article 8 establishes specific confidentiality obligations governing information acquired during official controls. The provision is particularly important because it does not treat confidentiality as a matter of administrative courtesy. It creates binding obligations within the Union's official control framework.

257.1. Information covered by professional secrecy

Article 8 requires competent authorities to prevent disclosure to third parties of information that is protected by professional secrecy under applicable Union or national law, subject to the Regulation's exceptions. The provision expressly

recognises protection of operators' commercial interests. It also addresses information whose disclosure could undermine inspections, investigations, audits, judicial proceedings or legal advice.

257.2. The obligation extends beyond individual inspectors

Article 8 applies not only to competent authorities. Its confidentiality framework also covers specified delegated bodies, individuals performing delegated control tasks and official laboratories. This is particularly significant in modern food safety enforcement. Regulatory information may circulate among public authorities, laboratories and delegated organisations. The legal duty of confidentiality must be considered throughout that institutional chain.

257.3. Public-interest disclosure

Confidentiality is not absolute.

Article 8 recognises circumstances involving overriding public interests and disclosures required by Union or national law. The authority must consider the relevant risks and the nature, severity and extent of those risks. A credible public health emergency may justify disclosure that would otherwise be restricted. However, the existence of a public health objective does not automatically justify disclosure of every technical detail contained in an inspection file.

257.4. Publication of official control outcomes

Article 8.5 permits publication of information concerning the outcomes of official controls relating to individual operators under specified conditions. Where the provision applies, the operator must ordinarily have an opportunity to comment before publication, taking account of urgency. The published information must also take account of those comments or be released together with them. This is a particularly important procedural safeguard. However, the provision must be read alongside disclosures required by other applicable legislation.

257.5. A practical distinction

An authority may be entitled to inform consumers that a particular food product presents a serious safety risk. That does not necessarily justify publishing the manufacturer's entire confidential formulation or unrelated manufacturing

protocols. The scope of lawful disclosure must correspond to the relevant statutory requirements and public interest.

258. Directive (EU) 2016/943: Trade secret protection and lawful regulatory acquisition

Directive (EU) 2016/943 establishes rules protecting undisclosed know-how and business information against unlawful acquisition, use and disclosure. However, the Directive expressly preserves legitimate regulatory functions.

258.1. Lawful acquisition

Article 3 recognises circumstances in which acquisition of trade secrets is lawful. The Directive also accommodates acquisition, use or disclosure required or permitted by Union or national law. Consequently, a regulator acting within lawful statutory powers does not automatically commit a trade secret infringement by examining confidential technical information.

258.2. Unlawful acquisition, use and disclosure

Article 4 addresses unlawful conduct concerning trade secrets. The legal analysis must identify the relevant act. Obtaining information unlawfully differs from using lawfully obtained information for an unauthorised purpose. Disclosure to an unauthorised third party may constitute a separate problem. The fact that the initial acquisition was lawful does not automatically make every subsequent use or disclosure lawful.

258.3. Article 1: Preservation of regulatory disclosure obligations

The Directive does not affect the application of Union or national rules requiring holders to disclose information to public authorities for the performance of their duties. This is central to food safety regulation. The Directive is not a general basis for withholding information that a competent authority is legally entitled to obtain.

258.4. Public interest and legally permitted disclosure

The Directive also recognises circumstances in which disclosure serves protected public interests. Article 5 addresses specified situations in which applications for measures, procedures and remedies under the Directive must be dismissed. These include legally defined circumstances involving freedom of expression, reporting

misconduct to protect the general public interest and other legitimate interests recognised by law. The exceptions should not be expanded beyond their legal conditions.

258.5. The correct relationship between the two instruments

Regulation (EU) 2017/625 establishes inspection and confidentiality obligations within official controls. Directive (EU) 2016/943 establishes a framework against unlawful trade secret acquisition, use and disclosure.

The instruments are complementary.

They do not establish a hierarchy under which trade secret protection automatically defeats inspection powers, or inspection powers automatically extinguish trade secret protection.

259. Spanish Law 1/2019: Acquisition, use and disclosure of trade secrets

Law 1/2019 of 20 February provides the principal Spanish civil-law framework for protecting trade secrets.

259.1. Article 1: Protected information

Article 1 encompasses technological, scientific, industrial, commercial, organisational and financial information satisfying the statutory requirements. This breadth is important for food biotechnology. Protection is not confined to a chemical formula. A combination of process steps, technical validation data and operational know-how may also qualify where the statutory requirements are met.

259.2. Article 2: Lawful acquisition

Article 2 identifies lawful means of obtaining trade secrets and preserves acquisition, use or disclosure required or permitted by law. Consequently, acquisition during a lawful official inspection is not automatically unlawful. The existence of a trade secret does not extinguish the Administration's statutory inspection powers.

259.3. Article 3: Infringement

Article 3 addresses unlawful acquisition, use and disclosure. A legally important distinction arises between the official who receives information for regulatory

verification and a third party who subsequently obtains or exploits that information without authorisation. The original regulatory access may be lawful while a subsequent disclosure or use is unlawful. Whether a particular act constitutes an infringement depends upon the statutory requirements and any applicable exceptions.

259.4. Articles 8-11: Civil protection

The law provides civil remedies against trade secret infringements. These include declaratory and prohibitory relief, measures addressing infringing goods and compensation under the applicable conditions. However, the identity of the defendant and the nature of the alleged conduct matter. Claims concerning unlawful administrative conduct may engage public-law rules and jurisdictional requirements distinct from an ordinary civil claim against a commercial competitor.

259.5. Article 15: Protection during litigation

Article 15 establishes safeguards concerning confidentiality of trade secrets in judicial proceedings. These provisions are particularly important because litigation may otherwise create a second opportunity for disclosure. The court may need to examine confidential information to resolve the dispute. However, access to the information by the court does not necessarily require unrestricted disclosure to every person involved in the proceedings. The applicable safeguards must be balanced against procedural fairness and the rights of defence.

260. The Court of Justice: Varec and the protection of confidential information in judicial proceedings

260.1. Case identification

Court of Justice of the European Union, Varec SA v Belgian State, Case C-450/06, judgment of 14 February 2008, ECLI:EU:C:2008:91.

The dispute concerned public procurement proceedings and the protection of confidential commercial information during judicial review. It did not concern food inspection. Nevertheless, its reasoning is relevant to the broader legal problem of reconciling confidentiality with effective judicial protection.

260.2. The central holding

The Court held that the body responsible for review proceedings must protect confidential information and business secrets while ensuring effective judicial protection and respect for the rights of defence. The reviewing body may need access to confidential information to decide the dispute. However, it must determine how confidentiality should be preserved when considering disclosure to other parties.

260.3. The distinction between judicial access and adversarial disclosure

The judgment recognises that a court may require access to confidential information without necessarily making that information freely available to a commercial competitor involved in the litigation.

This distinction is significant.

A court's ability to examine evidence should not be confused with an unrestricted entitlement of every litigant to obtain commercially sensitive material. At the same time, confidentiality must not undermine the fairness of the proceedings.

260.4. Application to food safety litigation

Suppose a manufacturer challenges an official finding concerning a proprietary preservation process. The court may need to examine technical documentation. The manufacturer may seek protection against disclosure to a competitor participating in related proceedings. The reasoning in Varec provides a useful analogy concerning the balance between confidentiality and judicial protection. However, the precise procedural safeguards must be derived from the legislation governing the actual proceedings.

Doctrinal status: Varec establishes relevant Union-law principles within public procurement review. Its application to food safety litigation is analogical, not a direct holding concerning official food controls.

261. Further CJEU developments: Klaipėdos and Antea Polska

261.1. Klaipėdos regiono atliekų tvarkymo centras, C-927/19

Judgment of 7 September 2021, ECLI:EU:C:2021:700.

The case concerned public procurement, confidentiality and the right to effective judicial protection. The Court examined the interaction between procurement

confidentiality requirements, Directive (EU) 2016/943 and judicial remedies. Its reasoning confirms that trade secret protection and procedural fairness require reconciliation rather than mechanical priority for either interest.

261.2. Antea Polska, C-54/21

Judgment of 17 November 2022, ECLI:EU:C:2022:888.

The case concerned the treatment of confidential information in public procurement. The Court addressed the limits of confidentiality claims and the need to provide access to information necessary for effective remedies, while protecting genuinely confidential material. The judgment is important because it rejects an undifferentiated approach under which all information submitted by an economic operator is automatically confidential.

261.3. The relevance of these decisions

The decisions support three general analytical propositions:

- Confidentiality claims must be assessed substantively.
- Judicial protection may require access to information that one party wishes to withhold.
- Disclosure arrangements should distinguish genuinely protected material from information that can lawfully be communicated.

These propositions are relevant by analogy to food safety disputes involving proprietary manufacturing information. However, neither judgment establishes a specific right for a food manufacturer to withhold information from a competent inspector.

262. Corporate premises, documents and constitutional protection

262.1. Article 18 of the Spanish Constitution

Article 18 protects several distinct constitutional interests. Article 18.2 concerns the inviolability of the home. Article 18.3 concerns the secrecy of communications. Article 18.4 addresses limitations on the use of information technology to protect constitutional rights. These provisions should not be treated as a single general constitutional right to corporate secrecy.

262.2. Corporate domicile protection

Spanish Constitutional Court jurisprudence recognises that legal persons may benefit from protection of their constitutionally protected premises. STC 137/1985 and STC 69/1999 are particularly relevant. However, the constitutional protection of corporate premises differs from the protection of natural persons' homes. Not every industrial production area constitutes a protected domicile.

262.3. Confidential documents

The fact that a document contains trade secrets does not automatically mean that examining it constitutes an infringement of Article 18.2. The constitutional protection of premises and the statutory protection of trade secrets concern different legal interests. They may overlap, but their requirements must be analysed separately.

262.4. Electronic information

Inspection of digital records may raise additional questions concerning statutory powers, proportionality, personal data and confidentiality. The operator may possess legitimate interests in preventing unnecessary access to unrelated material. However, the applicable legal requirements depend upon the nature of the information and the powers exercised.

262.5. The importance of differentiated protection

A manufacturing file may contain several categories of information:

- Data necessary to verify food safety compliance.
- Proprietary industrial know-how.
- Personal data concerning employees.
- Legally privileged communications.
- Commercial information concerning customers or suppliers.

Different legal rules may govern each category. The authority should not assume that all information within a single file possesses identical legal status.

263. The distinction between regulatory verification and disclosure of industrial know-how

263.1. Verification of compliance

An authority may need to determine whether a manufacturing process satisfies the applicable food safety requirements. This may involve reviewing process validation, hazard analysis, monitoring records and technical specifications. The scope of lawful access depends upon the relevant statutory powers and the necessity of the information for official controls.

263.2. Disclosure of manufacturing details

The information necessary to verify compliance may include commercially sensitive details. Where those details must lawfully be provided, the operator should seek appropriate confidentiality safeguards rather than assuming that secrecy permits refusal.

263.3. The principle of differentiated access

This research proposes distinguishing three levels of information access.

Level	Information category	Appropriate analytical approach
A	Ordinary compliance documentation	Standard regulatory access under applicable law
B	Confidential technical evidence necessary for verification	Lawful access with appropriate confidentiality controls
C	Proprietary information not shown to be necessary for the particular control	Examine legal basis, relevance and necessity before requiring disclosure

The categories are analytical rather than statutory. They do not create a legally enforceable classification system.

263.4. The risk of excessive disclosure

A manufacturer may provide more information than is necessary because it assumes that every inspection request requires unrestricted disclosure. This may increase the risk of inadvertent dissemination. A structured confidentiality procedure can help identify which documents contain protected information and which legal safeguards apply.

263.5. The risk of excessive withholding

The opposite error is equally serious. A manufacturer may refuse to provide essential information by describing it as proprietary. Such refusal may obstruct lawful official controls and create separate regulatory consequences. The correct approach is not blanket withholding. It is lawful cooperation accompanied by appropriate protection of confidential information.

264. Official laboratories and delegated control bodies

264.1. The institutional chain of information

Official food controls frequently involve external laboratories or delegated organisations. Confidential information may therefore move beyond the original inspecting authority.

This creates additional risks.

The information may be stored, analysed, transmitted or retained by several entities.

264.2. Article 8.2 of Regulation (EU) 2017/625

Article 8.2 extends the relevant confidentiality obligations to specified delegated bodies and official laboratories. This is important because the operator's legitimate confidentiality interests do not disappear merely because the authority delegates technical tasks.

264.3. Analytical reports

A laboratory report may contain information concerning product composition, manufacturing methods or other commercially sensitive details. The handling of such reports must comply with the applicable legal framework. However, the operator cannot automatically prevent the competent authority from using relevant analytical results for lawful enforcement purposes.

264.4. Data retention

Retention of confidential records may be required by applicable legislation or justified by legitimate administrative purposes. Nevertheless, retention should not be treated as unrestricted. The authority must comply with applicable information-management, confidentiality and data protection obligations.

264.5. Access controls

Appropriate safeguards may include controlled access, secure transmission, audit records and restrictions upon unnecessary duplication. These are proposed organisational measures. Their precise legal necessity depends upon the applicable rules and circumstances.

265. Unauthorised disclosure: Administrative, civil, disciplinary and criminal consequences

265.1. Administrative responsibility

An unauthorised disclosure by a public authority may constitute unlawful administrative functioning. The legal consequences depend upon the applicable confidentiality obligations, the circumstances of disclosure and the available remedies.

265.2. Public liability

Where disclosure causes legally compensable damage, the operator may examine a claim under Articles 32–34 of Law 40/2015. The claimant must establish the relevant injury, causation and statutory conditions. The mere existence of an unauthorised disclosure does not automatically determine the amount of compensation.

265.3. Civil trade secret protection

Law 1/2019 provides remedies against unlawful trade secret conduct. However, the applicable jurisdiction and procedural route must be determined according to the identity of the defendant and the nature of the alleged conduct. A civil action against a commercial competitor differs from a claim concerning damage attributable to a public authority.

265.4. Disciplinary responsibility

Public employees may be subject to duties of confidentiality and professional conduct. A breach may justify disciplinary examination under the applicable regime. However, disciplinary responsibility must be established through the legally required procedure.

265.5. Criminal responsibility

Article 417 of the Spanish Criminal Code addresses specified unlawful disclosures of secrets or information by public authorities or officials. Its application requires satisfaction of the statutory elements. Not every administrative confidentiality breach constitutes a criminal offence. The criminal classification must not be assumed from the commercial importance of the disclosed information alone.

265.6. The importance of separating legal consequences

One incident may raise several distinct questions.

Was the disclosure unlawful?

Did it constitute a trade secret infringement?

Did it cause compensable damage?

Did an official commit a disciplinary infringement? Were the elements of a criminal offence satisfied? These questions must be answered independently.

266. Original doctrinal contribution: The Regulatory Access and Trade Secret Protection Framework

The present research proposes the Regulatory Access and Trade Secret Protection Framework (RATSPF). Its purpose is to organise the legal assessment of information requests and disclosures arising during official food controls. RATSPF is an original academic proposal, not a judicially established test.

266.1. Eight dimensions

Dimension	Principal inquiry
1. Legal authority	Does the competent authority possess a lawful basis for requesting the information?
2. Regulatory necessity	Is the information relevant and necessary for the official control?
3. Information classification	Does the material qualify as a trade secret or other protected information?
4. Access arrangements	What lawful safeguards can protect the information during examination?
5. Institutional handling	Which persons or bodies may receive and retain the information?
6. Permitted disclosure	Is disclosure required or authorised by applicable law or overriding public interest?

Dimension	Principal inquiry
7. Procedural protection	What safeguards apply during administrative or judicial proceedings?
8. Remedies	What legal consequences follow from unlawful acquisition, use or disclosure?

266.2. The model's principal contribution

The framework distinguishes the legitimacy of obtaining information from the legitimacy of subsequent handling.

This prevents two opposite errors.

The first is assuming that trade secret protection creates an unconditional right to refuse inspection. The second is assuming that lawful inspection access authorises unrestricted disclosure.

266.3. A proposed operational sequence

RATSPF · Proposed information-handling sequence

1

Identify

Specify the regulatory question and the information requested.

2

Classify

Determine whether the material contains legally protected information.

3

Verify authority

Identify the statutory basis and necessity of access.

4

Protect

Apply appropriate confidentiality arrangements without obstructing lawful controls.

5

Record

Document access, transmission and relevant disclosure decisions.

6

Review

Assess the legal basis for any proposed wider dissemination.

7

Remedy

Use the appropriate administrative or judicial mechanism where unlawful conduct occurs.

266.4. Relationship with existing law

RATSPF integrates the access requirements of Regulation (EU) 2017/625, the trade secret protections of Directive (EU) 2016/943 and Law 1/2019, and the relevant administrative and judicial safeguards. It does not replace those provisions.

266.5. The need for empirical validation

The framework could be evaluated through comparative analysis of inspection procedures, confidentiality incidents and judicial disputes. Such research could identify whether structured information-handling protocols reduce unnecessary disclosure without impairing regulatory effectiveness.

267. Applied industrial scenarios

Scenario A. Inspection of a proprietary food preservation process

A manufacturer employs a proprietary preservation technology. The competent authority requests technical documentation demonstrating compliance. The manufacturer identifies certain documents as containing trade secrets. The operator must cooperate with lawful inspection requirements. However, it may seek appropriate confidentiality safeguards concerning access, retention and disclosure. The authority must distinguish the information necessary for verification from material unrelated to the regulatory question.

Scenario B. Disclosure of a confidential formulation to a third party

An inspector obtains a confidential formulation during an official control. The information is subsequently communicated to a commercial competitor without an identified lawful basis. The operator may examine the applicable

confidentiality obligations and possible remedies. The legal analysis must establish the disclosure, its circumstances, the protected character of the information and the relevant consequences.

Scenario C. Publication of inspection findings

A competent authority intends to publish information concerning an operator's non-compliance. The operator argues that publication would reveal confidential manufacturing information. The authority must examine Article 8 of Regulation (EU) 2017/625 and any other applicable disclosure obligations. Public health transparency may justify publication of relevant findings. However, the scope of publication must comply with the applicable legal requirements.

Scenario D. Judicial proceedings involving proprietary technology

A manufacturer challenges an administrative sanction based upon the alleged inadequacy of a confidential process. The court requires technical evidence. The operator seeks protection against unnecessary disclosure to third parties. The applicable procedural safeguards must reconcile effective judicial review with protection of genuinely confidential information. The reasoning of Varec, Klaipėdos and Antea Polska may be relevant by analogy, subject to the governing procedural law.

Scenario E. Confidential information held by an official laboratory

A laboratory receives a sample and supporting technical information. The documentation contains commercially valuable process data. The laboratory must comply with the confidentiality obligations applicable to its official control functions. The operator may seek clarification of the relevant handling arrangements. However, it cannot automatically prohibit lawful communication of results to the competent authority.

268. Conclusions of the seventh instalment of Part II

The protection of industrial know-how is a legitimate legal interest within food safety enforcement. European Union law recognises both the necessity of effective official controls and the importance of protecting confidential business information. Article 15 of Regulation (EU) 2017/625 establishes obligations of cooperation and access. Article 8 establishes confidentiality obligations governing information acquired through official controls.

Directive (EU) 2016/943 and Spanish Law 1/2019 protect trade secrets against unlawful acquisition, use and disclosure while preserving lawful regulatory functions. The jurisprudence of the Court of Justice demonstrates that confidentiality and effective judicial protection must be reconciled through legally appropriate safeguards. However, decisions arising from public procurement litigation should not be presented as direct judgments concerning food inspection powers.

The central conclusion is:

A food manufacturer's obligation to disclose information necessary for lawful regulatory verification does not extinguish the legal protection of that information against unauthorised use or disclosure. Regulatory access and industrial confidentiality are complementary obligations that must be administered within their respective statutory limits.

The proposed RATSPF framework provides a structured methodology for achieving that balance.

Primary legislation and verified jurisprudence

1. Regulation (EU) 2017/625 — Articles 8, 13–15 and related official control provisions.
2. Directive (EU) 2016/943 — Articles 1–5 and 9.
3. Spanish Law 1/2019 on Trade Secrets — Articles 1–3, 8–11 and 15.
4. CJEU, Varec, C-450/06, 14 February 2008 — Confidentiality and effective judicial protection.
5. CJEU, Klaipėdos, C-927/19, 7 September 2021 — Trade secrets and procedural rights.
6. CJEU, Antea Polska, C-54/21, 17 November 2022 — Confidentiality claims and effective remedies.
7. Spanish Constitution — Article 18 and relevant constitutional guarantees.
8. Law 40/2015 — Administrative responsibility and public liability.
9. Spanish Criminal Code — Article 417.

CHAPTER 22

269. Scientific Evidence, Novel Food Technologies and Judicial Review of Regulatory Expertise: The Limits of Administrative Technical Discretion

Scientific uncertainty, evidentiary sufficiency, technological neutrality, precautionary measures and the judicial control of expert assessments in the European food industry.

Abstract

Scientific expertise is indispensable to modern food regulation. Competent authorities routinely assess microbiological hazards, chemical contaminants, process validation, emerging preservation technologies, analytical uncertainty and complex questions concerning exposure and risk.

Yet the existence of technical complexity does not place administrative decisions beyond judicial review. Nor does the invocation of scientific expertise automatically establish the legality of a restrictive measure.

European Union food law requires the distinction between scientific risk assessment and regulatory risk management. It recognises the precautionary principle where scientific uncertainty persists, but does not authorise restrictions based exclusively upon hypothetical risks unsupported by an adequate scientific foundation.

At the same time, technological innovation does not confer an exemption from binding safety requirements. A novel process may require validation, regulatory approval or specific authorisation before lawful commercial deployment.

This instalment examines the interaction between scientific evidence, administrative technical judgment, precautionary intervention and judicial control. It draws upon Regulation (EC) No 178/2002, Regulation (EU) 2017/625, Regulation (EC) No 852/2004, Regulation (EU) 2015/2283 and the jurisprudence of the Court of Justice and General Court of the European Union.

It proposes an original Scientific Evidence and Regulatory Technology Assessment Framework (SERTAF) to distinguish the scientific validity of a technology from its regulatory classification, and both from the legality of administrative intervention. The central thesis is that scientific complexity justifies specialised administrative assessment, but it does not justify replacing evidence with institutional preference, nor substituting precaution for the identification and evaluation of a scientifically plausible risk.

Keywords: Scientific evidence; official food controls; novel food technologies; precautionary principle; risk assessment; technical discretion; judicial review; process validation; technological neutrality; regulatory innovation.

269.1. Introduction: The limits of regulatory expertise

The food industry is experiencing substantial technological transformation. New preservation processes, non-thermal treatments, advanced fermentation systems, enzymatic applications, alternative protein technologies and digitally controlled manufacturing systems increasingly challenge conventional inspection practices. Some innovations fit within established regulatory categories. Others require specific authorisation. Still others raise questions concerning how existing performance-based requirements should be demonstrated.

These developments create a recurring legal problem. An inspector may encounter a process that differs from familiar industrial practice. The inspector may question its safety. The manufacturer may present experimental validation or technical evidence supporting its effectiveness. The authority must then determine whether the process complies with the applicable legal framework. The disagreement may be scientific, legal or both. A scientifically effective process may nevertheless require an authorisation that has not been obtained.

A legally permitted process may still be operated under unsafe conditions. Conversely, an unfamiliar process may satisfy the applicable requirements even though it differs from conventional technology.

The legal analysis must therefore distinguish three questions:

1. Scientific validity: Does reliable evidence support the claimed technical performance?
2. Regulatory status: What legal requirements govern the technology, its products and its intended use?

3. Administrative legality: Has the authority assessed the evidence and exercised its powers in accordance with applicable law?

Confusing these questions can produce regulatory error. The central objective of this instalment is to establish a method for keeping them analytically separate.

270. The architecture of scientific decision-making under Regulation (EC) No 178/2002

270.1. Article 6: Risk analysis

Article 6 establishes the general framework for risk analysis in food law.

Risk analysis consists of three interconnected components:

- Risk assessment.
- Risk management.
- Risk communication.

The distinction is fundamental.

Risk assessment concerns the scientific evaluation of risk. Risk management involves the selection of appropriate policy and regulatory measures. Risk communication concerns the exchange of relevant information among interested parties. The three functions interact, but they should not be collapsed into one undifferentiated administrative judgment.

270.2. Scientific independence and objectivity

Article 6 requires risk assessment to be based on available scientific evidence and undertaken in an independent, objective and transparent manner. These requirements provide a normative foundation for scrutinising the scientific reasoning supporting regulatory intervention. However, the provision does not establish that every local inspection decision must be accompanied by a new independent scientific study. The evidentiary requirements depend upon the applicable legislation and circumstances.

270.3. Risk management

Risk management must take account of risk assessment results and other legitimate factors relevant to the matter under consideration. The regulatory authority is therefore not mechanically bound to select the option preferred by a

particular scientific expert. Risk management may involve public health priorities, enforceability, uncertainty and other legally relevant considerations. Nevertheless, the authority must act within the applicable legal framework.

270.4. The distinction between hazard and risk

A hazard is a biological, chemical or physical agent, or a condition of food, with the potential to cause an adverse health effect. Risk concerns the probability and severity of an adverse health effect consequent upon exposure to a hazard.

The distinction matters.

The mere identification of a hazardous substance or microorganism does not necessarily establish the level of risk under every possible exposure scenario. Conversely, the absence of demonstrated injury does not necessarily establish the absence of risk. A legally sound regulatory assessment should distinguish the nature of the hazard from the circumstances determining exposure and risk.

271. The precautionary principle: Scientific uncertainty is not an evidentiary vacuum

271.1. Article 7 of Regulation (EC) No 178/2002

Article 7 permits provisional risk-management measures where assessment of available information identifies the possibility of harmful effects on health, but scientific uncertainty remains. The provision contains several cumulative safeguards. The intervention must respond to an identified potential health risk.

It must be provisional.

It must be proportionate and no more restrictive of trade than necessary to achieve the chosen level of health protection. And it must be reviewed within a reasonable period, considering the nature of the risk and the information required for a more complete assessment.

271.2. Uncertainty does not mean absence of evidence

The precautionary principle operates where scientific information is incomplete or uncertain. It does not require the Administration to demonstrate harm conclusively before taking protective action. However, it does not authorise intervention based solely upon speculation. There must be a scientifically supportable basis for identifying a possible risk.

271.3. The difference between precaution and prevention

Prevention generally addresses risks whose relevant characteristics are sufficiently established. Precaution addresses situations where scientific uncertainty persists concerning potentially harmful effects. The distinction is analytical rather than absolute. Regulatory decisions may involve both established hazards and unresolved questions concerning their consequences.

271.4. Provisional does not mean necessarily short-lived

The provisional character of a measure does not establish a universal maximum duration. A scientifically complex investigation may require time. However, a measure must remain subject to reassessment in accordance with the Regulation. The authority cannot treat uncertainty as a permanent justification for avoiding further evaluation.

271.5. The operator's role

A manufacturer may submit additional scientific evidence addressing the authority's concerns. The Administration should examine its relevance. However, the operator's evidence does not automatically require withdrawal of the measure. The legal question is whether the evidence changes the assessment of risk and the proportionality of continued intervention.

272. Pfizer Animal Health v Council: The judicial limits of precaution

272.1. Identification

General Court, Pfizer Animal Health SA v Council, Case T-13/99, judgment of 11 September 2002, ECLI:EU:T:2002:209. The case concerned the withdrawal of authorisation for an antibiotic used as a growth promoter in animal feed. Although it did not concern an ordinary food establishment inspection, it remains an important judgment on scientific uncertainty, precaution and regulatory risk management.

272.2. The distinction between hypothetical and scientifically supported risk

The General Court rejected the proposition that precautionary action may be founded on purely hypothetical risk. The Court recognised that protective action

may be taken before the existence and seriousness of a risk have been fully demonstrated. Nevertheless, the potential risk must have an adequate foundation in the scientific information available when the measure is adopted.

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272.3. Judicial control of complex scientific assessment

The judgment recognised the broad discretion available to Union institutions when making complex scientific and policy assessments. That discretion does not eliminate judicial review. The court examines matters including procedural regularity, the adequacy of reasoning, factual accuracy and the limits governing the exercise of discretion. However, judicial review does not mean that the court substitutes its own preferred scientific assessment whenever experts disagree.

272.4. The significance of scientific disagreement

The existence of competing expert opinions does not automatically establish that a precautionary measure is unlawful. Scientific disagreement may itself be relevant to the existence of uncertainty. The critical question is whether the authority's assessment is grounded in sufficiently reliable and relevant information and complies with the applicable legal standards.

272.5. Application to innovative food processing

Suppose an authority restricts a novel preservation process because it considers that the process may leave an unidentified hazardous residue. The manufacturer presents analytical evidence concerning the composition of the treated food and the absence of the suspected residue under validated conditions. The authority may examine the quality and scope of that evidence. However, if it continues to rely exclusively upon an unsubstantiated hypothetical possibility, the reasoning in Pfizer may become relevant by analogy.

This does not establish that every novel technology must be accepted. It establishes the importance of a defensible scientific foundation for precautionary intervention.

273. Scientific uncertainty and the allocation of institutional responsibilities

273.1. Scientific assessment and regulatory choice

A scientific assessment may identify several plausible risk scenarios. The competent authority must determine the appropriate regulatory response within the applicable law. The resulting decision may involve considerations extending beyond the scientific calculation itself. These may include the severity of possible consequences, available protective alternatives and the chosen level of health protection.

273.2. The limits of the expert's function

A technical expert may provide evidence concerning microbiological effectiveness, toxicological exposure or process validation. The expert does not necessarily determine the legal classification of the technology. Nor does the expert independently possess the power to impose sanctions or authorisations. Those matters depend upon the applicable statutory allocation of competence.

273.3. The limits of the legal decision-maker

Conversely, a decision-maker cannot transform an unsupported technical assumption into scientific fact merely by including it in an administrative resolution. The authority must distinguish scientific findings from legal conclusions. Where the decision depends upon complex technical matters, the quality of the scientific foundation is central to its defensibility.

273.4. The significance of transparent reasoning

A reasoned decision should make it possible to identify the relevant scientific question, the evidence considered, the uncertainty remaining and the regulatory consequence adopted. This does not require disclosure of every confidential technical detail. It requires an explanation sufficient to permit the exercise of the applicable rights of defence and judicial review.

274. Monsanto Agricoltura Italia: Scientific evidence and national protective measures

274.1. Identification

Court of Justice, Monsanto Agricoltura Italia and Others, Case C-236/01, judgment of 9 September 2003, ECLI:EU:C:2003:431. The case concerned the application of Regulation (EC) No 258/97, the former Union regime for novel foods, and an Italian measure restricting certain foods derived from genetically modified maize. It is especially relevant because it involved food products, scientific risk assessment and national precautionary intervention.

274.2. The Court's approach

The Court explained that national protective measures under the applicable safeguard provision could not rest upon merely hypothetical risks. The scientific assessment had to provide specific evidence supporting the existence of a potential risk. Nevertheless, precautionary measures could be justified even where incomplete scientific information prevented a comprehensive assessment.

The Court therefore rejected both extremes: requiring conclusive proof of harm before intervention and permitting restrictions based solely upon unsupported conjecture.

274.3. The burden upon the Member State

The Court emphasised that the Member State invoking the safeguard clause had to substantiate the relevant potential risk. General assertions were insufficient. The authority needed evidence permitting a reasonable conclusion that the protective measure was necessary.

274.4. The significance of substantial equivalence

The judgment also examined substantial equivalence under the former novel foods framework. The Court distinguished comparison with existing foods from a full safety assessment. This distinction is scientifically important. Similarity to a conventional product may provide relevant evidence, but it does not necessarily resolve every safety question.

274.5. The limitation of the precedent

Regulation (EC) No 258/97 has been repealed and replaced by Regulation (EU) 2015/2283. Consequently, the judgment must not be cited as establishing the current authorisation procedure. Its continuing relevance concerns the judicial reasoning on scientific evidence, precaution and the justification of protective measures.

274.6. Application to official food controls

Suppose a competent authority restricts a product processed through an unfamiliar technology. The authority identifies a plausible risk but lacks conclusive evidence concerning its magnitude. The reasoning in Monsanto may support precautionary action where the available scientific evidence meets the applicable legal requirements. However, the judgment does not permit an authority to presume that every unfamiliar technology is unsafe. The existence of a scientifically supported potential risk remains central.

275. Performance-based hygiene requirements and technological alternatives

275.1. Regulation (EC) No 852/2004

Regulation (EC) No 852/2004 establishes general hygiene obligations for food business operators. It includes requirements concerning premises, equipment, cleaning, contamination prevention and procedures based upon HACCP principles. Some provisions prescribe particular requirements. Others are framed in terms of the results that must be achieved. This distinction is essential when assessing innovative technologies.

275.2. Prescriptive obligations

Where legislation expressly requires a particular procedure, condition or authorisation, the operator must comply. Evidence that an alternative approach is scientifically effective does not automatically permit departure from a binding legal requirement. A regulator cannot waive an applicable statutory obligation merely because the alternative appears technically promising.

275.3. Performance-based obligations

Other requirements may permit flexibility concerning the means used to achieve the legally required result. For example, where the law requires effective cleaning or prevention of contamination without prescribing one exclusive method, the operator may be able to demonstrate compliance through a validated alternative. The relevant question becomes whether the alternative satisfies the applicable requirement.

275.4. HACCP and process validation

Article 5 of Regulation (EC) No 852/2004 requires relevant operators to establish, implement and maintain procedures based on HACCP principles. These procedures involve identifying hazards, determining critical control points where appropriate, establishing controls and maintaining verification and documentation. An innovative process should be integrated into the operator's hazard analysis where applicable. A marketing assertion that a process is effective is not equivalent to a scientifically adequate validation.

275.5. The distinction between validation and verification

Validation asks whether a control measure is capable of achieving its intended outcome under defined conditions. Verification asks whether the implemented system is operating as intended. A manufacturer may validate a process experimentally but subsequently operate it outside the validated conditions. The existence of a validation report does not automatically establish continuing compliance.

275.6. The inspector's role

The authority may examine whether the validation is relevant, methodologically sound and applicable to the actual industrial conditions. It may question the adequacy of the evidence. However, where the legislation permits alternative means of compliance, the mere fact that a technology differs from familiar practice is not, by itself, proof of non-compliance. This proposition follows from the structure of performance-based regulation; it is not an unconditional statutory right to deploy any alternative technology.

276. Novel food authorisation: Innovation does not imply freedom from regulatory classification

276.1. Regulation (EU) 2015/2283

Regulation (EU) 2015/2283 governs novel foods within its scope. The definition includes foods not used for human consumption to a significant degree within the Union before 15 May 1997 and falling within one of the categories established by Article 3.

276.2. New production processes

Article 3.2(a)(vii) addresses food resulting from a production process not used for food production within the Union before 15 May 1997 where that process causes significant changes in the food's composition or structure affecting nutritional value, metabolism or levels of undesirable substances.

The conditions are cumulative within this category. A process is not automatically covered merely because it is technologically new. The relevant effects upon the resulting food must be assessed.

276.3. The distinction between technology and resulting food

The Regulation concerns novel foods. It does not establish that every new item of processing equipment is itself a novel food. A new treatment technology may be used to produce a food whose regulatory status must be assessed. The relevant question is whether the resulting food falls within the statutory definition.

276.4. Other regulatory regimes

A processing technology may also engage legislation concerning food additives, processing aids, food-contact materials, residues or other sector-specific matters. These regimes must be assessed separately. A conclusion that a food is not novel does not automatically establish compliance with every other applicable requirement.

276.5. Authorisation and safety evidence

Where a food requires novel food authorisation, scientific evidence supporting safety is necessary but does not itself replace the applicable authorisation procedure. The operator must satisfy the relevant statutory requirements before placing the food on the Union market.

276.6. The regulatory classification problem

The same technology may raise different legal questions depending upon how it is used. For example, a treatment applied to process water may require examination of the resulting water, any substances introduced, the intended technological function and any relevant residues. A process applied directly to a food may raise different questions. The legal classification must follow the actual application and applicable legislation rather than the manufacturer's preferred commercial description.

277. Scientific evidence: What constitutes an adequate validation dossier?

A scientific validation dossier should be designed around the claim that the operator intends to establish. A dossier demonstrating microbiological reduction does not necessarily demonstrate toxicological safety. A dossier establishing chemical composition does not necessarily demonstrate industrial reproducibility. A dossier showing effectiveness in laboratory conditions does not automatically establish performance in commercial production.

277.1. Identification of the scientific question

The first step is to define the intended outcome. Examples include microbial inactivation, prevention of contamination, reduction of an undesirable substance or preservation of a particular product characteristic. The claim must be sufficiently precise to permit testing.

277.2. Experimental design

The study should employ an appropriate design for the question under investigation. Relevant considerations may include controls, replication, sample selection, operating conditions and predefined acceptance criteria. The required methodology depends upon the technology and hazard.

277.3. Reproducibility

A result obtained under a single laboratory condition may not establish general industrial performance. Validation should examine the range of conditions relevant to the intended use.

277.4. Analytical uncertainty

Measurements possess uncertainty.

Where a regulatory conclusion depends upon a numerical result, uncertainty may affect interpretation. The applicable decision rule and legal framework must be identified. Uncertainty cannot be ignored merely because a result appears precise.

277.5. Independent corroboration

Independent studies may strengthen a scientific claim. However, independence alone does not guarantee quality. The study's design, relevance and methodological soundness remain decisive.

277.6. Mechanistic evidence

A plausible mechanism may support a scientific hypothesis. However, mechanistic plausibility is not equivalent to demonstrated industrial efficacy. Likewise, observed efficacy does not automatically establish the proposed molecular mechanism. The two forms of evidence should be distinguished.

277.7. Safety and efficacy as separate endpoints

A technology may be effective for its intended purpose while creating unacceptable secondary effects. Conversely, it may be safe but insufficiently effective. A complete dossier should address the endpoints required by the applicable legal and technical context.

278. The judicial assessment of conflicting expert opinions

278.1. Expert disagreement is not administrative illegality

An operator may submit a technical report contradicting the authority's assessment. The existence of disagreement does not automatically invalidate the administrative decision. The authority may have legitimate grounds for preferring one interpretation. However, the decision must comply with applicable procedural and substantive requirements.

278.2. The importance of methodological comparison

A court examining conflicting expert evidence may need to consider the relevance and reliability of the underlying methods. Two reports may reach different conclusions because they address different endpoints. For example, one study may

evaluate microbial reduction immediately after treatment. Another may examine microbial recovery during storage. The findings may not be genuinely contradictory.

278.3. The evidentiary value of official reports

Article 77.5 of Law 39/2015 establishes evidentiary value for properly formalised records of facts verified by authorised officials, subject to contrary evidence. It does not automatically transform every technical interpretation into an irrebuttable fact. The distinction between observation, expert inference and legal classification remains important.

278.4. The role of judicial expertise

A court may require expert assistance to evaluate complex scientific questions. However, the judicial function remains legal. The court must determine whether the administrative decision satisfies the applicable legal standards. It is not required to become the primary scientific regulator.

278.5. The importance of the administrative record

The authority's reasoning should be traceable through the administrative file. Relevant documents may include inspection reports, analytical findings, expert assessments, correspondence and the operator's submissions. A complete record allows the court to examine whether the authority considered the relevant evidence and remained within the limits of its powers.

279. Technological neutrality: A conditional principle, not a universal exemption

279.1. The conceptual meaning

Technological neutrality, in the present context, means that regulatory assessment should not reject a method solely because it differs from conventional practice where the law permits alternative means of compliance. This is an analytical principle derived from performance-based regulation and general administrative-law requirements. It is not an independent universal exemption from food safety legislation.

279.2. When neutrality is relevant

The principle is particularly relevant where the applicable legal obligation concerns an outcome rather than an exclusive method. For example, where effective cleaning is required, the authority should examine whether the proposed method achieves the legally required result.

279.3. When neutrality is insufficient

Technological neutrality does not override:

- Express statutory prohibitions.
- Mandatory authorisation requirements.
- Binding compositional or residue limits.
- Specific processing requirements.
- Applicable conditions governing regulated substances.

An operator cannot rely upon innovation to avoid these obligations.

279.4. The risk of regulatory conservatism

An authority may be institutionally more familiar with established technologies. This familiarity can influence technical judgment. However, preference for familiar methods is not automatically a legally sufficient basis for rejecting an alternative where the law permits alternatives. The authority should identify the relevant deficiency in compliance or evidence.

279.5. The risk of technological exceptionalism

The opposite problem occurs where an innovator assumes that novelty itself demonstrates superiority.

A new technology may be promising.

However, scientific validation and legal classification remain necessary.

Innovation is not proof of safety.

280. Original doctrinal contribution: The Scientific Evidence and Regulatory Technology Assessment Framework

The research proposes the Scientific Evidence and Regulatory Technology Assessment Framework (SERTAF). SERTAF is an original academic model, not

an established judicial test. Its purpose is to organise the scientific, regulatory and administrative assessment of innovative food technologies.

280.1. Nine-stage assessment

Stage	Principal question
1. Technology definition	What is the technology, its intended function and its actual industrial application?
2. Regulatory classification	Which legal regimes govern the technology and resulting products?
3. Statutory obligations	Are the applicable requirements prescriptive, performance-based or authorisation-dependent?
4. Scientific claims	What technical outcomes are claimed?
5. Validation quality	Does the evidence adequately support those claims?
6. Safety assessment	What hazards, exposure scenarios and uncertainties are relevant?
7. Regulatory reasoning	Has the authority identified the evidence and legal basis for its assessment?
8. Proportionality	Are any restrictions appropriate and no more burdensome than legally justified?
9. Review and adaptation	Is there a mechanism for reassessing the decision when new evidence becomes available?

280.2. The model's central contribution

SERTAF prevents three distinct issues from being treated as one. A technology may be scientifically effective. It may nevertheless require authorisation. And the authority's decision concerning that technology may still be legally defective.

These conclusions can coexist.

280.3. A proposed decision architecture

SERTAF · Scientific and regulatory decision sequence

1

Define the application

Identify the process, food matrix and intended function.

2

Classify the law

Determine applicable authorisations, restrictions and performance obligations.

3

Assess the evidence

Examine efficacy, safety, uncertainty and industrial reproducibility.

4

Identify the regulatory issue

Separate demonstrated non-compliance from unresolved scientific questions.

5

Select the lawful response

Determine whether approval, further evidence, monitoring or restriction is justified.

6

Provide reasons

Explain the factual, scientific and legal foundation.

7

Reassess

Review the decision when new evidence materially changes the assessment.

280.4. The relationship with judicial review

The model does not require courts to substitute their own scientific preferences for those of competent authorities. It requires identification of the scientific and legal reasoning supporting the administrative decision. A reviewing court may then assess whether the authority acted within the limits of its statutory powers.

280.5. Research potential

SERTAF could be tested through comparative examination of administrative decisions concerning novel processing technologies. Relevant variables might include the type of technology, regulatory classification, evidence submitted, reasons for rejection and subsequent judicial outcomes. The framework's usefulness would depend upon empirical validation.

281. Applied industrial scenarios

Scenario A. A non-thermal preservation process

A manufacturer develops a non-thermal treatment intended to reduce microbial contamination. The authority questions its effectiveness. The operator provides validation studies. The legal assessment must identify the applicable hygiene requirements and determine whether the method is permitted. Where alternative methods are legally permissible, the authority should assess the evidence rather than reject the process solely because it differs from thermal treatment. However, the manufacturer remains responsible for demonstrating compliance.

Scenario B. An innovative processing-water treatment

A manufacturer uses a proprietary technology to condition water before application in a food manufacturing process. The authority questions the legal classification and possible presence of residues. The assessment must distinguish the treatment technology, the composition of the resulting water, the intended technological function and the applicable statutory requirements. A claim that the treated medium is predominantly water does not, by itself, determine its regulatory status.

Scientific evidence concerning safety and function may be necessary.

Scenario C. A new ingredient produced through fermentation

A company develops an ingredient using a novel fermentation process. The manufacturer argues that the ingredient is safe because the microorganism has a history of use. The authority examines whether the resulting ingredient falls within Regulation (EU) 2015/2283. The safety history of the microorganism may be relevant. However, it does not automatically establish the regulatory status of the resulting ingredient. The applicable definition and authorisation requirements must be assessed.

Scenario D. A precautionary restriction based upon scientific uncertainty

An authority identifies a potential hazard associated with a new processing method.

The evidence is incomplete.

The authority adopts a temporary restriction. The legal assessment must examine whether the available scientific information supports a plausible risk, whether the

restriction is proportionate and whether reassessment occurs within the applicable framework. Scientific uncertainty may justify precaution. It does not justify indefinite restriction without appropriate review.

Scenario E. Conflicting laboratory findings

An official laboratory identifies non-compliance. An independent laboratory produces a different result. The authority maintains the restriction. The operator challenges the decision. The analysis must examine sampling, methods, uncertainty, representativeness and the applicable procedural safeguards. The existence of conflicting results does not automatically determine which conclusion is legally correct.

282. Conclusions of the eighth instalment of Part II

Scientific expertise is indispensable to food safety regulation. However, scientific complexity does not eliminate the legal limits governing administrative intervention. Regulation (EC) No 178/2002 distinguishes risk assessment from risk management and establishes the conditions for precautionary measures. The judgments in Pfizer Animal Health and Monsanto Agricoltura Italia demonstrate that precautionary action may be justified before risks are conclusively established, but must possess an adequate scientific foundation.

Regulation (EC) No 852/2004 establishes hygiene obligations that may, depending upon their wording, permit alternative technical methods. Regulation (EU) 2015/2283 separately establishes authorisation requirements for foods falling within its definition of novel foods. These regimes must not be confused. A technology may be scientifically effective without being legally authorised. It may be legally permissible but inadequately validated.

And an administrative restriction may be unlawful even where the underlying scientific issue is genuinely complex.

The central conclusion is:

The legality of regulatory intervention concerning innovative food technologies depends upon the interaction of scientific evidence, correct regulatory classification, statutory competence and proportionate administrative reasoning. Neither technological novelty nor administrative familiarity is a substitute for that analysis.

The proposed SERTAF framework provides a structured methodology for integrating those elements.

Primary legislation and verified judicial authorities

1. Regulation (EC) No 178/2002 — Articles 6–7, risk analysis and precautionary principle.
2. Regulation (EC) No 852/2004 — Article 5 and Annex II, hygiene and HACCP-based procedures.
3. Regulation (EU) 2015/2283 — Articles 3 and 6–12, novel food classification and authorisation.
4. Regulation (EU) 2017/625 — Official controls, scientific and technical verification and enforcement.
5. General Court, Pfizer Animal Health v Council, T-13/99, 11 September 2002 — Scientific uncertainty, precaution and judicial review.
6. Court of Justice, Monsanto Agricoltura Italia, C-236/01, 9 September 2003 — Scientific foundation of protective measures concerning novel foods under the former Regulation 258/97.
7. Spanish Law 39/2015 — Articles 35, 77 and applicable procedural guarantees.
8. Spanish Law 40/2015 — General principles of administrative intervention.

CHAPTER 23

283. Judicial Review of Food Safety Risk Assessment: Expert Evidence, Measurement Uncertainty, Burden of Proof and the Legal Treatment of Scientific Error

From the collection of an official sample to the judicial evaluation of analytical findings: scientific reliability, procedural contradiction and the different evidentiary thresholds governing preventive and punitive intervention.

Abstract

Laboratory evidence plays a decisive role in official food controls. Analytical findings may lead to product immobilisation, withdrawal, recall, destruction, suspension of manufacturing operations or administrative sanctions. Their legal significance, however, depends upon more than the numerical result reported by an official laboratory.

An analytical result is the final output of a sequence involving sample selection, collection, identification, preservation, transportation, preparation, measurement, interpretation and application of a legal decision rule. Defects at any stage may affect the scientific reliability or legal significance of the conclusion.

European Union law addresses these questions through Articles 34 and 35 of Regulation (EU) 2017/625. Spain has developed the corresponding procedural framework through Royal Decree 562/2025, which establishes detailed rules governing official sampling, second expert opinions, documentary review and second analyses.

This instalment examines those provisions alongside the right to effective judicial protection, the presumption of innocence, the evidentiary status of official records and the jurisprudence of the Court of Justice in Steffensen. Particular attention is devoted to measurement uncertainty, heterogeneous contamination, microbiological sampling, laboratory accreditation, chain of custody and the legal significance of contradictory results.

The article distinguishes the scientific validity of an analytical result from the legal classification of non-compliance and the evidentiary requirements applicable to different administrative consequences. It introduces an original Official Analytical Evidence and Judicial Reliability Framework (OAE-JRF) for evaluating whether a scientific finding provides a legally sufficient foundation for regulatory intervention.

The central thesis is that the authority of official laboratory evidence derives not from its institutional origin alone, but from the legal regularity, scientific reliability and appropriate interpretation of the entire analytical process.

Keywords: Official food controls; sampling; analytical evidence; measurement uncertainty; second expert opinion; Royal Decree 562/2025; Regulation (EU) 2017/625; presumption of innocence; scientific error; judicial review; food safety sanctions.

283.1. The laboratory result as an administrative decision-making instrument

An official laboratory result is not merely a scientific observation. In regulatory practice, it may become the factual foundation for measures affecting property, economic activity and commercial reputation. A finding of non-compliance may lead to immobilisation of a consignment. A microbiological result may support withdrawal of food from the market. A chemical determination may be used to establish an infringement. The legal significance of the result depends upon the applicable statutory requirements.

However, the laboratory does not necessarily determine every legal consequence. The laboratory may establish the presence or concentration of an analyte. The competent authority must determine the applicable legal requirement, interpret the finding and decide which intervention is authorised. A court may subsequently examine whether the authority's decision was legally justified.

This creates three distinct levels of assessment:

Scientific level: Was the sample properly collected and analysed? Regulatory level: Does the result establish, or support a suspicion of, non-compliance under the applicable legislation? Judicial level: Was the resulting administrative measure lawful, adequately reasoned and supported by sufficient evidence? The levels are related but not interchangeable. A scientifically valid finding may be legally irrelevant to the alleged infringement.

Conversely, a scientifically defective result may undermine the evidentiary foundation of an otherwise correctly identified statutory obligation.

284. Article 34 of Regulation (EU) 2017/625: Scientific reliability as a legal requirement

284.1. The hierarchy of analytical methods

Article 34 establishes the framework governing methods used for official sampling, analyses, tests and diagnoses. Where Union rules prescribe particular methods or performance criteria, those rules apply. In their absence, the Regulation establishes a hierarchy involving internationally recognised methods, relevant reference laboratory methods and other appropriately validated approaches. This hierarchy matters because scientific validity is not established merely by selecting a method that a laboratory considers convenient.

The method must satisfy the applicable legal and technical requirements.

284.2. Method validation

Validation concerns whether a method is suitable for its intended analytical purpose. Relevant characteristics may include specificity, accuracy, precision, detection capability, quantification limits and robustness. The characteristics required depend upon the analyte, matrix and legal context. A method validated for one food matrix cannot automatically be assumed suitable for every other matrix.

284.3. Sample integrity

Article 34.5 requires samples to be collected, handled and labelled in a manner ensuring their legal, scientific and technical validity. This is particularly important where the relevant analyte is unstable or contamination may change during transportation. The laboratory result cannot be assessed independently of the condition in which the sample arrived.

284.4. The distinction between method validity and sample representativeness

A laboratory may employ a fully validated method. Nevertheless, the result may not adequately represent the relevant consignment if the sampling procedure was unsuitable. Analytical validity and sampling representativeness are separate

requirements. The first concerns the reliability of the measurement. The second concerns the relationship between the material analysed and the larger population or lot about which the authority seeks to draw conclusions.

284.5. The legal significance of this distinction

An authority may possess a reliable result demonstrating contamination of the tested sample. That finding does not automatically establish that every unit in a larger consignment possesses the same characteristics. Whether a conclusion may be extended to the lot depends upon the applicable sampling plan, legal decision criteria and scientific evidence. Conversely, a legally prescribed sampling plan may permit lot-level conclusions even though contamination is not uniformly distributed.

The applicable sector-specific legislation remains decisive.

285. Royal Decree 562/2025: A necessary distinction between two procedural regimes

Royal Decree 562/2025 contains provisions governing activities within the scope of Regulation (EU) 2017/625 and a separate framework for certain other official activities outside that scope. This distinction is essential for accurate legal citation.

285.1. Official controls within the Regulation's scope

For the framework addressed in Title II, the relevant provisions include:

Subject	Royal Decree 562/2025
Written official control records	Article 7
Transparency and confidentiality	Article 8
General sampling procedure	Article 9
Second expert opinion	Article 13
Documentary review	Article 14
Second analysis, test or diagnosis	Article 15

285.2. Other activities covered by Title III

The separate framework contains:

Subject	Royal Decree 562/2025
Written records	Article 23
Transparency and confidentiality	Article 24
General sampling procedure	Article 25
Exceptions concerning sufficient sample quantity	Article 27
Second expert opinion	Article 29
Documentary review	Article 30
Second analysis, test or diagnosis	Article 31

285.3. Why the distinction matters

It would be legally imprecise to cite Article 29 as the universal provision governing every second expert opinion under the Royal Decree. For ordinary official controls within the scope of Regulation (EU) 2017/625, Article 13 must be examined. Article 29 belongs to the distinct Title III framework. The provisions share important features, including a ten-working-day request period, but they must be applied according to their respective scope.

This clarification is relevant to the earlier discussion in this research series and should be preserved in the consolidated manuscript.

286. The right to a second expert opinion: Article 35 of Regulation (EU) 2017/625

286.1. A substantive procedural guarantee

Article 35 requires competent authorities to ensure that operators whose animals or goods undergo official sampling, analysis, testing or diagnosis have access to a second expert opinion at their own expense. The right is not merely a discretionary concession. It forms part of the Union framework governing the reliability and reviewability of official controls. Its minimum content includes the possibility of requesting a documentary review by another recognised and appropriately qualified expert.

286.2. Documentary review is not synonymous with reanalysis

The distinction is fundamental.

A documentary review may examine the original sampling and analytical process without repeating the laboratory determination. A second analysis requires suitable sample material and compliance with the relevant statutory conditions. Therefore, an operator's right to a second expert opinion must not be inaccurately described as an unconditional right to a fresh laboratory analysis.

286.3. Sample availability

Article 35.2 addresses the collection of sufficient material for subsequent review where relevant, appropriate and technically feasible. The provision expressly recognises practical limitations arising from the characteristics of the hazard, perishability and the amount of available material. Where sufficient material cannot be collected, the competent authority must comply with the applicable information requirements.

286.4. Further review of disputed findings

Article 35.3 permits Member States to establish arrangements allowing additional documentary review or analysis by another official laboratory in circumstances involving disputes arising from the second expert opinion. The precise national procedure must be examined.

286.5. Immediate protective action

Article 35.4 establishes a crucial qualification. The request for a second expert opinion does not affect the competent authority's obligation to take prompt action to eliminate or contain relevant risks. Accordingly, exercising the right does not automatically suspend an immobilisation, withdrawal or other protective measure. This does not make the second expert opinion irrelevant. It means that procedural contradiction and immediate risk management operate simultaneously.

287. Spain's ten-working-day period and the consequences of procedural choice

287.1. Article 13.3 of Royal Decree 562/2025

For the relevant Title II controls, Article 13.3 establishes a period of ten working days, counted from the day following notification of an unfavourable result, to

request the second expert opinion. The operator must identify the form of review sought and provide the information required by the provision.

287.2. Selection of a qualified expert

Where documentary review is requested, the operator must identify an appropriately qualified expert and demonstrate compliance with the requirements established by the Royal Decree. The expert's role is not merely to express disagreement. The review should address identifiable technical or procedural questions.

287.3. Selection of a laboratory

Where a second analysis is available, the operator's choice of laboratory is subject to the statutory framework. A private laboratory report commissioned independently may be relevant evidence, but it should not automatically be treated as the statutory second official analysis. The distinction affects both procedure and legal consequences.

287.4. The importance of the notification date

The date on which an unfavourable result is notified can determine the deadline. The operator should preserve the notification and verify the applicable rules for calculating working days. A laboratory's internal completion date is not necessarily the statutory starting point.

287.5. Parallel protective measures

Where goods are immobilised, the operator may need to address two questions at once. The first concerns exercising the statutory right to expert review. The second concerns the continuing legality and proportionality of the protective measure. The second expert opinion procedure does not automatically resolve the latter question.

288. Documentary review: Examining the entire evidentiary chain

The documentary review should not be confined to checking whether the final laboratory report contains a numerical value. A scientifically meaningful assessment must examine the evidence supporting that value.

288.1. Sampling records

The review may address the identity of the sampled goods, lot definition, collection method, quantity and relevant circumstances. Errors in identifying the lot may undermine the relationship between the result and the merchandise affected by enforcement.

288.2. Preservation and transportation

The review may examine temperature, storage duration, packaging, transport conditions and laboratory receipt. These matters are particularly important where analyte concentrations or microbiological populations may change over time.

288.3. Laboratory competence

The laboratory's designation and accreditation status may be relevant. However, accreditation should not be treated as a guarantee that every individual result is correct. The specific analytical method, matrix and applicable accreditation scope may need examination.

288.4. Analytical method

The review should identify the method used and determine whether it satisfies the applicable legal requirements. A scientifically sophisticated method may nevertheless be unsuitable for the particular regulatory purpose.

288.5. Interpretation

The final stage concerns the authority's interpretation of the result. The expert may examine whether the correct legal limit, sampling plan and decision rule were applied. This is where scientific and legal reasoning frequently intersect.

288.6. The separate Title III procedure

For activities governed by Title III, Article 30 expressly identifies categories of documentation relevant to documentary review, including sampling records, conservation conditions, laboratory accreditation, analytical methods and the official interpretation of results. Article 30.3 also establishes a ten-working-day period following access to the information for submission of the optional, non-binding expert report and specifies a consequence for failure to submit it.

That provision should not be transposed automatically to Title II without examining the corresponding Article 14 rules.

289. Second official analysis and the legal priority of its result

289.1. Article 15 and Article 31

Royal Decree 562/2025 establishes procedures for second analyses within its respective Titles. The relevant provision depends upon the scope of the control. Both the scientific conditions and the formal procedural requirements matter.

289.2. A significant statutory rule

Article 31.4, within Title III, expressly provides that the result of the second analysis, test or diagnosis, when performed, prevails over the first. This is a legally significant provision. It differs from a general principle under which every contradictory private report would automatically displace official evidence.

289.3. Scope of the priority rule

The priority concerns a second analysis carried out under the relevant statutory procedure. It should not be interpreted as establishing that any later result, obtained from any sample by any laboratory, necessarily prevails. The conditions governing the second determination remain important.

289.4. Scientific interpretation

A second result may differ because of analytical variation, sample heterogeneity, changes during storage or methodological differences. Legal priority does not establish that the first laboratory acted negligently. Nor does it necessarily establish why the findings differ. The legal consequence and the scientific explanation are separate questions.

289.5. Reconsideration of enforcement measures

Where the statutory second result materially changes the evidentiary foundation of an administrative restriction, the authority must consider the implications under the applicable enforcement framework. However, other independent evidence may remain relevant. A favourable result concerning one analyte does not automatically establish compliance with every other food safety requirement.

290. Steffensen: A directly relevant CJEU judgment on food sampling and the rights of defence

290.1. Identification

Court of Justice, Criminal proceedings against Joachim Steffensen, Case C-276/01, judgment of 10 April 2003, ECLI:EU:C:2003:228. Unlike the procurement judgments examined in the previous instalments, Steffensen concerned the official control of foodstuffs and the right to a second opinion following analysis of food samples. The judgment arose under Directive 89/397/EEC, a predecessor of the current official controls framework.

290.2. The legal question

The referring court sought guidance concerning the operator's right to a second opinion and the admissibility of analytical evidence where that right had not been respected. The case therefore directly connected official food sampling with procedural fairness.

290.3. The Court's approach

The Court recognised the significance of the right to a second opinion and its relationship with the rights of defence. It addressed whether an infringement of that right affected the use of the original analytical findings as evidence. The judgment did not establish a universal rule that every procedural defect automatically renders analytical evidence inadmissible. Rather, it required consideration of the applicable procedural framework and whether the operator's ability to defend itself had been impaired.

The Court's reasoning gives particular importance to situations where the operator has no effective means of challenging analytical findings that form the basis of proceedings.

290.4. Why the judgment remains important

The applicable Directive has been superseded. Consequently, the judgment cannot be cited as the current source of the second expert opinion procedure. That procedure is now governed principally by Regulation (EU) 2017/625 and the relevant national provisions. Nevertheless, Steffensen remains significant as jurisprudence addressing the relationship between food sampling, evidentiary fairness and effective defence.

290.5. Its doctrinal significance

The judgment supports an important distinction. A right to challenge evidence must be effective in the relevant procedural context. However, the legal consequence of a defect depends upon the applicable law and its effect upon the proceedings. A scientifically unreliable finding and a procedurally defective finding are not necessarily the same thing. Both may be relevant, but their legal consequences require separate assessment.

291. Measurement uncertainty: When a numerical result is not a complete legal conclusion

291.1. The nature of measurement uncertainty

Every quantitative measurement is subject to uncertainty. A reported concentration is an estimate derived from a measurement process. The uncertainty reflects the dispersion of values reasonably attributable to the measurand under the applicable methodology. It should not be confused with an allegation that the laboratory performed its work incorrectly. A result can be scientifically valid while possessing non-zero uncertainty.

291.2. Legal limits and analytical results

Suppose a statutory maximum concentration is established for a contaminant. The laboratory reports a concentration slightly above that limit. The authority must determine how the applicable legislation requires the result to be interpreted. Some regimes prescribe specific decision rules or methods for accounting for measurement uncertainty. Others may establish different requirements. There is no universal rule allowing every operator to subtract uncertainty from every unfavourable analytical result.

291.3. Illustrative example

A hypothetical food product is subject to a maximum concentration of 10.0 mg/kg.

An official laboratory reports:

Illustrative analytical finding

Legal limit **10.0** mg/kg

Measured result **10.4** mg/kg

Illustrative expanded uncertainty: ±1.0 mg/kg, with a stated coverage factor and coverage probability that must be specified in the laboratory report. The numerical result exceeds the hypothetical limit. However, the lower endpoint of the illustrative uncertainty interval is below the limit. What follows legally depends upon the applicable decision rule. Under a rule requiring the lower bound to exceed the limit, this result would not establish an exceedance on that basis. Under a different legally applicable rule, the conclusion may differ.

The example demonstrates a methodological question, not a universal rule of food law.

291.4. The distinction between uncertainty and tolerance

Measurement uncertainty is not automatically a legal tolerance. A legal tolerance may be established for particular regulatory purposes. Uncertainty arises from the measurement process. The concepts should not be conflated.

291.5. Uncertainty in microbiological testing

Microbiological determinations may involve substantial variability. However, the legal interpretation depends upon the applicable microbiological criterion and sampling plan. The statistical treatment of a qualitative presence/absence test differs from that of a quantitative concentration determination. A single uncertainty formula cannot be applied indiscriminately.

292. Sampling representativeness and heterogeneous contamination

292.1. The problem of heterogeneity

Food contaminants are not always uniformly distributed. Some hazards may occur in localised areas or particular units. A small analytical portion may therefore fail to reflect the entire lot unless sampling is appropriately designed.

292.2. The legal sampling plan

Where legislation prescribes a sampling plan, the authority must apply the relevant rules. A court should not replace a legally established plan with an arbitrary preference for a different number of samples. However, the authority must demonstrate compliance with the applicable procedure.

292.3. Lot definition

The definition of the lot may be legally decisive. A result from one production batch does not automatically establish non-compliance across all batches manufactured at the establishment. Conversely, a legally defined lot may encompass multiple units subject to a common sampling plan.

292.4. Microbiological hazards

For certain microbiological hazards, the absence of detection in a sample does not prove that the entire lot is free from the microorganism. The probability of detection depends upon prevalence, distribution, sample size and method sensitivity. Likewise, detection in a validly sampled unit may have consequences for the relevant lot under applicable microbiological criteria.

292.5. A scientifically important distinction

Failure to detect a hazard is not equivalent to proof that the hazard is absent. Equally, detection in one sample does not automatically establish the concentration or distribution of that hazard throughout every unit. The applicable legal and statistical framework determines what conclusions may be drawn.

293. Chain of custody: From collection to courtroom

293.1. Why chain of custody matters

The evidentiary value of an analytical finding depends partly upon establishing that the material analysed corresponds to the material collected. Relevant questions include sample identification, sealing, transportation, receipt and storage.

293.2. Documentary traceability

Royal Decree 562/2025 establishes requirements concerning identification and handling of official samples. The relevant records should permit reconstruction of the sampling and analytical process.

293.3. Not every irregularity has the same consequence

A minor clerical error may be correctable without undermining sample identity. A serious discrepancy concerning the sampled lot may affect the reliability of the

finding. The legal consequence depends upon the nature and significance of the defect.

293.4. Sample degradation

Some analytes or microorganisms may change during storage. Where preservation conditions are inadequate, the analytical result may no longer accurately represent the condition of the product at the relevant time. The expert assessment should address whether the identified deviation could materially affect the result.

293.5. The distinction between procedural and scientific integrity

A sample may have been handled in a scientifically appropriate manner but inadequately documented. Alternatively, the documentation may be complete while the preservation conditions were unsuitable. Both dimensions require examination.

294. The evidentiary status of inspection reports under Spanish law

294.1. Article 77.5 of Law 39/2015

Article 77.5 recognises evidentiary value for documents formalised by officials possessing the relevant legal status and recording facts verified by them, subject to statutory requirements. The provision expressly permits contrary evidence. This is not an irrebuttable presumption.

294.2. Facts and inferences

An inspector may record that a sample was collected at a specified location and time.

Those are factual observations.

A conclusion that the sample demonstrates a particular statutory infringement may require additional technical and legal reasoning. The evidentiary value of the recorded observation does not automatically establish the correctness of every inference derived from it.

294.3. Technical conclusions

An inspection report may incorporate analytical results or expert assessments. Those conclusions may possess substantial evidentiary value. However, they

remain subject to the applicable rules concerning evidence, contradiction and judicial evaluation.

294.4. The presumption of innocence

Where the Administration seeks to impose a sanction, the presumption of innocence becomes central. The authority must establish the facts supporting the infringement and the required responsibility. The operator is not required to prove innocence merely because an official report contains an unfavourable conclusion.

294.5. Preventive intervention

A precautionary measure may be justified by a credible suspicion of risk under the applicable legislation. It does not necessarily require the same degree of factual establishment as a punitive sanction. The legal thresholds must therefore be distinguished. The same analytical evidence may be sufficient to justify temporary containment while being insufficient, without further proof, to establish culpability for an administrative infringement.

295. Preventive measures and sanctions: Different evidentiary functions

295.1. Suspicion of non-compliance

Article 137 of Regulation (EU) 2017/625 governs action where competent authorities suspect non-compliance. The provision requires investigation and permits appropriate measures within the statutory framework. The purpose is to establish the relevant facts and manage risks.

295.2. Established non-compliance

Article 138 addresses action where non-compliance has been established. The authority must adopt appropriate measures under the applicable conditions. However, established non-compliance does not automatically establish every element required for an administrative sanction under national law.

295.3. The punitive threshold

Sanctioning proceedings require proof of a legally classified infringement and the applicable basis of responsibility. A laboratory result may establish an important

element. But the authority must still identify the relevant legal obligation and attribute responsibility under the applicable sanctioning framework.

295.4. The risk of evidentiary transposition

A common analytical error is to treat evidence sufficient for a temporary precautionary measure as automatically sufficient for punishment. The converse error is to require conclusive proof of an infringement before taking any urgent protective action. Both approaches disregard the distinction between prevention and punishment.

295.5. Judicial review

The court must examine the evidentiary threshold appropriate to the measure challenged. A preventive restriction and a punitive sanction may arise from the same laboratory result. Nevertheless, their legality may require different conclusions.

296. Original doctrinal contribution: The Official Analytical Evidence and Judicial Reliability Framework

The present research proposes the Official Analytical Evidence and Judicial Reliability Framework (OAE-JRF). The model is an original academic analytical proposal, not an established judicial test. Its purpose is to assess whether official analytical evidence provides a legally sufficient basis for the particular administrative consequence imposed.

296.1. Ten dimensions

Dimension	Principal inquiry
1. Legal basis	Was the sampling authorised under the applicable framework?
2. Lot definition	What goods or production units were legally and scientifically represented?
3. Sampling validity	Was the applicable sampling plan followed?
4. Sample integrity	Were identification, preservation and transport adequate?
5. Laboratory competence	Was the laboratory appropriately designated and qualified?
6. Method suitability	Was the analytical method legally and scientifically appropriate?

Dimension	Principal inquiry
7. Uncertainty	Was uncertainty treated according to the applicable decision rule?
8. Expert contradiction	Were statutory review rights respected?
9. Legal interpretation	Did the authority correctly connect the finding to the applicable requirement?
10. Evidentiary threshold	Was the evidence sufficient for the specific measure or sanction?

296.2. The model's central contribution

OAE-JRF rejects the treatment of laboratory results as isolated numerical facts. It requires reconstruction of the entire evidentiary chain. It also distinguishes the validity of the analytical process from the legality of the resulting administrative decision.

296.3. A proposed sequence

1

Sampling

Establish the relevant lot, sampling plan and collection conditions.

2

Integrity

Verify identification, preservation and traceability.

3

Analysis

Examine method validity, laboratory competence and results.

4

Interpretation

Apply the correct limit, uncertainty treatment and decision rule.

5

Contradiction

Examine the availability and exercise of expert-review rights.

6

Legal qualification

Identify the substantive obligation and possible non-compliance.

7

Intervention

Determine whether the evidence supports prevention, correction or punishment.

8

Judicial review

Assess the legality of the measure and the adequacy of the evidentiary foundation.

296.4. The significance of different outcomes

The framework permits different legal conclusions from the same scientific record. For example, a result may justify temporary immobilisation pending further investigation. The same result may be insufficient to establish a sanctionable infringement. A later second official analysis may change the legal position. The model is designed to make those distinctions explicit.

296.5. The need for validation

OAE-JRF should be tested against a systematic corpus of administrative decisions and judicial judgments. Its practical value would depend upon whether it improves consistency, transparency and the identification of material evidentiary defects.

297. Applied industrial scenarios

Scenario A. A chemical contaminant near the legal limit

An official laboratory reports a concentration marginally above the applicable maximum. The operator challenges the treatment of measurement uncertainty. The authority must identify the relevant analytical method and legally applicable decision rule. A numerical exceedance does not automatically answer every legal question.

Scenario B. A microbiological finding in a heterogeneous product

A pathogen is detected in a sample collected from a large consignment. The authority orders immobilisation. The operator disputes the extension of the result

to the entire lot. The analysis must examine the legal lot definition, applicable sampling plan and scientific characteristics of the hazard.

Scenario C. A second official analysis contradicts the first

An operator requests a second analysis under the applicable Royal Decree procedure. The second result differs from the first. The authority must apply the relevant statutory rules governing the second determination. A contradictory private report cannot automatically be equated with the statutory second analysis.

Scenario D. An incomplete chain of custody

A sample arrives at the laboratory without adequate documentation concerning its preservation. The operator questions the reliability of the result. The relevant inquiry is whether the deficiency could materially affect sample integrity and whether the legal requirements were satisfied. The mere existence of an administrative error does not necessarily establish invalidity.

Scenario E. A sanction based upon an analytical finding

An official result establishes the presence of a prohibited substance. The authority initiates sanctioning proceedings. The operator argues that the finding does not establish culpability. The Administration must distinguish proof of the relevant factual condition from proof of the statutory infringement and the required responsibility. The evidentiary requirements governing punishment remain applicable.

298. Conclusions of the ninth instalment of Part II

Official analytical evidence is central to food safety enforcement. However, its legal significance depends upon the integrity of the entire evidentiary process. Regulation (EU) 2017/625 establishes requirements governing sampling, analytical methods and the right to a second expert opinion. Royal Decree 562/2025 develops detailed Spanish procedures and distinguishes controls within the Regulation's scope from certain other official activities. The distinction between Articles 13–15 and Articles 29–31 is essential for accurate legal analysis.

The judgment in Steffensen demonstrates the longstanding relationship between official food sampling, the right to expert contradiction and procedural fairness. Measurement uncertainty, sample representativeness and chain of custody may affect the reliability or interpretation of a finding. Nevertheless, the legal

consequences of an analytical defect depend upon the applicable rules and circumstances. Finally, preventive measures and sanctions must not be subjected to an undifferentiated evidentiary standard.

The central conclusion is:

A scientifically credible laboratory finding may justify regulatory investigation or protective intervention, but its use to establish an administrative infringement requires a separate examination of the applicable legal obligation, the reliability of the evidence and the statutory requirements governing punitive responsibility.

The proposed OAE-JRF framework provides a structured method for conducting that examination.

Primary legislation and judicial authorities

1. Regulation (EU) 2017/625 — Articles 34–35 and 137–138.
2. Royal Decree 562/2025 — Articles 7–15 and 23–31, according to the applicable scope.
3. Court of Justice, Steffensen, C-276/01, 10 April 2003 — Official food sampling and the right to a second opinion.
4. Law 39/2015 — Article 77 and the evidentiary requirements of administrative proceedings.
5. Law 40/2015 — Principles governing administrative sanctions.
6. Regulation (EC) No 178/2002 — Risk analysis and precautionary principle.

CHAPTER 24

299. Institutional Fragmentation, Conflicting Administrative Criteria and the Right to Consistent Food Safety Enforcement

Constitutional distribution of powers, European regulatory uniformity, inter-administrative coordination, legitimate expectations and judicial control of contradictory enforcement.

Abstract

Spain's food safety enforcement system operates within a constitutionally decentralised administrative structure. European Union regulations establish directly applicable obligations, while national, autonomous-community and local authorities exercise different powers concerning public health, food safety, consumer protection, economic activity and official controls.

Decentralisation permits administrative proximity, specialised supervision and responsiveness to territorial circumstances. It may also generate overlapping inspections, inconsistent technical interpretations, duplicative documentary requirements and uncertainty for operators conducting business across several territories.

Such differences are not necessarily unlawful. Competent authorities may legitimately respond differently to distinct factual situations, risks or regulatory responsibilities. Nevertheless, the legal system imposes obligations of coordination, consistency, objectivity, proportionality and compliance with Union law.

Article 4 of Regulation (EU) 2017/625 expressly requires Member States operating through multiple competent authorities to ensure effective coordination and consistent official controls. Articles 14–16 of Spanish Law 17/2011 establish complementary mechanisms concerning administrative cooperation, national control planning and audits.

The constitutional principle of territorial autonomy must therefore be reconciled with the uniform application of binding Union requirements and the protection of economic operators against unjustified regulatory fragmentation.

This instalment examines the distinction between legitimate territorial diversity and legally defective inconsistency. It considers conflicting inspection criteria, previous favourable administrative decisions, legitimate expectations, the principle of equality, the Spanish market unity framework and the procedural routes available when administrative disagreement becomes an obstacle to lawful economic activity.

It introduces an original Inter-administrative Consistency and Regulatory Legitimacy Framework (ICRLF).

The central thesis is that administrative decentralisation may justify diversity in enforcement organisation, but it does not authorise competent authorities to replace binding legal requirements with incompatible territorial interpretations or unexplained discretionary preferences.

Keywords: Food safety enforcement; administrative coordination; autonomous communities; regulatory fragmentation; legitimate expectations; legal certainty; market unity; Regulation (EU) 2017/625; Law 17/2011; judicial review; institutional consistency.

299.1. Introduction: One European food market, multiple enforcement authorities

A food manufacturer may operate from one Spanish autonomous community while supplying customers throughout Spain and the European Union. Its products may be manufactured under a harmonised European regulatory framework. Nevertheless, the company may encounter different administrative interpretations concerning the same technological process, documentation or compliance obligation. An inspector in one territory may accept a particular validation method. An inspector elsewhere may demand a different procedure.

One authority may regard a particular activity as falling within an established regulatory category. Another may question that classification. These situations create a legal problem that cannot be resolved merely by asserting that all authorities should act identically. The relevant authorities may exercise different competences. The products may present different risks.

The facts may differ.

The applicable national or regional legislation may also differ within the limits permitted by the Constitution and Union law.

The correct legal question is therefore:

When does administrative diversity remain a legitimate consequence of decentralisation, and when does it become an unlawful inconsistency affecting the rights and obligations of food business operators?

Answering that question requires examining four interacting legal systems:

1. European Union food law.

2. The Spanish constitutional distribution of competences. 3. National legislation concerning coordination and official controls. 4. The administrative and judicial guarantees applicable to individual decisions.

300. The constitutional distribution of competences in Spain

300.1. Territorial autonomy and constitutional unity

Article 2 of the Spanish Constitution recognises and guarantees the right to autonomy of nationalities and regions within the constitutional framework. This principle forms part of the institutional structure governing food safety enforcement. Spain is not organised as a single centralised inspection authority exercising every relevant function. However, autonomy does not imply unlimited regulatory sovereignty.

The Constitution establishes a distribution of competences, and public authorities must act within their legally assigned responsibilities.

300.2. Article 148.1.21: Health and hygiene

Article 148.1.21 identifies health and hygiene among matters in which autonomous communities may assume competences. The precise scope of each autonomous community's powers must be determined through the Constitution, its Statute of Autonomy and the applicable legislation.

300.3. Article 149.1.16: State competences

Article 149.1.16 reserves to the State competences concerning external health, the foundations and general coordination of health, and legislation on pharmaceutical products. The distinction between basic legislation, coordination and implementation is important. A State competence to establish basic rules does

not automatically mean that State authorities conduct every inspection. Conversely, autonomous-community enforcement powers do not authorise disregard of applicable State basic legislation.

300.4. Other relevant competences

Food industry regulation may also engage competences concerning consumer protection, agriculture, fisheries, trade, environmental protection and economic activity. A particular dispute may therefore require identifying more than one constitutional basis. For example, a food processing establishment may be subject to public health controls and separate environmental or municipal requirements. Those controls should not automatically be treated as exercises of the same power.

300.5. Competence as a threshold question

Before alleging contradictory enforcement, the operator must identify which authority acted and under which legal competence. Two authorities may reach different conclusions because they are deciding legally distinct questions. A municipal activity licence does not necessarily determine compliance with food hygiene requirements. Similarly, an official food safety inspection does not automatically resolve environmental authorisation requirements. The first analytical requirement is therefore to separate overlapping regulatory regimes.

301. Regulation (EU) 2017/625: Coordination as a binding European obligation

301.1. Article 4.2: Multiple competent authorities

Article 4.2 expressly addresses Member States in which responsibility for official controls is distributed among multiple national, regional or local authorities. It requires efficient and effective coordination and consistency in the performance of official controls. The provision also requires designation of a single authority responsible for coordinating cooperation and contacts with the Commission and other Member States in each relevant regulatory area, consistently with national constitutional requirements.

This is not merely a recommendation favouring administrative convenience. It is an obligation imposed by directly applicable Union legislation.

301.2. Consistency does not require identical outcomes

Article 4.2 does not require every establishment to receive the same inspection frequency or regulatory decision. Article 9 of the same Regulation requires risk-based controls. Different risk profiles may justify different treatment. Consistency therefore concerns the lawful and coherent application of the regulatory framework, not mechanical uniformity of results.

301.3. Article 5.1(b): Quality and consistency at all levels

Article 5.1(b) requires competent authorities to maintain procedures or arrangements ensuring the impartiality, quality and consistency of official controls at all levels. This obligation complements Article 4. Article 4 addresses the coordination of multiple authorities. Article 5 addresses the institutional quality of the control system itself. Together, they provide a legal basis for evaluating systemic inconsistencies.

301.4. Inspector training

Article 5.4 requires personnel performing official controls to receive appropriate training and maintain relevant competence. This matters where contradictory interpretations arise from insufficient technical training rather than deliberate administrative disagreement. A systematic problem may require institutional training or guidance rather than litigation against an individual inspector.

301.5. The legal consequences of non-compliance

A failure to coordinate may be relevant to the legality of particular administrative decisions. However, Article 4 does not establish that every difference between regional authorities automatically invalidates an inspection or sanction. The claimant must identify the applicable obligation, the defect alleged and its legal significance.

302. Spanish Law 17/2011: National coordination and official control planning

302.1. Article 14: Competences, coordination and cooperation

Article 14 of Law 17/2011 recognises that different public administrations conduct official controls within their respective competences. It also establishes coordination and cooperation mechanisms. The provision identifies the Spanish

Agency for Food Safety and Nutrition as a contact point with the European Commission and other Member States for the purposes addressed by the legislation. The State, autonomous communities and local entities may establish cooperation arrangements, including joint control or inspection structures.

302.2. Article 15: The national official control plan

Article 15 establishes the framework for a multiannual national official control plan covering the food chain. This mechanism is important because individual inspection decisions should be understood within a broader institutional system. A national plan can promote coherent priorities, comparable control procedures and coordinated implementation. However, the existence of a national plan does not mean that every establishment must be inspected identically. Risk-based differentiation remains necessary.

302.3. Article 16: Audits

Article 16 requires competent authorities to conduct internal audits or arrange external audits and to take appropriate action in light of their findings. The purpose includes verifying whether official controls are effective and appropriate for achieving the relevant legislative objectives. The provision also addresses consistency in auditing arrangements. This creates an important institutional dimension. A disagreement concerning one inspection may be an individual administrative dispute.

Repeated contradictory criteria across authorities may indicate a broader quality-assurance or coordination problem.

302.4. Individual rights and institutional obligations

Articles 14–16 establish obligations concerning the organisation of official controls. They do not automatically create an individual right to compel a particular inspection result. Nevertheless, systemic failures may be relevant when assessing the legality, consistency or adequacy of administrative action. The relationship between institutional obligations and individual remedies requires examination of the particular decision challenged.

303. Law 40/2015: Coordination, good faith and legitimate expectations

303.1. Article 3: General principles

Article 3 of Law 40/2015 establishes principles governing public administration. These include objectivity, effectiveness, good faith, legitimate expectations, institutional loyalty and cooperation among administrations. The provision is important because it situates consistency within the general legal framework of public administration. It does not treat coordination as an optional administrative preference.

303.2. Institutional loyalty

Institutional loyalty concerns the relationships between public authorities. An authority should not exercise its powers in a manner that unjustifiably obstructs the lawful functions of another competent authority. However, institutional loyalty does not require one administration to accept every conclusion reached by another. Different authorities may have distinct legal responsibilities.

303.3. Good faith

Good faith is relevant to the conduct of administrative relationships. An operator may legitimately expect the Administration to act coherently and transparently. However, good faith does not prevent an authority from correcting an erroneous interpretation or responding to new evidence.

303.4. Legitimate expectations

The principle of legitimate expectations protects certain reliance interests created by public authority conduct. It is not equivalent to an unconditional right to preserve previous administrative treatment. The claimant must identify the relevant conduct, its legal significance and the circumstances supporting reliance. The principle cannot ordinarily be invoked to require continuation of conduct contrary to binding law.

303.5. The difference between an expectation and a legal entitlement

An operator may expect that a favourable inspection outcome will be repeated. That expectation may be commercially understandable. But a previous inspection does not necessarily constitute a legally binding authorisation for every future

production activity. The legal effect depends upon the nature of the earlier administrative act.

303.6. The need for precise classification

Three situations must be distinguished:

- A formal favourable administrative decision with identifiable legal effects.

- An official written interpretation or communication.

- An informal statement or absence of objection during an inspection.

They may possess different legal significance. A robust legitimate-expectations claim cannot simply treat them as equivalent.

304. Article 35 of Law 39/2015: Departures from previous administrative criteria

304.1. The duty to give reasons

Article 35.1(c) requires administrative acts departing from criteria followed in previous actions, or from the opinion of advisory bodies, to be reasoned. The provision has particular importance where an authority changes its interpretation of a technical requirement.

304.2. Change is legally possible

The Administration may change its criteria where justified. New scientific evidence, revised legislation or recognition of an earlier error may support a different approach. The legal system does not require authorities to perpetuate mistakes. However, the change must comply with the applicable requirements.

304.3. The role of motivation

A reasoned departure should identify the factual and legal basis for the change. A statement that the new inspector simply prefers another method may be inadequate where the decision requires legal justification. The authority should explain why the previous criterion is no longer applicable or appropriate.

304.4. Same authority versus different authorities

A distinction is necessary between an authority departing from its own previous criteria and a different authority reaching another conclusion. Article 35.1(c) is particularly relevant to the former situation. It should not be assumed that every

difference between separate authorities automatically constitutes a departure from the same administrative criterion within the meaning of the provision. Other legal principles may apply to interadministrative inconsistency.

304.5. The evidentiary value of previous inspection records

A previous favourable inspection report may demonstrate that an authority was aware of a particular process. However, the legal consequences depend upon what was actually examined and decided. A report that did not identify non-compliance is not necessarily a formal approval of every aspect of the process.

304.6. A hypothetical example

An inspector examines a manufacturer's process validation dossier and records no objection. Two years later, another inspector considers the same dossier insufficient. The manufacturer may reasonably request an explanation. Nevertheless, the earlier inspection does not automatically prevent the later authority from identifying a genuine deficiency. The decisive questions concern the applicable legal requirements, the evidence and the reasons for the changed assessment.

305. The Spanish Constitutional Court and the limits of market unity

305.1. STC 79/2017

Spanish Constitutional Court, Judgment 79/2017 of 22 June 2017, ECLI:ES:TC:2017:79. This judgment concerned the constitutionality of provisions of Law 20/2013 on the Guarantee of Market Unity. It is particularly important because it addresses the relationship between the unity of the Spanish market and the regulatory autonomy of the autonomous communities.

305.2. The constitutional problem

The challenged framework sought to facilitate economic activity across Spain by giving broad territorial effect to decisions and regulatory requirements originating in one autonomous community. The Court examined whether the State could impose that approach consistently with the constitutional distribution of competences.

305.3. The Court's central distinction

The Court recognised the constitutional importance of market unity. However, it also emphasised that market unity does not require absolute regulatory uniformity. Territorial autonomy may produce legitimate differences in regulatory regimes. The Constitution requires reconciliation of unity and autonomy rather than elimination of one principle by the other.

305.4. Invalidity of the general national-effect mechanism

The Court declared unconstitutional and void the challenged general mechanism concerning nationwide effectiveness of origin-authority decisions. The judgment therefore prevents reliance upon the original broad version of the principle as if it remained fully operative.

305.5. Recognition in harmonised or equivalent regulatory contexts

The judgment distinguished the invalid general mechanism from situations involving harmonised Union rules, common State legislation or legally relevant equivalent standards. Recognition across territories may be justified under the applicable constitutional conditions. The decision therefore does not prohibit every form of mutual recognition.

305.6. Consequences for food businesses

A manufacturer cannot simply argue that acceptance of an activity by one autonomous community automatically obliges every other autonomous community to accept every aspect of that activity. The legal effect of the original decision must be established. Where directly applicable Union rules govern the matter, those rules must be respected. Where constitutionally valid territorial requirements remain permissible, the relevant authority may enforce them.

305.7. Why this judgment is central

STC 79/2017 prevents two opposite errors. The first is treating decentralisation as a licence for arbitrary regulatory inconsistency. The second is treating market unity as a constitutional requirement of complete uniformity.

Established holding: The Constitutional Court invalidated the general nationwide-effect mechanism challenged in the case.

Doctrinal implication: Regulatory consistency must be achieved through constitutionally valid coordination, harmonisation and recognition mechanisms, not by disregarding the distribution of competences.

306. Law 20/2013 after constitutional review: What operators may legitimately invoke

306.1. The danger of relying on the original text

Law 20/2013 has been affected by constitutional judgments and subsequent legislative amendments. Legal arguments must therefore be based upon the applicable consolidated text and the effects of the relevant judgments. Reliance upon provisions invalidated by the Constitutional Court may undermine an otherwise credible challenge.

306.2. Necessity and proportionality

The market unity framework addresses restrictions affecting access to and exercise of economic activities. However, the applicable requirements must be interpreted within the constitutional distribution of competences and any relevant sector-specific legislation. A measure justified by genuine public health concerns may satisfy necessity and proportionality requirements. Conversely, an unjustified restriction may raise legal concerns.

306.3. Non-discrimination

The framework also addresses unjustified discrimination affecting economic operators. Nevertheless, not every difference in regulatory treatment constitutes prohibited discrimination. The relevant circumstances and legal criteria must be examined.

306.4. Mechanisms for identifying barriers

The law provides mechanisms through which operators and other interested parties may bring potential market barriers to the attention of the relevant institutional structures. Article 28 establishes an additional mechanism for reporting obstacles and barriers. Its procedural nature and consequences must be distinguished from ordinary administrative appeals and judicial actions.

306.5. Article 26 and the specialised framework

Article 26 establishes a procedure concerning certain acts, provisions or administrative actions incompatible with the principles of market unity. Its admissibility requirements, deadlines and relationship with other remedies must be examined in the current statutory text. It should not be treated as a universal substitute for challenging food safety sanctions or precautionary measures.

306.6. The limits of market unity arguments

A manufacturer cannot rely upon market unity to market unsafe food. Nor does the principle exempt products from mandatory Union authorisation requirements. Market unity concerns the lawful functioning of economic activity within the applicable regulatory framework. It is not an exception to food safety legislation.

307. Legitimate expectations and the judicial protection of regulatory reliance

307.1. The central problem

Industrial investment often depends upon regulatory predictability. A manufacturer may invest in equipment, validation studies and production capacity after receiving favourable administrative communications. If the authority subsequently changes its interpretation, the company may suffer significant losses. However, the legal protection of that reliance depends upon the nature of the assurances and the circumstances.

307.2. A formal authorisation

A formal authorisation may create identifiable legal effects. Its withdrawal, revision or annulment must comply with the applicable legislation. The authority cannot necessarily disregard the authorisation as though it never existed. However, authorisations may be subject to conditions, review powers and statutory limitations.

307.3. An informal technical opinion

An informal statement by an inspector generally has a different legal status. It may be relevant evidence of the Administration's previous understanding. Nevertheless, it does not automatically constitute a binding authorisation.

307.4. Reliance upon an unlawful assurance

A difficult situation arises where an authority previously communicated an interpretation inconsistent with binding law. The operator may have relied upon that communication. However, legitimate expectations do not ordinarily authorise continued infringement of applicable legislation. The potential consequences of reliance may require separate examination, including whether any legally compensable injury arose.

307.5. The relevance of good faith

The operator's conduct matters.

An operator who supplied incomplete or misleading information may have difficulty establishing legitimate reliance. Conversely, a manufacturer that disclosed the relevant facts and obtained a clear formal decision may possess a stronger evidentiary position.

307.6. The difference between legal stability and scientific immobility

Food safety regulation must respond to new scientific evidence. A favourable decision based upon the information available at one time may legitimately require reassessment when material risks emerge. The legal system must reconcile predictability with the continuing protection of public health.

308. Judicial control of conflicting technical interpretations

308.1. The judicial function

Courts may review whether administrative decisions comply with the applicable law. This includes questions concerning competence, motivation, factual foundation and the limits of discretion. However, judicial review does not necessarily require the court to choose its preferred technical approach whenever experts disagree.

308.2. Upjohn, C-120/97

Court of Justice, Upjohn Ltd v The Licensing Authority, Case C-120/97, judgment of 21 January 1999, ECLI:EU:C:1999:14. The case concerned judicial review of the withdrawal of a medicinal product marketing authorisation. The Court addressed the review of complex scientific and technical assessments. Its reasoning is relevant to the distinction between judicial control of legality and

substitution of judicial technical judgment. However, it arose under pharmaceutical legislation rather than food inspection law.

308.3. The importance of transferability

The decision may be used by analogy to illustrate the judicial treatment of technical discretion. It should not be presented as establishing a specific rule concerning Spanish autonomous-community food inspections. The applicable food safety legislation and Spanish procedural framework remain decisive.

308.4. Review of legal classification

A disagreement may concern the legal classification of a process rather than its scientific performance. For example, an authority may classify a substance as a food additive while the manufacturer considers it a processing aid. The classification depends upon the applicable legal definitions and facts. A court may review whether the authority correctly applied the law. Technical evidence may assist, but the final legal classification is not determined by the manufacturer's preferred terminology.

308.5. Review of factual assumptions

An authority may adopt a decision based upon an incorrect factual assumption. For example, it may assume that a process introduces a particular substance into the finished food. The manufacturer may provide analytical evidence contradicting that assumption. The court may examine whether the factual foundation of the decision was adequately established.

308.6. Review of inconsistent decisions

Where the same authority adopts contradictory decisions concerning materially identical circumstances, the court may examine the reasons for the difference. However, previous decisions must be analysed carefully. Differences in evidence, legislation or operating conditions may justify different outcomes.

309. Conflicting criteria as an industrial and economic problem

309.1. Compliance uncertainty

A manufacturer may need to satisfy several authorities with different documentary expectations. This can increase the cost of compliance. However,

not every additional requirement is unlawful. The relevant question is whether it possesses a legal basis and is appropriate to the authority's functions.

309.2. Duplicative testing

Different authorities may request similar analytical evidence. Where the requests concern the same legal requirement and factual conditions, duplication may raise questions concerning coordination and administrative efficiency. Nevertheless, a new test may be justified by changes in production, sampling conditions or risk.

309.3. Investment uncertainty

Unpredictable interpretations can discourage investment in innovative technologies. Manufacturers may hesitate to adopt new processes where the applicable compliance criteria remain unclear. This effect is economically relevant, although it does not by itself establish a legal infringement.

309.4. Competitive asymmetry

If comparable operators face materially different requirements without adequate justification, competitive conditions may be distorted. However, a legal challenge requires identification of the applicable obligations and evidence of relevant comparability.

309.5. The danger of regulatory forum shopping

Operators may seek the authority perceived as most permissive. Such behaviour may be commercially understandable. However, it cannot establish compliance where the applicable legislation imposes mandatory requirements. The correct objective is consistent lawful enforcement, not selection of the least demanding interpretation.

310. Inter-administrative coordination as a quality-assurance system

310.1. Beyond formal cooperation

Coordination should not be understood solely as exchanging administrative correspondence. It may require common technical criteria, shared training, consistent risk classification and effective mechanisms for resolving interpretative disagreements.

310.2. National control planning

The multiannual national control planning system provides an institutional basis for harmonising approaches. However, planning must remain compatible with the competences of the participating authorities.

310.3. Auditing consistency

Audits may identify divergent practices. For example, they may reveal that different authorities apply incompatible interpretations of the same directly applicable Union requirement. Such findings may justify corrective institutional action.

310.4. Common technical guidance

Guidance may promote consistency.

However, its legal status must be identified. Non-binding guidance cannot automatically impose new obligations beyond the applicable legislation. The relationship between guidance, binding law and administrative instructions requires careful analysis.

310.5. Escalation mechanisms

Where inspectors disagree concerning a technically complex issue, referral to appropriately qualified technical or legal specialists may improve decision-making. This is a proposed institutional practice rather than a universal statutory requirement.

310.6. The need for documented resolutions

Interpretative disagreements should be resolved through documented reasoning. A recorded institutional decision can improve future consistency. However, such decisions must remain compatible with binding legislation and any applicable confidentiality requirements.

311. Original doctrinal contribution: The Interadministrative Consistency and Regulatory Legitimacy Framework

The research proposes the Interadministrative Consistency and Regulatory Legitimacy Framework (ICRLF). ICRLF is an original academic model, not an

established judicial test. Its purpose is to distinguish lawful territorial variation from inconsistent or legally defective administrative enforcement.

311.1. Ten dimensions

Dimension	Principal inquiry
1. Competence	Which authority possesses the relevant statutory power?
2. Regulatory hierarchy	Which Union, State, autonomous-community or local provisions apply?
3. Factual comparability	Are the situations being compared materially equivalent?
4. Technical evidence	Do differences arise from distinct scientific or operational facts?
5. Administrative precedent	What previous decisions or criteria are relevant?
6. Motivation	Has any departure from applicable previous criteria been adequately reasoned?
7. Coordination	Were relevant interadministrative mechanisms used where required?
8. Proportionality	Are differences in regulatory treatment legally justified?
9. Market effects	Does the measure create a potentially unlawful barrier to economic activity?
10. Remedies	Which administrative, institutional or judicial mechanisms are available?

311.2. The model's principal contribution

ICRLF distinguishes three categories of divergence. Category I - Lawful diversity. Different outcomes arise from legitimate differences in competence, facts, risk or applicable legislation. Category II - Correctable inconsistency. Divergence arises from unclear guidance, inadequate coordination or inconsistent administrative practice, without necessarily establishing invalidity of an individual act.

Category III - Legally defective enforcement. The particular measure violates an applicable legal requirement, exceeds competence, lacks required justification or otherwise satisfies a recognised ground of challenge.

The categories are analytical.

They do not replace the statutory rules governing validity or remedies.

311.3. A proposed decision sequence

Stage	Required action	Purpose
1	Identify the authorities	Determine the institutions involved and their respective competences.
2	Identify the legal rules	Separate binding Union, State, regional and local requirements.
3	Compare the facts	Establish whether the affected operators or processes are materially comparable.
4	Examine the evidence	Identify technical differences that may justify divergent treatment.
5	Review administrative history	Examine formal decisions, previous criteria and relevant communications.
6	Test the justification	Assess motivation, proportionality and consistency obligations.
7	Classify the divergence	Distinguish lawful diversity, institutional inconsistency and legal defect.
8	Select the remedy	Determine the appropriate coordination, appeal or judicial mechanism.

311.4. The significance of constitutional balance

The framework does not presume that uniformity is always legally required. STC 79/2017 demonstrates that territorial autonomy may justify regulatory diversity. However, binding Union requirements and statutory coordination duties limit the permissible scope of inconsistency.

311.5. The significance of legal certainty

Predictability is particularly important for industrial investment. Nevertheless, legal certainty must be reconciled with the Administration's obligation to correct errors and respond to new risks.

311.6. Research potential

ICRLF could be tested through comparative analysis of official control decisions across autonomous communities. Relevant variables might include inspection frequency, technical criteria, legal grounds, risk classification, documentary demands and judicial outcomes. Such research could identify whether administrative fragmentation produces measurable differences in regulatory burden.

312. Applied industrial scenarios

Scenario A. Different interpretations of the same Union hygiene requirement

A manufacturer operates two establishments in different autonomous communities. Both employ the same validated process. One authority accepts the compliance evidence. Another requires additional documentation. The analysis must determine whether the difference arises from distinct factual conditions, lawful risk assessment or an inconsistent interpretation of the same binding requirement. Acceptance by one authority does not automatically invalidate the other's position.

However, the difference may justify a request for reasoned clarification and appropriate coordination.

Scenario B. A previous favourable inspection followed by an adverse decision

An operator has used a process for several years without recorded objection. A new inspector identifies a legal deficiency. The manufacturer invokes legitimate expectations. The analysis must distinguish the legal effects of previous inspection records from those of a formal authorisation. The authority may correct an earlier mistake. However, the applicable motivation and procedural requirements remain relevant.

Scenario C. Contradictory regional classifications of a processing technology

Two authorities adopt different legal classifications of the same technology. The manufacturer argues that the technology is governed by a directly applicable Union definition. The dispute requires identification of the relevant Union legislation and the actual technological function. Where the legal definition is harmonised, territorial administrative preference cannot replace it. Nevertheless, different factual applications may justify different classifications.

Scenario D. Duplicative official controls

A manufacturer receives overlapping requests from different competent authorities. The requests concern substantially identical documentation. The operator alleges unnecessary regulatory burden. The analysis must identify the separate statutory functions of the authorities and whether coordination mechanisms apply. Duplication may reveal inefficiency without necessarily establishing that either request is unlawful.

Scenario E. Market access restrictions based upon regional criteria

An operator lawfully manufactures a food product in one autonomous community. Another authority restricts its commercialisation. The manufacturer invokes market unity. The legal analysis must consider the applicable Union rules, the competence of the restricting authority, the current market unity legislation and the constitutional limits established by STC 79/2017. Lawful manufacture in one territory does not automatically exempt the product from every applicable requirement elsewhere.

313. Conclusions of the tenth instalment of Part II

Spain's decentralised food safety enforcement system operates within a complex legal structure combining European Union requirements, constitutional competences and national coordination obligations. Administrative diversity is not inherently unlawful. Different authorities may legitimately exercise different powers and respond to different risks. However, decentralisation does not eliminate the duty to apply binding Union legislation consistently.

Regulation (EU) 2017/625 expressly requires effective coordination and consistency among competent authorities. Law 17/2011 establishes national mechanisms concerning official control planning and auditing. Law 40/2015 incorporates coordination, good faith and legitimate expectations among the general principles of public administration. Law 39/2015 requires reasons for specified departures from previously followed administrative criteria.

STC 79/2017 establishes that market unity must be reconciled with constitutionally protected territorial autonomy.

The central conclusion is:

The legal objective is not absolute uniformity of food safety enforcement, but consistency in the application of binding requirements, reasoned differentiation where relevant circumstances differ, and effective institutional mechanisms for correcting unjustified administrative divergence.

The proposed ICRLF framework provides a structured methodology for distinguishing lawful diversity from correctable inconsistency and legally defective enforcement.

Primary legislation and verified jurisprudence

1. Spanish Constitution — Articles 2, 9.3, 14, 38, 103, 106, 139, 148 and 149.

2. Regulation (EU) 2017/625 — Articles 4–5, 9 and 109–111.

3. Spanish Law 17/2011 on Food Safety and Nutrition — Articles 14–16.

4. Spanish Law 40/2015 — Article 3 and the framework for inter-administrative relations.

5. Spanish Law 39/2015 — Articles 34–35 and the rules governing administrative decisions.

6. Spanish Law 20/2013 on the Guarantee of Market Unity — Current consolidated provisions, subject to constitutional review and subsequent amendments.

7. Spanish Constitutional Court, STC 79/2017, 22 June 2017 — Market unity and territorial autonomy, ECLI:ES:TC:2017:79.

8. Court of Justice, Upjohn, C-120/97, 21 January 1999 — Judicial review of complex scientific assessments in pharmaceutical regulation; cited by analogy.

CHAPTER 25

314. Regulatory Silence, Failure to Act and Administrative Delay in Food Safety Enforcement

Judicial remedies against institutional inaction, the continuing legality of precautionary restrictions and the distinction between administrative silence, material inactivity and enforceable duties.

Abstract

Administrative inaction may cause economic consequences as serious as an unlawful inspection order. A food manufacturer may face prolonged product immobilisation, unresolved requests for authorisation, delayed laboratory decisions, unanswered submissions or continued restrictions after the factual circumstances supporting them have changed.

Spanish administrative law establishes several mechanisms for addressing such situations. Law 39/2015 requires administrative authorities to issue express decisions and regulates the consequences of administrative silence. Law 29/1998 provides judicial remedies concerning administrative inactivity, failure to execute final administrative acts and material action undertaken without an adequate legal basis.

These mechanisms are not interchangeable.

The expiry of a decision-making period does not automatically authorise every food-related activity. Nor does every failure to respond constitute actionable inactivity under Article 29 of Law 29/1998. Conversely, an authority cannot necessarily preserve a restrictive measure indefinitely by declining to reconsider the evidence supporting it.

The European official controls framework introduces a further dimension: precautionary and corrective measures must remain connected to their statutory purpose, the relevant evidence and the continuing circumstances of the risk. This instalment examines administrative delay as a distinct regulatory problem, with

particular attention to the relationship between procedural deadlines, judicial protection, scientific reassessment and economic injury.

It proposes an original **Administrative Inaction and Continuing Restriction Assessment Framework (AICRAF)** to distinguish legally permissible administrative processing from unjustified institutional paralysis. The central thesis is that **administrative legality requires not only that an initial regulatory intervention possess a lawful foundation, but also that competent authorities fulfil their continuing duties to decide, reassess and act within the limits established by law**.

Keywords: Administrative silence; administrative inactivity; food safety enforcement; precautionary restrictions; product immobilisation; judicial review; Article 29 LJCA; Law 39/2015; regulatory delay; public liability; effective judicial protection.

314.1. Introduction: The legal significance of regulatory inaction

Official food controls are commonly analysed through positive administrative acts. An inspector orders immobilisation. A competent authority requires withdrawal. A laboratory reports non-compliance. An administration imposes a sanction. However, regulatory intervention may also produce legal and economic consequences through omission. An authority may fail to issue a required decision. It may delay reconsideration of a restriction. It may decline to execute a final administrative resolution.

It may leave an operator without an effective response to material evidence. These situations require careful legal classification.

Not every delay is unlawful.

Not every unanswered request creates a judicially enforceable obligation to act in the precise manner demanded by the operator. And not every administrative silence mechanism produces a favourable decision. Nevertheless, institutional inactivity cannot be treated as legally irrelevant merely because the Administration has not adopted a new formal act.

The decisive questions are whether a legally enforceable duty exists, whether the applicable procedural requirements have been satisfied and whether the Administration's omission produces consequences subject to judicial control.

315. Article 21 of Law 39/2015: The duty to issue an express decision

Article 21 establishes the general obligation of the Administration to issue and notify an express decision in administrative proceedings, subject to the statutory exceptions. This obligation is a cornerstone of administrative legality.

315.1. The distinction between deciding and deciding favourably

The duty to resolve does not mean that the authority must accept the operator's request. A manufacturer may submit an application seeking recognition of a particular regulatory classification. The Administration may be required to decide. However, the substantive outcome depends upon the applicable legislation and evidence.

315.2. Maximum periods

The maximum period for issuing and notifying a decision is generally established by the legislation governing the relevant procedure. Where no specific period is prescribed, Article 21 establishes a general period of three months. The period may be subject to legally authorised suspension or extension. It would therefore be incorrect to assume that every food safety proceeding must conclude within three months.

315.3. The obligation survives silence

The occurrence of administrative silence does not generally extinguish the duty to issue an express decision. The legal effects of a later decision depend upon whether the silence is positive or negative and upon the applicable statutory provisions.

315.4. Practical importance

A food operator should identify the specific procedure, its legal basis, the applicable decision period and any valid suspension or extension. Without those elements, an allegation of unlawful delay may be premature.

316. Administrative silence under Article 24: A legal fiction with defined limits

316.1. Positive and negative silence

Article 24 of Law 39/2015 establishes the general framework for administrative silence in proceedings initiated at the request of an interested party. As a general rule, the expiry of the maximum period without notification produces positive silence, subject to the exceptions established by legislation or applicable Union or international law. The provision expressly establishes negative silence in certain categories, including public liability proceedings and specified procedures involving environmental interests.

The legal effect must therefore be determined for the particular proceeding.

316.2. Positive silence is not universal regulatory authorisation

A manufacturer cannot assume that an unanswered request permits it to market a food, ingredient or technological application requiring prior authorisation under Union law. Where the applicable Union framework requires an express authorisation or establishes a contrary silence rule, the national general presumption cannot override that requirement.

316.3. Positive silence and essential statutory requirements

Article 47.1(f) of Law 39/2015 addresses acts by which rights or powers are acquired without the essential requirements for their acquisition. Its application to purported authorisations arising by silence requires a precise legal assessment. The Administration cannot simply disregard every favourable silent act by asserting that it considers the underlying activity undesirable. Equally, positive silence cannot be treated as a mechanism for bypassing essential legal requirements.

316.4. Negative silence is not substantive rejection

Negative silence generally operates as a procedural mechanism enabling the interested party to pursue the applicable remedies. It does not necessarily establish that the Administration has examined the evidence and lawfully rejected the application on its merits. This distinction is particularly important where the authority has failed to assess a complex technical dossier.

316.5. Subsequent express decisions

Article 24.3 distinguishes the consequences of later express decisions. Following positive silence, the subsequent decision must ordinarily confirm the favourable result. Following negative silence, the Administration is not bound to reproduce the presumed rejection. This reinforces the distinction between silence as a procedural consequence and an actual reasoned decision.

317. Proceedings initiated ex officio: Article 25

317.1. The different legal structure

Article 25 governs the failure to issue an express decision in proceedings initiated by the Administration. The consequences depend upon the nature of the proceeding. Where proceedings may produce favourable rights or legal situations, appearing interested parties may be entitled to treat their claims as rejected. Where the Administration exercises sanctioning or other intervention powers capable of producing adverse effects, expiry of the applicable period may result in *caducidad* under the statutory conditions.

317.2. Caducity is not acquittal

The expiry of an administrative proceeding does not necessarily establish that the underlying conduct was lawful. Nor does it automatically prevent the Administration from initiating new proceedings where legislation permits and the relevant infringement has not prescribed.

317.3. The relationship with precautionary measures

The consequences of procedural expiry for an associated precautionary measure require examination of the applicable legal provisions and the nature of the measure. An authority cannot automatically preserve every restriction merely because it remains concerned about the product. However, expiry of one proceeding does not necessarily prevent a new, independently justified protective intervention under a separate lawful power.

317.4. Distinguishing proceedings

A sanctioning proceeding, an investigation into suspected non-compliance and an application for authorisation may be governed by different procedural rules. Their deadlines and consequences must not be conflated.

318. Article 29 of Law 29/1998: Judicial protection against administrative inactivity

318.1. A specific judicial remedy

Article 29 establishes a mechanism for challenging administrative inactivity. However, it does not create a universal action compelling the Administration to perform every activity requested by a citizen or business. The provision distinguishes two legally defined situations.

318.2. Article 29.1: A concrete obligation

Article 29.1 applies where the Administration is obliged, by a general provision requiring no implementing act or by an administrative act, contract or agreement, to perform a concrete obligation in favour of one or more identified persons. The entitled person may demand performance. If the Administration does not comply within three months of the demand, the claimant may bring the corresponding contentious-administrative action. The existence of a concrete enforceable obligation is decisive.

318.3. Article 29.2: Failure to execute a final administrative act

Article 29.2 concerns failure to execute a final administrative act. The interested party may request execution. If the Administration fails to act within one month, the corresponding judicial action may be brought. The legal object differs from that of Article 29.1. The claimant is seeking execution of an existing final act, not the creation of a new discretionary decision.

318.4. The limits of Article 29

A manufacturer may demand that an authority approve a new processing technology. However, if approval requires technical evaluation and the exercise of legally conferred judgment, Article 29.1 will not necessarily permit a court to compel the authority to grant that approval. The operator may have a right to a decision. It does not follow that it has a right to a particular favourable outcome.

318.5. The Supreme Court's approach

The Supreme Court has emphasised that Article 29.1 requires a sufficiently concrete obligation and cannot be extended to claims requiring the court to define

the content of a discretionary administrative task. This distinction is central to selecting the correct judicial remedy.

319. STS 559/2025: Administrative inactivity is not every failure to perform a desired action

319.1. Identification

Spanish Supreme Court, Third Chamber, Section Four, Judgment 559/2025 of 13 May 2025, proceedings 620/2024, ECLI:ES:TS:2025:2262. The proceedings concerned an alleged failure to review allowances established under Royal Decree 462/2002. They did not concern food safety enforcement.

319.2. The central issue

The claimant sought to characterise the absence of regulatory revision as administrative inactivity actionable under Article 29.1. The Supreme Court rejected the claim because the statutory requirements for that particular remedy were not satisfied. The Court emphasised that Article 29.1 requires a concrete obligation whose performance does not depend upon the further exercise of administrative discretion or the determination of elements not already established.

319.3. The distinction between obligation and discretion

The judgment demonstrates that a general administrative responsibility does not necessarily amount to a specific enforceable obligation under Article 29.1. A statutory power to regulate, inspect or assess does not automatically create an individual right to compel a particular result through that procedure.

319.4. Application to food safety

A manufacturer may argue that an authority should conduct further scientific research or establish new regulatory criteria. Those requests may concern legitimate institutional responsibilities. However, they do not necessarily constitute concrete obligations enforceable under Article 29.1. The appropriate remedy may instead concern the authority's failure to decide a specific application or the legality of an existing restriction.

Established holding: Article 29.1 cannot be extended to obligations lacking the statutory specificity required by that provision.

Application to food controls: The judgment provides a general administrative-law principle; it is not a direct precedent concerning food inspection.

320. STS 915/2026: A recent reaffirmation of the limits of Article 29.1

320.1. Identification

Spanish Supreme Court, Third Chamber, Section Four, Judgment 915/2026 of 15 July 2026, cassation appeal 5797/2023, ECLI:ES:TS:2026:3204. The case concerned an alleged obligation to construct an educational facility in the Valencian Community. Although unrelated to food regulation, the judgment provides a particularly recent and explicit statement of the requirements governing administrative inactivity.

320.2. The legal doctrine

The Supreme Court confirmed that Article 29.1 requires a concrete obligation arising from one of the legally recognised sources. The obligation must concern a specific performance in favour of identified persons entitled to demand it. Crucially, the performance must not require the Administration to exercise an unresolved margin of assessment or discretion.

320.3. Why the judgment matters

The Court distinguished legally actionable inactivity from the broader problems of administrative inefficiency, delay or failure to fulfil general public responsibilities. Not every unsatisfactory omission falls within Article 29.1. This distinction prevents the exceptional judicial remedy from becoming a mechanism through which courts assume ordinary administrative decision-making functions.

320.4. Application to food regulation

Consider an operator requesting the immediate lifting of an immobilisation order. If lifting requires assessment of new laboratory findings and unresolved safety risks, the operator cannot assume that Article 29.1 automatically entitles it to an order compelling release. The correct route may involve challenging the existing measure, seeking a decision on reconsideration and requesting interim judicial protection. By contrast, failure to execute a final administrative act ordering a specific action may engage Article 29.2.

320.5. The significance of the precedent

Established holding: Article 29.1 is confined to sufficiently concrete obligations meeting the statutory requirements.

Original sectoral implication: Food businesses should classify the Administration's alleged omission before selecting the judicial remedy. The judgment supports procedural precision rather than a general judicial power to compel every regulatory action requested by an operator.

321. The continuing legality of precautionary restrictions

321.1. Initial legality is not permanent justification

A product immobilisation may be justified when the authority possesses credible evidence of a potential food safety risk. However, the factual circumstances may change. Further analyses may become available. The operator may correct the identified deficiency. The product may be shown to satisfy the applicable requirements. The legal question then concerns whether continued restriction remains justified.

321.2. Article 137 of Regulation (EU) 2017/625

Article 137 requires competent authorities to investigate suspected non-compliance in order to confirm or eliminate the suspicion. Where necessary, the authority may adopt intensified controls or official detention for an appropriate period. The provision therefore connects protective intervention with investigation. It does not establish that suspicion alone authorises indefinite detention without regard to subsequent findings.

321.3. Article 138: Established non-compliance

Where non-compliance is established, Article 138 requires appropriate corrective measures. The authority must consider the nature of the non-compliance and the operator's previous compliance record. The measures selected must remain connected to the statutory objectives.

321.4. The importance of new evidence

Suppose the original immobilisation rests upon a laboratory result suggesting contamination. A subsequent legally relevant determination materially undermines that finding. The authority must assess the implications of the new

evidence under the applicable legal framework. However, the new result may not eliminate every relevant concern. Other evidence or independent grounds for restriction may remain.

321.5. Dynamic proportionality

This research uses the expression **dynamic proportionality** to describe the need to assess the continuing justification of a restriction as relevant circumstances evolve. The expression is an analytical formulation, not a separate statutory doctrine. The underlying legal requirements arise from the applicable provisions governing the measure, proportionality and administrative decision-making. A measure proportionate when adopted may become excessive if its factual justification materially changes.

321.6. No automatic release rule

The existence of delay does not automatically entitle an operator to release potentially unsafe food. Public health protection remains central. The relevant question is whether the authority possesses a lawful and adequately supported basis for maintaining the measure.

322. Article 56 of Law 39/2015: Modification and termination of provisional measures

Article 56 provides a particularly important statutory mechanism where restrictions have been adopted as provisional measures in an administrative proceeding.

322.1. Proportionality and lesser burden

Article 56.1 requires sufficient grounds and compliance with proportionality, effectiveness and the principle of lesser onerousness when adopting provisional measures during proceedings. This matters where several measures could achieve the same legitimate protective objective.

322.2. Measures before commencement

Article 56.2 permits specified provisional measures before proceedings begin in situations of urgent necessity. Such measures must be confirmed, modified or lifted in the commencement decision adopted within fifteen days. They cease to

have effect if proceedings are not initiated within that period or the commencement decision fails expressly to address them.

322.3. Modification during proceedings

Article 56.5 permits provisional measures to be lifted or modified, ex officio or at the request of a party, because of circumstances arising later or circumstances that could not previously have been considered. This is a direct statutory basis for examining new information affecting an existing measure.

322.4. Expiry upon final resolution

Article 56.5 also provides that provisional measures expire when the administrative resolution ending the relevant proceeding takes effect. The provision must be applied according to the legal nature of the measure. Not every restriction adopted under food safety legislation is necessarily governed exclusively by Article 56. Sector-specific powers may require separate analysis.

322.5. The central distinction

A manufacturer should identify whether the disputed restriction is:

- A provisional measure under Article 56.
- An official detention or protective measure under sector-specific food law.
- A final corrective measure following established non-compliance.
- A material intervention without an adequate formal legal basis.

Different categories may engage different rules concerning duration, review and judicial challenge.

323. *Vía de hecho*: Material intervention without an adequate legal foundation

323.1. Article 30 of Law 29/1998

Article 30 establishes a judicial route for challenging *vía de hecho*. The interested party may demand that the Administration cease the relevant conduct. If the demand is not made, or is not satisfied within ten days after submission, the claimant may bring the corresponding judicial action under the applicable procedural rules.

323.2. The distinction from ordinary inactivity

Administrative inactivity concerns failure to perform an obligation. *Vía de hecho* concerns material administrative action lacking the legally required foundation. The concepts are not interchangeable.

323.3. An illustrative example

An authority physically prevents a manufacturer from operating a production line without identifying a legally adequate order or power supporting the intervention. The operator may need to examine whether the circumstances constitute *vía de hecho*. However, the absence of a document immediately available to the operator does not automatically establish that the Administration lacks legal authority. The full factual and procedural context must be examined.

323.4. Continuing material intervention

A material restriction may continue after the legal basis supporting it has expired or ceased to apply. That situation may raise questions concerning the continued lawfulness of the intervention. Nevertheless, classification as *vía de hecho* depends upon the statutory and jurisprudential requirements.

323.5. Procedural consequences

The route selected affects deadlines and available judicial remedies. A claimant should not characterise every defective administrative act as *vía de hecho* merely to avoid the ordinary procedural requirements for challenging acts.

324. Interim judicial protection against continuing regulatory damage

324.1. Articles 129–136 of Law 29/1998

The contentious-administrative framework permits interim measures under the applicable conditions. These mechanisms are particularly important where continued restriction may cause irreversible commercial consequences before final judgment.

324.2. Article 130: Loss of the legitimate purpose of the appeal

Article 130 requires consideration of whether enforcement or application of the challenged action could cause the appeal to lose its legitimate purpose. The court

must also consider whether interim relief would seriously disturb general or third-party interests. Food safety disputes frequently require careful balancing.

324.3. Public health and interim relief

An operator may demonstrate substantial economic harm. However, the court must consider the public health risks associated with suspending the measure. The economic importance of a consignment does not automatically justify its release.

324.4. Article 135: Particular urgency

Article 135 establishes a procedure for situations of particular urgency. The statutory conditions and subsequent adversarial safeguards must be respected. The procedure should not be treated as an automatic emergency remedy whenever the operator considers a restriction commercially damaging.

324.5. Article 136: Inactivity and *vía de hecho*

Article 136 contains specific provisions concerning interim measures in proceedings involving Article 29 inactivity and Article 30 *vía de hecho*. These provisions may be significant where the legal dispute concerns continuing omission or material intervention. However, their application depends upon the correct procedural classification of the claim.

324.6. The importance of selecting the correct relief

A manufacturer may seek suspension of a restriction, an order requiring specific administrative performance or another legally available protective measure. The relief must correspond to the legal nature of the dispute. The court cannot necessarily grant an interim measure that effectively creates an authorisation the operator has no substantive right to obtain.

325. Administrative delay and public liability

325.1. Delay as a possible source of damage

Regulatory delay may cause identifiable economic losses.

Products may deteriorate.

Storage costs may increase.

Contracts may be cancelled.

Production capacity may remain unused. However, the existence of these losses does not automatically establish public liability.

325.2. The substantive requirements

Articles 32–34 of Law 40/2015 establish the general public liability framework. The claimant must demonstrate effective, economically assessable and individualised injury, causation and the absence of a legal duty to bear the damage, subject to the applicable exclusions.

325.3. The distinction between lawful and unlawful delay

Some regulatory investigations legitimately require time. A scientifically complex contamination incident may demand additional testing. The relevant question is whether the duration and administrative conduct comply with the applicable law. An operator's preference for faster resolution is not, by itself, proof of unlawful delay.

325.4. Identifying the compensable period

Suppose an immobilisation was justified for the first ten days. The authority then received evidence requiring reassessment but did not act for a further thirty days. A compensation analysis may need to distinguish losses attributable to the initial lawful period from losses attributable to any later legally unjustified continuation. However, the point at which continued restriction became unlawful must be established rather than assumed.

325.5. The counterfactual assessment

A useful economic question is:

What would probably have occurred if the Administration had performed its legal duties at the relevant time? The answer may depend upon the time reasonably required for review, the quality of the new evidence and the measures the authority could lawfully have adopted.

325.6. The danger of assuming automatic causation

A product may become commercially unusable during immobilisation. However, deterioration may also result from its inherent shelf life, inadequate storage or other causes. The claimant must establish the relevant causal relationship.

326. The right to an administrative decision and the right to a favourable outcome

326.1. A necessary distinction

An operator may possess a right to have an application processed and decided. That does not necessarily mean that the operator possesses a right to the authorisation requested.

326.2. Regulatory classification requests

A manufacturer may ask an authority to determine whether a particular substance or process falls within a regulatory category. The applicable law may require a formal procedure. The authority's duty to decide depends upon the statutory framework. However, the operator cannot necessarily compel a particular classification merely by invoking administrative delay.

326.3. Requests for scientific reconsideration

An operator may submit new evidence and request reconsideration of a protective measure. The authority must act consistently with the applicable procedural and substantive rules. However, the legal consequences of failing to respond depend upon the nature of the request and the measure.

326.4. Requests for general regulatory guidance

An operator may seek general interpretative guidance.

Such a request may be useful.

However, the Administration does not necessarily possess a legally enforceable obligation to issue a binding interpretation in every circumstance. The distinction between formal proceedings and informal consultations must be maintained.

326.5. The judicial boundary

Courts control administrative legality. They do not generally replace competent authorities in every scientific or discretionary decision. The correct remedy may require the Administration to decide lawfully rather than require the court to impose the operator's preferred substantive outcome.

327. Original doctrinal contribution: The Administrative Inaction and Continuing Restriction Assessment Framework

The research proposes the **Administrative Inaction and Continuing Restriction Assessment Framework (AICRAF)**. AICRAF is an original academic analytical proposal, not an established judicial test. Its purpose is to distinguish ordinary procedural delay, actionable inactivity and the unlawful continuation of regulatory restrictions.

327.1. Nine dimensions

Dimension	Principal inquiry
1. Administrative conduct	Is the problem failure to decide, failure to perform, failure to execute or continuing material intervention?
2. Legal obligation	What statutory or administrative duty is allegedly unfulfilled?
3. Procedural classification	Which administrative or judicial procedure applies?
4. Time limits	What deadline governs the duty and how is it calculated?
5. Scientific circumstances	Has new evidence materially changed the regulatory assessment?
6. Continuing justification	Does the restriction remain supported by the applicable legal and factual grounds?
7. Proportionality	Is continued intervention appropriate and no more burdensome than legally justified?
8. Economic consequences	What actual damage is attributable to the relevant administrative conduct?
9. Remedies	Which administrative, interim or judicial mechanism is available?

327.2. The model's central contribution

AICRAF separates three propositions frequently confused in regulatory disputes.

The Administration has not acted.

The Administration has failed to fulfil a legally enforceable duty. The failure gives rise to a particular judicial remedy. The first proposition may be factually obvious. The second requires legal classification. The third depends upon the procedural framework.

327.3. A proposed decision sequence

1

Identify the omission

Determine precisely what the Administration has failed to do.

2

Establish the duty

Identify the provision, act or agreement allegedly requiring performance.

3

Determine the deadline

Calculate the applicable period and any lawful suspension.

4

Classify the remedy

Distinguish silence, Article 29 inactivity, non-execution and vía de hecho.

5

Assess new evidence

Determine whether circumstances supporting the restriction have changed.

6

Examine proportionality

Assess the continuing necessity and legal foundation of intervention.

7

Evaluate damage

Identify actual losses and their causal relationship with the omission.

8

Seek protection

Select the appropriate administrative or judicial mechanism.

327.4. The importance of continuing assessment

AICRAF places particular emphasis upon the legal status of restrictions after their initial adoption. The framework recognises that new evidence may alter the

justification for continued intervention. However, it does not presume that every delay or new laboratory report requires immediate release of goods.

327.5. The framework's limits

AICRAF does not create new procedural rights. It does not expand Article 29 beyond the limits established by statute and jurisprudence. Its function is to organise legal analysis and evidence.

328. Applied industrial scenarios

Scenario A. An unanswered request for regulatory classification

A food ingredient manufacturer submits a formal request concerning the regulatory classification of a new application. The authority fails to issue a decision within the applicable period. The operator must determine whether the request initiated a legally regulated proceeding, whether a decision period applies and what effect administrative silence produces. The absence of a response does not automatically establish authorisation.

Scenario B. Immobilisation followed by new analytical evidence

An authority immobilises a consignment following a credible analytical concern. The operator subsequently provides new evidence. The authority does not reassess the restriction. The analysis must identify the legal nature of the measure, the significance of the new evidence and the applicable duties concerning reconsideration.

Scenario C. Failure to execute a final administrative decision

A competent authority adopts a final decision requiring a specific administrative action. The responsible service fails to execute it. The operator may examine Article 29.2 of Law 29/1998, subject to the statutory requirements.

Scenario D. Material restriction without an adequate legal basis

An establishment remains physically closed despite the absence of an identifiable legal basis supporting continued closure. The operator may need to examine whether the circumstances constitute *vía de hecho*. However, the legal characterisation depends upon the actual administrative acts, powers and factual circumstances.

Scenario E. Delay causing product deterioration

A manufacturer experiences prolonged immobilisation of perishable goods. The products lose commercial value. The operator alleges public liability. The analysis must distinguish lawful regulatory detention from any legally unjustified period and establish causation and economic loss.

329. Conclusions of the eleventh instalment of Part II

Administrative inaction is a significant dimension of food safety enforcement. Its legal treatment requires careful differentiation. Article 21 of Law 39/2015 establishes the general duty to issue express decisions. Articles 24 and 25 regulate the consequences of failure to decide in proceedings initiated by interested parties and by the Administration. Article 29 of Law 29/1998 establishes a specific judicial remedy concerning concrete administrative obligations and failure to execute final acts.

The Supreme Court's judgments 559/2025 and 915/2026 confirm that the remedy cannot be extended to every form of administrative inefficiency or discretionary omission. Article 30 separately addresses *vía de hecho*. Regulation (EU) 2017/625 requires investigation of suspected non-compliance and appropriate action where non-compliance is established. Article 56 of Law 39/2015 provides mechanisms for modifying or lifting provisional measures under its scope.

These provisions demonstrate that the legality of a restriction may require continuing assessment.

The central conclusion is:

An administration's initial authority to intervene does not confer an unlimited entitlement to preserve a restrictive measure without regard to subsequent evidence, applicable deadlines and continuing statutory requirements. Nevertheless, judicial remedies against inactivity must be selected according to the precise nature of the unfulfilled duty and the procedural conditions established by law.

The proposed AICRAF framework provides a structured method for making those distinctions.

Primary legislation and judicial authorities

1. Spanish Law 39/2015 — Articles 21–25 and 56.
2. Spanish Law 29/1998 — Articles 25, 29–32, 46 and 129–136.
3. Regulation (EU) 2017/625 — Articles 137–138.
4. Supreme Court, STS 559/2025, 13 May 2025 ECLI:ES:TS:2025:2262; Article 29.1 LJCA.
5. Supreme Court, STS 915/2026, 15 July 2026 — ECLI:ES:TS:2026:3204; concrete obligations and administrative inactivity.
6. Spanish Law 40/2015 — Articles 32–34 concerning public liability.
7. Regulation (EC) No 178/2002 — Articles 6–7 concerning risk analysis and precaution.

The present instalment adds particular value through its treatment of Article 56 of Law 39/2015, the distinction between provisional and sector-specific protective measures, and the explicit examination of STS 915/2026.

CHAPTER 26

330. Judicial Enforcement of Food Safety Judgments: Administrative Compliance, Execution of Court Orders, Institutional Resistance and Effective Remedies

The constitutional right to effective judicial protection, the binding force of judgments, administrative circumvention and the judicial powers necessary to secure genuine compliance.

Abstract

Judicial review of official food controls would offer incomplete protection if public authorities could disregard, postpone or neutralise the practical consequences of judicial decisions.

A food business may successfully challenge an unlawful product immobilisation, manufacturing suspension, administrative sanction or other restrictive measure. Nevertheless, the resulting judgment may be deprived of practical effect if the competent authority refuses to implement it, delays compliance, adopts measures reproducing the annulled decision or invokes administrative difficulties without satisfying the statutory conditions governing execution.

Spanish constitutional law recognises the execution of judicial decisions as an essential component of effective judicial protection. Article 118 of the Constitution establishes the duty to comply with final judgments and other judicial decisions. Articles 103–113 of Law 29/1998 develop the judicial execution framework for contentious-administrative proceedings.

The distinction between formal compliance and effective execution is especially important in food safety disputes, where time-sensitive commercial goods, perishable inventory, manufacturing capacity and market access may be affected.

This instalment examines the legal consequences of administrative resistance to judicial decisions, the limits of subsequent administrative action, the treatment of material or legal impossibility, and the powers available to courts when public authorities fail to execute judgments.

It also considers the relationship between judicial execution, interim protection, compensation and the continuing obligation to protect public health. The analysis proposes an original **Judicial Execution and Regulatory Compliance Assessment Framework (JERCAF)**.

Its central thesis is that **judicial protection is not exhausted by obtaining a favourable judgment: it requires implementation of the judgment's operative legal consequences, subject to the statutory limits of execution and the Administration's continuing lawful regulatory responsibilities**.

Keywords: *Judicial execution; food safety enforcement; Article 24 Spanish Constitution; Article 118 Spanish Constitution; Law 29/1998; administrative resistance; ineffective compliance; product immobilisation; regulatory circumvention; judicial remedies.*

330.1. Introduction: A judgment that is not executed may provide no effective remedy

Consider a food manufacturer whose products have been immobilised following an official inspection. The operator challenges the restriction. After judicial proceedings, the court annuls the administrative decision. However, the competent authority does not take the steps necessary to give effect to the judgment.

The products remain unavailable.

The company continues to incur storage costs.

Customers cancel contracts.

The economic consequences of the original intervention continue despite the judicial ruling. A related problem arises where the Administration formally acknowledges the judgment but adopts another decision producing substantially the same restriction. The new decision may be lawful if it rests upon genuinely new circumstances and a valid statutory basis. Alternatively, it may constitute an attempt to circumvent the judgment.

The distinction is fundamental.

Judicial execution must secure the result required by the judgment. At the same time, a judgment annulling a particular administrative act does not necessarily exempt the operator permanently from future lawful food safety controls.

The central legal questions are therefore:

- What exactly did the judgment decide?
- What concrete obligations follow from its operative provisions?
- Which authority must implement them?
- Has the Administration genuinely complied?
- Does any subsequent administrative action possess an independent legal foundation?
- What remedies are available when execution is obstructed?

These questions require analysis of constitutional law, contentious-administrative procedure and the substantive regulatory framework.

331. Constitutional foundations: Articles 24, 117 and 118

331.1. Article 24.1: Effective judicial protection

Article 24.1 of the Spanish Constitution guarantees effective judicial protection without defenselessness. This guarantee encompasses more than access to a court and the right to obtain a judicial decision. Constitutional jurisprudence recognises execution of judicial decisions as an essential dimension of effective judicial protection. A judgment that remains practically ineffective may fail to provide the protection required by the Constitution.

331.2. Article 117.3: Judicial authority to judge and enforce judgments

Article 117.3 attributes the exercise of judicial power, including judging and enforcing judgments, to the courts and tribunals established by law. This provision is central to the separation of powers. Once a dispute has been judicially determined, the Administration cannot assume authority to redefine the judgment's binding content.

331.3. Article 118: The duty to comply

Article 118 establishes the obligation to comply with final judgments and other judicial decisions and to provide the cooperation required by courts in the course of proceedings and execution. The duty applies to public authorities. Administrative disagreement with a judgment does not constitute a lawful basis for refusing execution.

331.4. The distinction between institutional autonomy and judicial authority

The Administration retains its legally assigned regulatory competences. However, those competences must be exercised consistently with binding judicial decisions. An administrative authority cannot use its general regulatory responsibilities as a means of nullifying a judgment. Conversely, a court's judgment must be interpreted according to its actual operative content. The judicial decision may annul one measure without determining every possible future regulatory question.

332. Article 103 of Law 29/1998: The court retains control over execution

Article 103 establishes the institutional foundation of judgment enforcement in the contentious-administrative jurisdiction.

332.1. Exclusive judicial power to enforce

Article 103.1 assigns the power to enforce judgments and other enforceable judicial instruments to the courts and tribunals of the contentious-administrative jurisdiction. The competent court is generally the court that heard the matter at first or sole instance. The Administration is responsible for carrying out the measures required of it, but it does not control the judicial meaning of the judgment.

332.2. Compliance in the terms of the judgment

Article 103.2 requires the parties to comply with judgments in the manner and terms established in them.

The obligation is substantive.

A public authority cannot satisfy a judgment by performing a different action that it considers administratively preferable if that action does not fulfil the judicial ruling.

332.3. Cooperation by public and private entities

Article 103.3 requires public and private persons and entities to provide the cooperation requested by the court for proper and complete execution. This may

be relevant where effective execution requires records, technical documentation or actions involving several public bodies.

332.4. Acts adopted to evade execution

Article 103.4 declares absolutely null acts and provisions that contradict judicial pronouncements and are adopted for the purpose of evading compliance. This is among the most important provisions for disputes involving administrative resistance. It recognises that an authority may attempt to defeat a judgment not through open refusal, but through a subsequent administrative act.

332.5. Judicial declaration of nullity

Article 103.5 provides a procedural mechanism for seeking a declaration of nullity of such acts and provisions before the court responsible for execution, subject to the statutory competence qualification. The provision refers to the procedure established in Article 109.2–3.

332.6. A necessary evidentiary qualification

The fact that a subsequent administrative decision produces an unfavourable result for the successful litigant does not automatically establish evasion. The requirements of Article 103.4 must be established. In particular, the relationship between the new act and the judgment, its contradiction with the judicial pronouncements and the purpose of evading compliance require examination.

333. Article 104: Communication of judgments and the administrative duty to execute

333.1. The execution mechanism

Article 104 establishes the process by which a final judgment is communicated to the administrative authority responsible for its implementation. The authority must take the measures necessary to give effect to the judgment.

333.2. Identification of the responsible body

Execution may require identifying the administrative organ competent to perform the relevant action. This is particularly important in food safety enforcement, where inspection, laboratory analysis, administrative sanctioning and authorisation functions may belong to different bodies. An authority cannot necessarily discharge its obligations by referring the matter indefinitely between

departments. However, the precise duties of each body depend upon the judgment and applicable competence rules.

333.3. The two-month reference period

Article 104.2 establishes a general mechanism under which, after two months from communication of the judgment—or the period established in the judgment for compliance—interested parties may seek compulsory execution. This must be read with the provisions governing the particular judgment and applicable exceptions. The two-month period is not a universal authorisation for the Administration to postpone all compliance without justification.

333.4. Administrative implementation

Compliance may require issuing a new administrative decision, withdrawing a measure, restoring a legal situation or paying an amount ordered by the court. The steps depend upon the judgment's operative content.

333.5. The role of the execution court

Where disagreement arises over whether compliance is complete, the court responsible for execution determines the relevant issues through the statutory procedures. The Administration's unilateral declaration that it has complied is not necessarily conclusive.

334. Article 105: Impossibility of execution and the prohibition of administrative suspension

334.1. The general prohibition

Article 105.1 establishes that compliance with a judgment cannot be suspended and that total or partial non-execution of the operative ruling cannot be declared as an ordinary administrative choice. This reinforces the binding nature of judicial decisions.

334.2. Material or legal impossibility

Article 105.2 provides a specific procedure where material or legal impossibility prevents execution. The administrative authority responsible for compliance must bring the matter before the court through the legally established mechanism. The court determines whether impossibility exists and adopts the appropriate measures.

334.3. Impossibility is not inconvenience

A judgment may be expensive or administratively difficult to execute. That does not necessarily establish legal or material impossibility. The concept requires a legally sufficient foundation.

334.4. Perishable goods

Food safety disputes present a particularly difficult situation. Suppose a court annuls the immobilisation of perishable food after the product has already deteriorated or been destroyed. Physical restitution may no longer be possible. The legal analysis must determine what the judgment requires and whether execution in its original terms is materially possible. Where statutory impossibility is established, the court may determine substitute measures and compensation under the applicable framework.

334.5. The limits of substitute execution

Substitute execution is not a general option allowing the Administration to purchase freedom from compliance. It is governed by the statutory conditions and judicial control.

334.6. Public interest and expropriation

Article 105.3 establishes a distinct exceptional mechanism involving expropriation of rights or legitimate interests recognised by a final judgment on specified grounds of public utility or social interest. Its strict statutory conditions must be respected. The provision cannot be invoked merely because an authority disagrees with the outcome of litigation.

335. Article 106: Monetary judgments and payment obligations

335.1. Judgments ordering payment

Article 106 governs execution of judgments requiring the Administration to pay a liquid sum. The provision establishes mechanisms for satisfying the monetary obligation and addresses interest.

335.2. Budgetary considerations

The existence of administrative budgetary procedures does not extinguish the judicial obligation. However, payment must be implemented through the applicable public finance framework.

335.3. Interest

Interest may be relevant where the Administration fails to satisfy a monetary judgment within the statutory framework. The applicable calculation depends upon the provision, the judgment and the circumstances.

335.4. The distinction between damages and execution

A judgment awarding compensation creates a monetary obligation. Its execution differs from a separate claim seeking damages arising from subsequent unlawful administrative conduct. The two questions may interact, but they should not be conflated.

335.5. Industrial significance

For food manufacturers, delayed payment may aggravate losses caused by an earlier unlawful restriction. However, compensation for additional consequences requires the applicable legal foundation.

336. Article 107: Publicity and registration of annulment judgments

Article 107 concerns publication and registration of certain judgments annulling administrative acts or general provisions.

336.1. The purpose of publication

Judicial annulment may affect legal situations extending beyond the immediate parties. Publication or registration can therefore be necessary to ensure that the judgment has the appropriate legal effects.

336.2. Annulment of individual acts

Where a final judgment annuls an act that has entered a public register, Article 107.1 permits registration of the ruling at a party's request. Publication may also be ordered under the statutory conditions.

336.3. General provisions and acts affecting an indeterminate plurality

Article 107.2 establishes publication in an official journal where a judgment annuls a general provision or an administrative act affecting an indeterminate plurality of persons.

336.4. Relevance to food regulation

A judgment annulling a general regulatory provision may have consequences for numerous operators. Its publication may be essential for legal certainty. By contrast, annulment of an individual product immobilisation does not automatically require the same form of public dissemination.

336.5. Commercial reputation

A manufacturer may consider publication of a favourable judgment important for restoring commercial confidence. However, the operator's reputational interest does not automatically create an unrestricted right to compel official publication under Article 107. The statutory conditions must be satisfied.

337. Article 108: Judicial powers to secure effective performance

Article 108 provides particularly significant enforcement mechanisms where the Administration has been ordered to perform an activity or issue an act.

337.1. Judicial execution through available means

Under Article 108.1, where the Administration fails to comply with a judgment requiring a specified activity or administrative act, the court may employ the mechanisms established by the provision. These include execution through the court's own means or by requiring cooperation from the responsible Administration or other public authorities.

337.2. Measures giving effect to the omitted act

The court may adopt measures necessary for the judgment to produce the effects inherent in the omitted administrative act. This may include subsidiary execution at the expense of the Administration. The scope of these powers depends upon what the judgment actually requires.

337.3. Administrative activity contradicting the judgment

Article 108.2 addresses situations where the Administration undertakes activity contrary to the operative ruling. At the request of interested parties, the court may restore the situation required by the judgment and determine the damage caused by non-compliance. This provision is especially relevant to attempts to frustrate a favourable judicial outcome through subsequent administrative conduct.

337.4. Distinguishing enforcement from new adjudication

The execution court may ensure compliance with the judgment. However, execution proceedings are not a general mechanism for resolving every new dispute between the operator and the authority. Where a genuinely new regulatory decision raises distinct legal issues, separate proceedings may be necessary.

337.5. Application to food safety

Suppose a judgment requires an authority to issue a specified administrative document or take a particular legally defined action. If the authority refuses, Article 108 may provide an enforcement mechanism. However, a judgment merely annulling an earlier restriction does not automatically authorise the court to issue every future food safety approval the operator might require.

338. Article 109: The execution incident as a procedural instrument

338.1. The scope of the procedure

Article 109 permits the Administration, the parties and persons affected by the judgment to raise questions concerning execution while complete compliance has not been recorded. The procedure is particularly important where disagreement concerns the content or completeness of compliance.

338.2. Questions expressly contemplated

Article 109.1 identifies issues including:

- The administrative body responsible for execution.
- The maximum period for compliance.
- The means and procedure necessary to implement the judgment.

These are not the only possible questions, but they illustrate the provision's function.

338.3. Adversarial procedure

Article 109.2 provides for submissions by the parties within a common period not exceeding twenty days. Article 109.3 requires the court to decide the incident by order within the statutory period.

338.4. The limits of the incident

The procedure cannot contradict the judgment. Its function is to resolve execution questions, not to reopen the merits of the original dispute.

338.5. A practical example

A judgment requires a competent authority to reconsider a regulatory application in accordance with specified legal criteria. The authority issues a new decision. The operator alleges that the new decision ignores the judgment's binding reasoning. The execution court may need to determine whether the authority has complied or whether the new decision constitutes a distinct matter requiring separate challenge. The answer depends upon the judgment's operative content and legally determinative reasoning.

339. Article 112: Coercive fines and possible criminal referral

339.1. Judicial powers following non-compliance

Article 112 permits the court, after expiry of the periods established for complete execution and following the required procedural safeguards, to adopt measures necessary to secure compliance. The provision includes coercive fines and referral of relevant material for possible criminal responsibility.

339.2. Coercive fines

Article 112(a) permits coercive fines ranging from **€150 to €1,500** against authorities, officials or agents who fail to comply with judicial requirements. The fines may be repeated until execution is achieved. The statutory conditions include establishment of responsibility and prior warning with an opportunity to make submissions.

339.3. Their legal nature

Coercive fines are instruments designed to secure compliance. They should not automatically be equated with criminal punishment or with compensation payable to the affected operator.

339.4. Referral for possible criminal responsibility

Article 112(b) permits the court to refer the relevant material for examination of any criminal responsibility that may arise. Such referral does not establish that a criminal offence has been committed. Criminal responsibility requires separate examination of the applicable statutory elements.

339.5. Article 410 of the Criminal Code

Article 410 addresses specified conduct involving open refusal by public authorities or officials to comply with judicial decisions and other legally relevant orders. Its application requires satisfaction of the offence's elements and consideration of its statutory qualifications. An administrative delay, procedural disagreement or incorrect interpretation does not automatically constitute criminal disobedience.

339.6. A necessary distinction

Three levels of conduct must be distinguished. **Incomplete execution:** The judgment has not been fully implemented. **Contumacious non-compliance:** Responsible persons persist in failing to comply despite judicial requirements. **Criminally relevant disobedience:** The conduct satisfies the elements of an applicable criminal offence. The categories may overlap, but they are not legally identical.

340. Article 113: Enforcement of judicially approved agreements

Article 113 addresses compulsory execution of agreements reached under Article 77.3 of Law 29/1998.

340.1. Agreements with a fixed execution period

Where the agreement establishes a period for performance, compulsory execution may be requested after that period expires.

340.2. Agreements without a specified period

Where no period is established, the injured party may demand compliance. After two months, compulsory execution may be requested under the statutory conditions.

340.3. Distinction from ordinary judgments

Article 113 concerns a specific category of enforceable agreements. It should not be treated as the general provision governing execution of every contentious-administrative judgment.

340.4. Industrial application

A food manufacturer and an authority may reach a judicially approved agreement concerning specified administrative actions. If the agreement qualifies under Article 77.3, Article 113 may become relevant to enforcement. However, public authorities cannot lawfully settle matters beyond their competence or waive mandatory food safety requirements merely through agreement.

341. Constitutional jurisprudence: Execution and the intangibility of final judgments

341.1. STC 86/2005: Execution as an essential dimension of judicial protection

Spanish Constitutional Court, Judgment 86/2005 of 18 April 2005. The Court reaffirmed that the right to execute final judicial decisions forms part of the right to effective judicial protection. Without execution, judicial recognition of rights may remain practically ineffective. The judgment also recognised that execution in the precise terms of the ruling is the general principle, subject to legally permitted substitute performance where sufficient grounds exist.

The constitutional right therefore protects the practical effectiveness of the judgment while accommodating the exceptional mechanisms established by law.

341.2. STC 83/2022: The scope of judicial intangibility

Spanish Constitutional Court, Judgment 83/2022. The Court examined the constitutional protection of final judicial decisions. Its reasoning explains that the intangibility of a final judgment extends beyond a purely formal reading of the operative paragraph. Determining what was decided may require consideration of

the factual and legal premises essential to the ruling. This is important because administrative authorities may attempt to comply with the literal wording of a judgment while disregarding its determinative reasoning.

However, not every observation contained in a judgment possesses binding force. The distinction between the operative ruling, its necessary grounds and incidental reasoning remains essential.

341.3. STC 107/2024: Final judgments cannot be altered outside lawful procedures

Spanish Constitutional Court, Judgment 107/2024 of 9 September 2024. The Court reiterated that the intangibility of final judicial decisions forms part of Article 24.1 of the Constitution. The principle prevents judicial decisions from being altered outside the procedures expressly established by law. Its rationale includes legal certainty and the practical effectiveness of judicial protection.

341.4. STC 31/2025: Continued constitutional relevance

Spanish Constitutional Court, Judgment 31/2025. The Court reaffirmed the connection between effective judicial protection, legal certainty and respect for final judicial decisions. The judgment illustrates the continuing significance of the constitutional doctrine concerning *cosa juzgada* and the intangibility of final rulings. The case did not concern food safety enforcement. Its relevance to this study lies in the general constitutional principles governing judicial decisions.

341.5. The doctrinal consequence

The constitutional jurisprudence supports a principle of effective compliance. An administrative authority cannot treat a final judgment as a non-binding recommendation. However, the judgment's scope must be determined through legally appropriate interpretation. The constitutional guarantee protects what was actually decided, not every commercial objective that the successful party hoped litigation would achieve.

342. Administrative circumvention: When a new regulatory act may violate an earlier judgment

342.1. The central problem

A court annuls an administrative measure. The authority subsequently adopts another measure producing substantially the same consequences. Does the second act constitute unlawful circumvention? The answer depends upon the judgment, the new measure and the reasons supporting it.

342.2. Repetition of the same defect

Suppose a judgment annuls an immobilisation because the authority lacked the statutory competence required to impose it. The same authority issues an essentially identical measure without any relevant change in legal competence. The new act may raise a serious question under Article 103.4.

342.3. A new factual foundation

A different situation arises where the authority receives new laboratory evidence demonstrating a previously unidentified risk. The authority may possess an independent legal basis for intervention. The earlier judgment does not automatically immunise the product against future lawful controls.

342.4. The relevance of purpose

Article 103.4 expressly addresses acts adopted with the purpose of evading compliance. The analysis must therefore examine whether the new decision genuinely responds to a lawful regulatory objective or seeks to neutralise the judgment.

342.5. Objective indicators

Potential indicators of circumvention may include:

- Repetition of the same legal reasoning rejected by the court.
- Absence of materially new facts.
- Adoption of a measure incompatible with the judgment's operative consequences.
- Internal documentation revealing an intention to avoid execution.
- Unexplained disregard of the judgment's binding legal conclusions.

These are proposed evidentiary indicators, not an exhaustive statutory checklist.

342.6. The danger of assuming bad faith

Administrative disagreement with an operator does not itself establish an intention to evade a judgment.

The allegation requires evidence.

A credible legal challenge should distinguish demonstrated facts from inferences concerning institutional motivation.

343. Food safety and the limits of execution: Public health cannot be ignored

343.1. The continuing regulatory function

Food safety authorities retain their statutory responsibilities after litigation. A judgment annulling a particular measure does not necessarily eliminate their duty to respond to new or continuing risks.

343.2. Article 137 of Regulation (EU) 2017/625

Where competent authorities suspect non-compliance, Article 137 requires investigation and permits appropriate action under the applicable conditions. A final judgment concerning an earlier inspection does not automatically prevent a new investigation based upon genuinely new information.

343.3. Article 138: Established non-compliance

Where non-compliance is established, Article 138 requires appropriate action. The authority must comply with the applicable legal conditions and the judicial decision.

343.4. The distinction between compliance and regulatory abdication

Executing a judgment does not mean abandoning lawful public health responsibilities. The authority must implement the judgment while continuing to exercise any independent statutory powers properly.

343.5. The judicial boundary

A court may require the Administration to comply with a judgment. However, the court must also respect the legal framework governing future regulatory

action. The balance is not between judicial authority and food safety as mutually exclusive objectives. It is between the binding effect of the judgment and the lawful exercise of continuing administrative competence.

344. Execution, perishability and the irreversible loss of commercial value

344.1. The time-sensitive character of food products

Many food products have limited commercial lives. A delay in execution may make physical restitution impossible. The goods may expire, deteriorate or become commercially unusable.

344.2. The distinction between physical and legal restitution

A judgment may restore the operator's legal position. However, the physical goods may no longer exist or retain commercial value. This creates a potential need to examine statutory impossibility and substitute remedies.

344.3. Economic losses

Possible losses may include destroyed inventory, additional storage costs, production disruption and lost commercial opportunities. However, their compensability depends upon the applicable legal requirements.

344.4. Causation

The claimant must distinguish losses caused by the original administrative act from losses caused by subsequent failure to execute the judgment. The periods and causal mechanisms may differ.

344.5. The risk of double recovery

Compensation must not duplicate amounts already recovered under another legally applicable mechanism. For example, a loss compensated through an earlier public liability judgment cannot automatically be claimed again as damage arising from execution.

344.6. The importance of preserving evidence

A manufacturer seeking compensation should preserve relevant documentation concerning inventory, product shelf life, storage, contracts, sales and the timing

of administrative decisions. The evidentiary burden cannot be satisfied solely through general assertions of commercial harm.

345. The relationship between judicial execution and public liability

345.1. Two different legal functions

Judicial execution seeks to implement a binding judgment. Public liability seeks compensation for legally compensable injury attributable to administrative functioning. The mechanisms may interact, but they have distinct purposes.

345.2. Damage caused by failure to execute

Article 108.2 expressly addresses damage caused by administrative activity contrary to a judgment. Other losses may require examination under the applicable execution or public liability framework.

345.3. The importance of procedural classification

A claimant should determine whether the damage falls within the execution court's powers or requires a separate compensation procedure. The answer depends upon the nature of the injury, the judgment and the statutory provisions.

345.4. The absence of automatic compensation

Failure to execute a judgment may be unlawful. However, a particular compensation claim still requires establishment of the applicable conditions.

345.5. The economic significance of delay

Delayed execution may prolong commercial harm. Nevertheless, the amount recoverable depends upon proof of loss and causation. A calculation based solely upon projected turnover may overstate the actual economic injury.

346. Original doctrinal contribution: The Judicial Execution and Regulatory Compliance Assessment Framework

The present research proposes the **Judicial Execution and Regulatory Compliance Assessment Framework (JERCAF)**. JERCAF is an original academic model, not an established judicial test. Its purpose is to distinguish

genuine judicial compliance from incomplete execution, lawful subsequent regulation and unlawful circumvention.

346.1. Ten dimensions

Dimension	Principal inquiry
1. Judicial title	What final judgment or enforceable judicial instrument exists?
2. Binding content	What does the operative ruling require, read with its necessary reasoning?
3. Responsible authority	Which administrative body must perform the required action?
4. Execution period	What statutory or judicial deadline applies?
5. Actual performance	What concrete measures has the Administration undertaken?
6. Subsequent decisions	Do new acts comply with or contradict the judgment?
7. Independent regulatory grounds	Are any new restrictions supported by genuinely new facts or lawful powers?
8. Impossibility	Is material or legal impossibility established under Article 105?
9. Economic consequences	What injury is attributable to defective execution?
10. Judicial remedies	Which execution mechanisms, coercive measures or compensation procedures apply?

346.2. The model's principal contribution

JERCAF distinguishes four possible outcomes. **Outcome I - Complete compliance:** The Administration has performed the obligations imposed by the judgment. **Outcome II - Incomplete execution:** Compliance remains partial or outstanding. **Outcome III - Lawful subsequent intervention:** The Administration has complied with the judgment but subsequently adopted an independently justified regulatory measure.

Outcome IV - Unlawful circumvention: A new act or material intervention contradicts the judgment and satisfies the applicable legal requirements for judicial correction or nullity. The categories are analytical rather than statutory.

346.3. Proposed execution assessment sequence

1

Identify the judgment

Establish finality, operative terms and enforceable obligations.

2

Determine responsibility

Identify the authority and officials responsible for compliance.

3

Verify implementation

Examine actual administrative conduct and relevant deadlines.

4

Assess new measures

Distinguish independent regulatory action from potential circumvention.

5

Examine impossibility

Determine whether Article 105 applies and whether judicial determination is required.

6

Quantify consequences

Separate original regulatory injury from additional execution-related losses.

7

Select enforcement

Use the appropriate incident, judicial powers or coercive mechanism.

8

Confirm effectiveness

Assess whether the judgment has acquired its required practical legal effect.

346.4. The importance of effective compliance

The model rejects a purely formal approach. A declaration that the Administration has complied should be tested against the judgment's actual legal consequences. However, the model also rejects the assumption that every later adverse regulatory decision constitutes disobedience.

346.5. Research potential

JERCAF could be tested against judicial execution proceedings involving administrative restrictions on economic activity. Relevant variables might include the type of judgment, compliance period, subsequent administrative measures, judicial enforcement orders and economic consequences. Such research could contribute to the study of institutional compliance with judicial authority.

347. Applied industrial scenarios

Scenario A. Failure to release goods after annulment

A court annuls an immobilisation order. The competent authority fails to take the administrative steps required by the judgment. The operator may seek execution before the competent court. The specific relief depends upon the judgment's operative content and the applicable execution provisions.

Scenario B. A second immobilisation based upon the same grounds

An authority adopts a new immobilisation order after the earlier order has been annulled. The second order repeats the reasoning rejected by the court. The operator may examine Article 103.4–5 and the execution procedure. However, a finding of circumvention requires satisfaction of the statutory conditions.

Scenario C. A new restriction based upon new evidence

Following annulment of an earlier measure, the authority receives new laboratory findings establishing a different food safety concern. It adopts a new restriction under an applicable statutory power. The earlier judgment does not automatically prohibit this intervention. The new measure must be assessed on its own legal and factual foundation.

Scenario D. Destruction of goods before final judgment

A manufacturer successfully challenges an immobilisation after the affected products have been destroyed. Physical restitution is impossible. The legal analysis must distinguish the judgment's operative terms, the possibility of substitute execution and any separate compensable injury.

Scenario E. Repeated refusal to comply with judicial requirements

An authority fails to execute a judgment despite judicial requirements. The court may examine coercive measures under Article 112. Possible criminal responsibility requires separate satisfaction of the relevant statutory elements.

Scenario F. A favourable judgment followed by a nominal administrative response

A court orders the Administration to reconsider an application according to specified legal criteria. The authority issues a new decision that formally acknowledges the judgment but ignores its determinative reasoning. The operator may raise the issue through the appropriate execution mechanism. However, the court must determine whether the new decision genuinely contradicts the judgment or raises a distinct legal dispute.

348. Conclusions of the twelfth instalment of Part II

The execution of judicial decisions is an essential component of effective judicial protection. Articles 24, 117 and 118 of the Spanish Constitution establish the constitutional foundations of that protection. Articles 103–113 of Law 29/1998 provide the principal statutory mechanisms governing execution in contentious-administrative proceedings. Article 103 protects judgments against acts and provisions adopted to evade compliance. Article 105 regulates exceptional situations involving impossibility of execution.

Article 108 empowers courts to secure performance and address activity contrary to judicial rulings. Article 109 establishes a procedure for resolving execution disputes. Article 112 permits coercive measures under specified conditions. Constitutional jurisprudence confirms that final judicial decisions must be respected and that their binding content cannot be altered outside the legally established procedures.

These principles are particularly important in food safety enforcement because delays may produce irreversible commercial consequences. However, judicial execution does not eliminate the Administration's continuing duty to respond to genuine public health risks through lawful measures.

The central conclusion is: **Effective judicial protection requires genuine implementation of the obligations imposed by a judgment. An administration may continue to exercise its lawful food safety powers, but it cannot use those powers to contradict, neutralise or evade the binding consequences of a final judicial decision.**

The proposed JERCAF framework provides a structured methodology for distinguishing compliance, incomplete execution, lawful subsequent intervention and unlawful circumvention.

Primary legislation and verified jurisprudence

1. Spanish Constitution — Articles 24, 117 and 118.
2. Law 29/1998 on Contentious-Administrative Jurisdiction — Articles 103–113.
3. STC 86/2005, 18 April 2005 — Execution of final judicial decisions and effective judicial protection.
4. STC 83/2022 — Intangibility of final judicial decisions and the scope of what has been decided.
5. STC 107/2024, 9 September 2024 — Constitutional protection of the finality of judicial decisions.
6. STC 31/2025 — Legal certainty and the intangibility of final judicial rulings.
7. Regulation (EU) 2017/625 — Articles 137–138 concerning suspected and established non-compliance.
8. Spanish Criminal Code — Article 410 concerning specified forms of disobedience by public authorities or officials.

CHAPTER 27

349. Regulatory Retaliation, Repeated Inspections and the Misuse of Food Safety Enforcement Powers

Constitutional limits on administrative discretion, the evidentiary identification of retaliatory enforcement and the judicial protection of food business operators against arbitrary or improperly motivated official controls.

Abstract

Official food controls are indispensable to public health protection. Their legitimacy depends not only upon the existence of statutory inspection powers, but also upon the purposes for which those powers are exercised and the procedures governing their application. A food business may legitimately undergo repeated inspections because of its risk profile, previous non-compliance, complaints, emerging hazards or the need to verify corrective measures. Increased inspection frequency is therefore not inherently unlawful.

A different legal problem arises when inspection powers are allegedly used to punish an operator for exercising procedural rights, submitting complaints, challenging administrative decisions or obtaining favourable judicial rulings. Such conduct may engage the constitutional prohibition of arbitrariness, the principles of objectivity and impartiality, the doctrine of *desviación de poder* and the right to effective judicial protection.

Establishing regulatory retaliation, however, requires more than demonstrating that inspections were frequent, burdensome or commercially damaging. The analysis must distinguish legitimate risk-based enforcement from improper administrative purpose through documentary evidence, chronology, comparative treatment and the examination of stated reasons.

This instalment develops a systematic approach to the judicial evaluation of repeated official controls, potential institutional harassment and retaliatory regulatory conduct. It also examines the distinction between invalid administrative action, disciplinary responsibility, public liability and possible

criminal misconduct. The article introduces an original **Regulatory Retaliation and Administrative Purpose Assessment Matrix (RRAPAM)**.

Its central thesis is that **the legality of official food controls depends upon the lawful exercise of regulatory powers for their assigned public purposes; neither the existence of a genuine inspection competence nor the formal appearance of procedural regularity necessarily cures a proven misuse of that competence**.

Keywords: Regulatory retaliation; official food controls; administrative harassment; *desviación de poder*; arbitrariness; risk-based inspections; administrative impartiality; judicial review; evidentiary burden; institutional accountability.

349.1. Introduction: When legitimate regulatory powers become instruments of improper pressure

A manufacturer challenges an official inspection report. The competent authority subsequently increases the frequency of inspections.

The operator alleges retaliation.

The Administration argues that the inspections respond to the establishment's risk profile. Neither assertion resolves the legal question. The manufacturer's exercise of procedural rights does not exempt it from official controls. Equally, the Administration's possession of inspection powers does not authorise their use for purposes unrelated to food safety legislation. The legal analysis must identify the factual and regulatory explanation for the inspections.

Were there new complaints?

Had previous controls revealed deficiencies? Did the establishment introduce a new process? Was the inspection frequency consistent with the relevant risk classification? Were comparable operators treated differently? Did officials make statements indicating an improper purpose? These questions concern the distinction between the lawful exercise of administrative discretion and the misuse of public powers.

A rigorous analysis must also avoid a common methodological error: interpreting every adverse administrative action following a complaint or judicial challenge as retaliation. Temporal sequence may be relevant evidence. It is not, by itself, proof of causation or improper purpose.

350. The constitutional framework: Arbitrariness, objectivity and judicial protection

350.1. Article 9.3: Prohibition of arbitrariness

Article 9.3 of the Spanish Constitution guarantees, among other principles, legal certainty and the prohibition of arbitrariness by public authorities. The prohibition applies to administrative action. A competent authority must exercise its powers within the applicable legal framework and for legally permissible reasons. The existence of discretion does not eliminate judicial control.

350.2. Article 103.1: Objective service of the general interest

Article 103.1 requires public administration to serve the general interest objectively and act in accordance with the principles and legal requirements established by the Constitution. This is particularly significant in food safety enforcement. Official controls exist to protect legally recognised public interests. They are not instruments for settling personal disputes between inspectors and regulated operators.

350.3. Article 14: Equality before the law

Article 14 prohibits discrimination and establishes the constitutional principle of equality. However, a successful equality claim requires a legally relevant comparison. Different inspection frequencies may be justified by different risk profiles. A manufacturer cannot establish unconstitutional unequal treatment merely by identifying another business that received fewer inspections. The relevant circumstances must be materially comparable.

350.4. Article 24.1: Effective judicial protection

Article 24.1 guarantees effective judicial protection. Administrative measures allegedly adopted to punish an operator for pursuing judicial remedies may raise serious constitutional concerns. Nevertheless, the mere existence of litigation between an operator and an authority does not render subsequent official controls unlawful. The alleged connection must be established.

350.5. Article 106.1: Judicial control

Article 106.1 provides for judicial control of regulatory power, the legality of administrative action and its submission to the purposes justifying it. This last

element is especially important. Judicial review concerns not only whether the Administration possesses a power, but also whether that power has been exercised for its legally assigned purpose.

351. Article 9 of Regulation (EU) 2017/625: Risk-based controls and their lawful frequency

351.1. Regular official controls are mandatory

Article 9.1 requires competent authorities to perform official controls regularly, on a risk basis and with appropriate frequency. The provision identifies factors that authorities must consider when determining inspection priorities. These include identified risks associated with goods, activities, locations and relevant processes.

351.2. Previous compliance history

The authority may consider an operator's previous official control results and compliance history. A manufacturer with repeated verified deficiencies may legitimately receive more frequent controls. Conversely, an operator's record of compliance may be relevant to its risk assessment.

351.3. Reliability of internal controls

Article 9 also recognises the relevance of the operator's own controls and relevant third-party assurance arrangements. A robust internal quality management system may provide useful evidence. However, certification does not exempt an operator from official inspection.

351.4. Information indicating possible non-compliance

The authority may respond to information suggesting non-compliance. A complaint, laboratory finding or other credible information may justify additional scrutiny. Nevertheless, the authority must act within its powers and apply the relevant legal requirements.

351.5. The significance of proportionality

Risk-based inspection frequency must not be confused with unlimited administrative discretion. A control programme should remain connected to the regulatory objectives and relevant risk factors. A substantial increase in inspections may therefore warrant examination of its documented justification.

351.6. No numerical entitlement to fewer inspections

Article 9 does not establish a universal maximum number of inspections per operator. A business cannot claim that a particular number of visits is automatically unlawful. The legal analysis must examine the reasons, scope and circumstances of the controls.

351.7. Unannounced inspections

Article 9.4 establishes that official controls are generally performed without prior notice, except where notice is necessary and duly justified. The absence of advance notice is therefore not, by itself, evidence of harassment. The same applies to intensified controls that are justified by credible risk information.

352. Articles 5, 12 and 13: Impartiality, documented procedures and inspection records

352.1. Article 5: Institutional impartiality

Article 5 of Regulation (EU) 2017/625 requires competent authorities to maintain arrangements ensuring impartiality and the absence of conflicts of interest among personnel performing official controls. It also addresses quality and consistency. This provides an important institutional safeguard against personal or improper influences.

352.2. Article 12: Documented control procedures

Article 12 requires official controls to be performed according to documented procedures. The authority must also maintain verification arrangements and correct identified shortcomings. The existence of documented procedures may help determine whether a particular inspection followed the applicable institutional framework. However, procedural conformity does not automatically establish that the power was exercised for a proper purpose.

352.3. Article 13: Written records

Article 13 requires written records of official controls. These must include the purpose of the control, the methods applied, the results and, where appropriate, the measures required of the operator. The operator is generally entitled to request a copy, subject to the provision's qualifications.

352.4. Why records matter in retaliation disputes

Inspection records can provide objective evidence of the authority's stated reasons. They may establish whether controls concerned new risks, previous deficiencies or ordinary programme requirements. They may also reveal inconsistencies between the stated purpose and the activities actually performed.

352.5. The distinction between stated and actual purpose

An inspection report may state that the visit concerned hygiene verification. That statement is relevant evidence. However, it is not necessarily conclusive where other credible evidence indicates that the actual purpose was different. The legal assessment must consider the record as a whole.

353. *Desviación de poder*: The statutory doctrine of improper administrative purpose

353.1. Article 70.2 of Law 29/1998

Article 70.2 defines *desviación de poder* as the exercise of administrative powers for purposes different from those established by the legal system. The provision expressly recognises misuse of powers as a ground for upholding a contentious-administrative challenge.

353.2. The significance of the doctrine

The doctrine addresses situations in which the Administration may possess formal competence and appear to comply with procedural requirements but uses its power to pursue an improper objective. This distinguishes misuse of powers from an ordinary lack of competence or procedural defect.

353.3. An illustrative example

An inspector possesses authority to examine a food manufacturing establishment. The inspector conducts an inspection. The legal concern arises if the inspection power is exercised primarily to punish the operator for having successfully challenged an earlier administrative decision rather than to pursue the statutory food safety objective. The formal existence of inspection powers does not necessarily cure a proven improper purpose.

353.4. Improper purpose versus incorrect assessment

An authority may incorrectly interpret a technical requirement while genuinely seeking to protect public health. That error may make the decision unlawful. However, it does not automatically establish *desviación de poder*. The doctrine concerns the purpose for which the power was exercised.

353.5. Mixed motives

A difficult case arises where both legitimate regulatory concerns and improper personal motives appear to exist. The analysis must establish whether the improper purpose legally affected the exercise of the power. The existence of an unpleasant relationship between an inspector and an operator does not, without more, invalidate a justified inspection.

353.6. Evidentiary requirements

Improper administrative purpose is often difficult to prove directly. Relevant evidence may include documentary contradictions, communications, chronological patterns and other objective circumstances. However, suspicion cannot substitute for proof.

353.7. The statutory foundation

Article 70.2 provides the relevant legal definition. It does not establish a presumption that repeated inspections constitute misuse of powers. The claimant must establish the grounds of challenge through the applicable evidentiary framework.

354. Supreme Court jurisprudence: STS 1499/2023 and proof of improper purpose

354.1. Identification

Spanish Supreme Court, Third Chamber, Judgment 1499/2023 of 21 November 2023, proceedings 934/2022. The judgment concerned an appointment within the prosecutorial career. It did not concern official food controls. Nevertheless, it provides a particularly useful judicial discussion of *desviación de poder*.

354.2. The legal problem

The Supreme Court examined whether a formally valid exercise of appointment powers had been directed towards an improper objective. The Court considered the purpose underlying the decision and the evidence supporting that conclusion.

354.3. The difficulty of proof

The judgment recognised that improper administrative motives may remain concealed. Consequently, proof may depend upon circumstantial evidence. The Court also observed that the doctrine remains applicable where the improper purpose can be established.

354.4. Why the judgment matters

The decision demonstrates that formal compliance with an administrative procedure does not necessarily exclude misuse of powers. It also illustrates why courts may examine the actual purpose of an administrative decision.

354.5. Limits of application

The judgment arose in the context of a discretionary appointment. Its factual circumstances differ substantially from risk-based food inspections. It should therefore be used for its general doctrine concerning improper administrative purpose, not as direct authority establishing that a particular inspection pattern constitutes retaliation.

354.6. Established holding and sectoral implication

Established holding: The Court found misuse of administrative powers in the appointment decision under examination.

Sectoral implication: Where a food operator alleges that official control powers were exercised for retaliatory purposes, the analysis may draw upon the same statutory doctrine, provided the relevant facts and evidentiary requirements are established.

355. Evidence of retaliation: From chronology to judicially defensible inference

355.1. The evidentiary challenge

Regulatory retaliation is rarely established through an express written admission. More commonly, an operator may identify a sequence of events that appears inconsistent with ordinary enforcement. The challenge is to determine whether the sequence supports a legally reliable inference.

355.2. Chronology

A chronology may record:

1. Submission of an administrative complaint.
2. Filing of a judicial challenge.
3. Adoption of an adverse inspection decision.
4. Increase in inspection frequency.
5. Changes in the authority's stated reasons.
6. Subsequent administrative or judicial outcomes.

Chronology can reveal patterns.

However, sequence alone does not prove causation.

355.3. Documentary inconsistencies

An authority may state that an inspection was prompted by a particular complaint. If the complaint was received after the inspection was ordered, the inconsistency may require explanation. The significance depends upon the complete administrative record.

355.4. Comparative evidence

An operator may compare its inspection treatment with that of materially similar businesses. Relevant variables include product type, risk classification, compliance history, scale and recent incidents. Comparison without adjustment for these factors may be misleading.

355.5. Direct communications

Emails, official letters, meeting minutes or other admissible communications may provide evidence of administrative purpose. Their authenticity and context must be established.

355.6. Witness evidence

Witnesses may describe statements or conduct suggesting improper motivation. However, testimony must be evaluated according to the applicable evidentiary rules.

355.7. Statistical patterns

A substantial change in inspection frequency may be analytically significant. For example, an establishment may receive one inspection annually for several years and then receive numerous visits following a dispute. Nevertheless, the change may also reflect a new hazard, an outbreak or an altered risk classification. Statistical evidence is therefore supportive rather than automatically determinative.

355.8. The importance of alternative explanations

A rigorous allegation must address plausible lawful explanations. Failure to consider them may weaken the inference of retaliation. The strongest evidentiary approach is not simply to accumulate adverse events, but to examine whether the documented facts support improper purpose more convincingly than the relevant lawful explanations.

356. Administrative motivation and departures from established criteria

356.1. Article 35 of Law 39/2015

Article 35 requires specified administrative acts to be reasoned. These include acts limiting rights or legitimate interests and acts departing from criteria followed in previous administrative action. The provision is relevant where an authority changes its treatment of a manufacturer.

356.2. A changed criterion may be lawful

The Administration may revise its interpretation in light of new legislation, scientific evidence or correction of an earlier error. However, where the law requires motivation, the authority must provide the relevant factual and legal reasons.

356.3. The evidentiary role of inadequate reasoning

An unexplained change may support a challenge based upon insufficient motivation. It may also contribute to a broader evidentiary assessment of improper purpose. Nevertheless, lack of adequate motivation does not automatically prove retaliation.

356.4. The distinction between two grounds of challenge

A claimant may establish that a decision lacks the required reasoning without establishing *desviación de poder*. Conversely, a decision may contain extensive formal reasoning while other evidence establishes an improper purpose. The grounds are related but legally distinct.

357. Conflicts of interest, abstention and recusal

357.1. Article 23 of Law 40/2015

Article 23 establishes circumstances requiring authorities and public personnel to abstain from participation in administrative proceedings. These include specified personal interests, relationships and other legally defined circumstances.

357.2. Personal hostility

The provision includes manifest enmity as a ground for abstention. However, disagreement between an inspector and an operator does not automatically establish the statutory circumstance. The relevant facts must satisfy the legal requirements.

357.3. Article 24: Recusal

Article 24 establishes the procedure for requesting recusal. The interested party must identify the legally relevant grounds. The competent authority then addresses the request through the statutory mechanism.

357.4. Consequences of failure to abstain

Article 23.4 provides that participation by a person subject to an abstention ground does not necessarily imply invalidity of the acts in which that person participated.

This qualification is essential.

A conflict-of-interest allegation should not automatically be presented as sufficient to annul every associated administrative decision.

357.5. Institutional safeguards

Recusal concerns the participation of particular persons. It does not necessarily prevent the competent Administration from continuing a lawful investigation through other personnel. The objective is impartial enforcement, not immunity from inspection.

358. Repeated inspections and cumulative regulatory burden

358.1. The cumulative effect

Several individually justified inspections may impose a substantial combined burden. They may interrupt production, require repeated document preparation and consume management resources.

358.2. Burden does not establish illegality

A high compliance burden may arise from legitimate public health requirements. Its existence does not automatically establish harassment.

358.3. Repetition without new regulatory purpose

A different concern arises where authorities repeatedly demand identical information without a clear regulatory justification. The analysis may involve proportionality, coordination and procedural efficiency.

358.4. Inspection scope

An inspection should remain connected to the authority's legally assigned functions. However, the scope of a lawful control may be broad where necessary to verify compliance. An operator cannot unilaterally narrow the inspection to the matters it prefers.

358.5. The significance of cumulative assessment

The legality of each inspection must be examined. Nevertheless, the overall pattern may be relevant when assessing whether powers were exercised for an improper purpose. This is particularly important where no single inspection appears obviously unlawful in isolation.

359. Institutional accountability: Disciplinary, civil and criminal dimensions

359.1. Administrative invalidity

An administrative act may be annulled because it violates the legal system, including through *desviación de poder*. Invalidity does not automatically establish personal disciplinary or criminal responsibility.

359.2. Disciplinary responsibility

The Basic Statute of Public Employees, approved by Royal Legislative Decree 5/2015, establishes principles and rules concerning the conduct and disciplinary responsibility of public employees. Articles 52–54 address ethical and conduct obligations. Articles 93–98 govern disciplinary responsibility and related matters. A proven misuse of official powers may raise disciplinary questions under the applicable statutory regime. However, responsibility requires the corresponding procedure and legal classification.

359.3. Public liability

Articles 32–34 of Law 40/2015 establish the general framework governing public liability. A business harmed by unlawful administrative action may examine whether the statutory conditions for compensation are satisfied. Annulment of an administrative act does not automatically establish a right to compensation.

359.4. Criminal prevarication

Article 404 of the Spanish Criminal Code addresses the offence of administrative prevarication. Its application requires, among other elements, an arbitrary administrative resolution adopted knowingly in the relevant statutory circumstances. An incorrect inspection decision is not automatically criminal prevarication.

359.5. Documentary falsification

Article 390 concerns specified forms of falsification committed by authorities or public officials in the exercise of their functions. An inaccurate report does not automatically constitute criminal falsification. The statutory elements must be established.

359.6. The danger of conflating legal categories

A rigorous legal analysis should distinguish:

Legal category	Principal question
Administrative invalidity	Was the act legally defective?
Disciplinary responsibility	Did an official commit a sanctionable professional breach?
Public liability	Did administrative conduct cause legally compensable injury?
Criminal responsibility	Were the elements of a criminal offence established?

The same events may be relevant to several categories. However, the legal thresholds differ.

360. Original doctrinal contribution: The Regulatory Retaliation and Administrative Purpose Assessment Matrix

The present research proposes the **Regulatory Retaliation and Administrative Purpose Assessment Matrix (RRAPAM)**. RRAPAM is an original academic framework, not an established judicial test. It is designed to distinguish legitimate intensified supervision from potentially retaliatory enforcement.

360.1. Nine dimensions

Dimension	Principal inquiry
1. Legal competence	Did the authority possess the relevant inspection power?
2. Regulatory purpose	Was the power exercised for its assigned statutory purpose?
3. Risk justification	What documented risk factors supported the controls?
4. Procedural regularity	Were the required procedures and records maintained?
5. Impartiality	Were legally relevant conflicts of interest present?
6. Comparative treatment	Were materially comparable operators treated differently?

Dimension	Principal inquiry
7. Temporal pattern	Did inspection conduct change following protected procedural activity?
8. Evidentiary coherence	Do the documents and other evidence support the stated reasons?
9. Legal consequences	Which remedies or forms of responsibility may apply?

360.2. The framework's principal contribution

RRAPAM avoids two opposite errors.

The first is assuming that every increase in inspection frequency constitutes harassment. The second is assuming that possession of formal inspection powers makes improper administrative purpose legally irrelevant. The model requires analysis of both the legal authority and the actual exercise of that authority.

360.3. Proposed assessment sequence

1.- Establish the inspection history

Document dates, purposes, findings and measures.

2.- Identify the risk basis

Examine the authority's recorded risk assessment and compliance history.

3.- Identify relevant disputes

Record complaints, appeals and judicial proceedings without presuming causation.

4.- Assess impartiality

Examine legally relevant conflicts and recusal grounds.

5.- Compare treatment

Use materially comparable operators and regulatory circumstances.

6.- Examine inconsistencies

Test stated reasons against contemporaneous records.

7.- Evaluate improper purpose

Determine whether admissible evidence supports desviación de poder.

8.- Select the remedy

Distinguish annulment, institutional correction, compensation and individual responsibility.

360.4. The role of objective evidence

The model assigns particular importance to contemporaneous documentation. A retrospective allegation of retaliation may be difficult to establish without records supporting the relevant chronology and causal inference.

360.5. The role of lawful explanations

RRAPAM requires examination of legitimate regulatory explanations. An outbreak, repeated non-compliance or new scientific concern may justify intensified controls.

360.6. The framework's limits

RRAPAM does not create a presumption of retaliation. It does not replace the evidentiary requirements of contentious-administrative proceedings. Its function is to organise the relevant legal and factual analysis.

361. Applied industrial scenarios

Scenario A. Increased inspections after an administrative appeal

A manufacturer challenges an inspection finding. The authority subsequently increases inspection frequency.

The operator alleges retaliation.

The legal analysis must examine whether the increase reflects documented risk factors, new information or an improper purpose. Temporal proximity is relevant but not conclusive.

Scenario B. Repeated demands for the same documentation

An operator repeatedly supplies technical documentation. Inspectors request the same records during successive visits. The manufacturer alleges harassment. The analysis must consider the statutory purpose of each request, changes in circumstances and whether the repetition is justified.

Scenario C. Personal hostility between an inspector and an operator

An inspector and a manufacturer have a documented personal dispute. The inspector continues to participate in official controls.

The operator requests recusal.

The analysis must determine whether a statutory ground under Article 23 of Law 40/2015 exists and whether the recusal procedure applies. Personal disagreement alone does not automatically establish invalidity.

Scenario D. An adverse decision following a favourable judgment

A manufacturer obtains a judgment annulling a regulatory restriction. The authority subsequently adopts another restrictive measure. The operator alleges retaliation and circumvention. The analysis must distinguish the doctrine of *desviación de poder* from the specific execution provisions of Article 103 of Law 29/1998. The new measure may be lawful if independently justified.

Scenario E. Comparative inspection asymmetry

Two manufacturers operate comparable facilities. One receives substantially more inspections. The operator alleges unequal treatment. The analysis must account for differences in products, risk profiles, compliance history and other relevant circumstances. A numerical difference alone is insufficient.

Scenario F. Alleged fabrication of inspection findings

An operator alleges that an inspector deliberately recorded facts known to be false. The matter may raise questions concerning the evidentiary reliability of the report, administrative invalidity, disciplinary responsibility and possible criminal offences. Each question requires separate legal analysis and proof.

362. Conclusions of the thirteenth instalment of Part II

Official food controls are essential to public health protection. Their frequency and intensity may legitimately increase where relevant risks or compliance concerns justify additional scrutiny. However, regulatory powers must be exercised for their legally assigned purposes. Articles 9.3, 103.1 and 106.1 of the Spanish Constitution establish important limits upon arbitrariness and improper administrative conduct. Article 9 of Regulation (EU) 2017/625 requires risk-based official controls.

Articles 5, 12 and 13 establish complementary safeguards concerning impartiality, documented procedures and written records. Article 70.2 of Law 29/1998 recognises *desviación de poder* as a ground of judicial challenge. Supreme Court Judgment 1499/2023 demonstrates that improper administrative purpose may

invalidate a formally regular decision and that circumstantial evidence may be relevant to establishing that purpose.

Nevertheless, the existence of repeated inspections, commercial burden or previous litigation does not automatically establish retaliation.

The central conclusion is:

The legality of repeated food safety inspections depends upon their statutory foundation, documented risk justification, procedural regularity and actual regulatory purpose. Judicial protection against misuse of powers requires objective evidence capable of distinguishing improper enforcement from legitimate supervision.

The proposed RRAPAM framework provides a structured method for examining those questions.

Primary legislation and jurisprudence

1. Spanish Constitution — Articles 9.3, 14, 24, 103 and 106.
2. Regulation (EU) 2017/625 — Articles 5, 9, 12 and 13.
3. Law 29/1998 — Article 70.2 concerning *desviación de poder*.
4. Law 39/2015 — Articles 34–35 concerning administrative acts and motivation.
5. Law 40/2015 — Articles 23–24 concerning abstention and recusal; Articles 32–34 concerning public liability.
6. Supreme Court, STS 1499/2023, 21 November 2023 — Misuse of powers and evidence of improper administrative purpose.
7. Royal Legislative Decree 5/2015 — Articles 52–54 and 93–98 concerning public employee conduct and disciplinary responsibility.
8. Spanish Criminal Code — Articles 390 and 404.

The principal additional contribution of the present instalment is the inclusion of **STS 1499/2023**, providing an identified Supreme Court judgment directly concerning *desviación de poder*, albeit outside food regulation.

The original analytical frameworks RRAPAM and REIRAF should likewise be consolidated rather than presented as two independent methodologies addressing essentially the same problem.

CHAPTER 28

363. Scientific Disagreement, Administrative Discretion and the Judicial Review of Emerging Food Technologies

Regulatory classification, scientific uncertainty, evidentiary standards, precautionary intervention and the constitutional limits of technical deference.

Abstract

Emerging food technologies present a distinctive challenge for administrative law. Innovative manufacturing processes may not correspond neatly to established regulatory categories, while scientific evidence concerning their mechanisms, safety and technological function may remain incomplete or contested.

Disagreement between a food business operator and a competent authority may concern several fundamentally different questions: whether a substance falls within a legal definition, whether a technological process creates a relevant risk, whether a particular analytical method adequately characterises that risk, or whether the evidence satisfies the conditions of an existing authorisation regime.

These disputes must not be treated as interchangeable.

European Union food law combines scientific risk assessment, risk management and precautionary intervention with specific authorisation regimes. Spanish constitutional and administrative law subject the resulting decisions to requirements of legality, motivation, proportionality and judicial review.

The central difficulty lies in determining the proper relationship between administrative scientific expertise and judicial control. Courts must not assume the role of regulatory laboratories, yet technical complexity cannot render administrative decisions immune from legal scrutiny.

This instalment examines the distinction between scientific uncertainty and regulatory indeterminacy, the legal classification of innovative technologies, the evidentiary requirements supporting restrictive measures and the limits of administrative reliance upon technical guidance.

It also considers how operators may substantiate novel technological claims without confusing experimental hypotheses with established scientific findings. The article introduces an original Scientific Evidence, Regulatory Classification and Judicial Review Framework (SERC-JRF).

Its central thesis is that scientific complexity may justify specialised administrative assessment, but it cannot displace the legal obligation to identify the applicable regulatory category, evaluate relevant evidence rationally and explain why the resulting intervention is authorised and proportionate.

Keywords: Emerging food technologies; scientific uncertainty; regulatory classification; technical discretion; judicial review; precautionary principle; novel foods; processing aids; food additives; scientific evidence; administrative motivation.

363.1. Introduction: Innovation at the boundary between science and law

Food manufacturing increasingly incorporates technologies that challenge established regulatory classifications. Examples include non-thermal processing, novel extraction systems, innovative antimicrobial interventions, advanced fermentation, modified processing environments and new approaches to food-contact treatment. Such technologies may raise questions about their mechanism of action, technological function, safety, composition and legal status. A manufacturer may describe an intervention as a physical processing method.

A competent authority may regard it as the use of a regulated substance. The manufacturer may consider a material a processing aid. The authority may classify it as a food additive. An operator may present experimental evidence indicating that a process reduces microbial contamination. The authority may consider that evidence insufficient to support the proposed industrial application. These disputes require a structured analytical approach. The relevant scientific question may be whether the technology performs as claimed.

The regulatory question may be whether the technology falls within a statutory definition or requires prior authorisation. The administrative-law question may be whether the authority has correctly applied the relevant legal requirements and adequately justified its decision. A disagreement at one level does not necessarily determine the outcome at another. A process may be technologically effective but legally unauthorised. A product may fall outside one regulatory category while remaining subject to another.

A regulator may correctly identify scientific uncertainty but select a measure that exceeds the applicable statutory powers. The objective of judicial review is not to reward either innovation or regulatory caution as an abstract preference. It is to ensure that decisions are reached within the governing legal framework and on a sufficiently reasoned evidentiary basis.

364. Three distinct forms of uncertainty

364.1. Scientific uncertainty

Scientific uncertainty concerns the available knowledge about a phenomenon. Examples include uncertainty about the mechanism of a technological effect, the persistence of an antimicrobial outcome or the formation of unintended reaction products. Scientific uncertainty may remain despite substantial experimental work. It must be distinguished from mere absence of information.

364.2. Regulatory uncertainty

Regulatory uncertainty concerns the legal classification or treatment of a product or process. For example, the applicable legislation may contain definitions whose application depends upon the actual technological function. A dispute may arise even where the relevant scientific facts are substantially agreed.

364.3. Evidentiary uncertainty

Evidentiary uncertainty concerns whether the available material sufficiently establishes a relevant factual proposition. A technology may have a plausible scientific mechanism, but the manufacturer may lack validated evidence demonstrating effectiveness under the conditions of intended use.

364.4. Why the distinction matters

Each form of uncertainty requires a different response. Scientific uncertainty may justify further research or a risk assessment. Regulatory uncertainty may require interpretation of statutory definitions or a formal classification procedure. Evidentiary uncertainty may require additional testing, method validation or better documentation. An authority should not describe a legal classification disagreement as a scientific safety concern without identifying the relevant basis.

Equally, a manufacturer should not present unresolved scientific hypotheses as established facts merely because the regulatory category is disputed.

365. Regulation (EC) No 178/2002: The distinction between risk assessment and risk management

365.1. Article 6: A legally structured scientific process

Article 6 establishes risk analysis as a foundation of European food law, except where inappropriate to the circumstances or nature of the measure.

Risk analysis comprises three related but distinct activities:

- Risk assessment.
- Risk management.
- Risk communication.

The distinction prevents scientific evaluation from being confused with the administrative selection of regulatory measures.

365.2. Risk assessment

Risk assessment is a scientifically based process involving hazard identification, hazard characterisation, exposure assessment and risk characterisation. Article 6.2 requires assessment to be based upon available scientific evidence and conducted independently, objectively and transparently. A scientific assessment should therefore distinguish demonstrated findings from uncertainty, assumptions and limitations.

365.3. Risk management

Risk management involves weighing available policy options in light of risk assessment and other legitimate factors. It may consider the level of health protection, technical feasibility and the need for appropriate preventive action. The competent authority is not necessarily required to select the option preferred by the operator. However, its decision must remain within the applicable legal framework.

365.4. Risk communication

Risk communication concerns the exchange of information and opinions regarding hazards, risks, uncertainties and risk-management decisions. Its function is not simply to announce a regulatory conclusion. It contributes to transparency concerning the scientific and policy basis of decisions.

365.5. Why this distinction matters for innovation

A manufacturer may demonstrate that a new treatment produces a measurable technological effect. That does not necessarily establish the treatment's overall safety. Likewise, identification of a theoretical hazard does not automatically establish the probability or severity of adverse health effects under actual conditions of use. A legally defensible assessment should connect hazard, exposure, uncertainty and the relevant regulatory objective.

The central principle is that a hazard hypothesis, a completed risk assessment and a regulatory prohibition are three different propositions.

366. Article 7: Precaution is not an unrestricted substitute for evidence

366.1. Conditions for precautionary intervention

Article 7.1 permits provisional risk-management measures where assessment of available information identifies the possibility of harmful health effects, but scientific uncertainty persists. The provision does not require complete scientific certainty before protective action. However, it does require an evidentiary foundation for the possibility of harm.

366.2. The significance of uncertainty

Scientific uncertainty may arise from incomplete toxicological data, unresolved exposure questions or limitations in available analytical methods. The authority must identify the relevant uncertainty rather than relying upon a generic assertion that the technology is new. Novelty alone does not necessarily establish danger.

366.3. Proportionality

Article 7.2 requires precautionary measures to be proportionate and no more restrictive of trade than necessary to achieve the chosen level of health protection, taking account of relevant considerations. This requires examination of available regulatory options. Depending upon the circumstances, options may include additional testing, restricted conditions of use, monitoring, temporary detention or more extensive intervention.

The least restrictive option is not necessarily the correct option if it fails to provide the required level of protection.

366.4. Review within a reasonable period

Article 7.2 expressly requires review within a reasonable period, taking account of the nature of the risk and the information needed to clarify uncertainty. A precautionary measure is therefore not necessarily intended to remain unchanged indefinitely.

366.5. A fundamental qualification: Authorisation regimes

Article 7 must not be interpreted as permitting operators to bypass a mandatory prior-authorisation regime. If a technology or substance requires authorisation before marketing, the operator cannot ordinarily claim a right to market it merely because the authority has not proved that it is dangerous. The legal requirement to obtain authorisation is separate from the justification for adopting an additional precautionary restriction. This distinction is indispensable when assessing emerging technologies.

367. Regulatory classification: Why technological function matters

367.1. Classification is a legal determination

A substance's chemical identity may be scientifically established. Nevertheless, its regulatory classification may depend upon the function it performs, the circumstances of use and its presence in the final food. The same material may raise different regulatory questions when used in different ways.

367.2. Food additives

Article 3.2(a) of Regulation (EC) No 1333/2008 defines a food additive by reference to its characteristics, intentional addition for a technological purpose and the expected presence of the substance or its by-products in food. The legal definition contains further exclusions and qualifications. Classification cannot be determined solely by a manufacturer's commercial description.

367.3. Processing aids

Article 3.2(b) defines a processing aid through three cumulative elements:

1. The substance is not consumed as a food in itself.
2. It is intentionally used during processing for a technological purpose.

3. Any unintentional, technically unavoidable residues or derivatives in the final product present no health risk and have no technological effect in that final product.

The third element is particularly important. A manufacturer cannot establish processing-aid status simply by demonstrating that the substance was used during processing rather than added at the packaging stage.

367.4. The significance of residual technological function

A residue may be present in the finished food without automatically excluding processing-aid classification, provided the statutory conditions are satisfied. Conversely, a substance may have been used only briefly during manufacturing but still fail the processing-aid definition if its residual presence or technological function is incompatible with that definition.

367.5. Classification must follow the facts

Relevant evidence may include the substance's intended function, its behaviour during processing, its transformation products, residual presence and technological effects in the finished product. The applicable legislation determines which facts are legally decisive.

367.6. Processing-aid classification is not universal authorisation

Falling within the general definition of a processing aid does not establish that every proposed use is automatically lawful. Other Union or national rules may apply, including sector-specific requirements, safety obligations and restrictions concerning particular uses. The classification inquiry must therefore be followed by a separate compliance assessment.

368. Emerging processes involving conditioned water, reactive media and transient treatments

368.1. A particularly complex regulatory boundary

Some technologies operate by modifying a processing medium rather than introducing a conventional ingredient directly into food. Examples may include conditioned water, reactive processing environments and transient physicochemical treatments. Their classification cannot be resolved merely by calling the medium water or the intervention physical.

368.2. The relevant questions

A competent assessment may need to determine whether:

- A substance is intentionally introduced into the processing medium.
- That substance or its reaction products contact the food.
- The treatment changes the chemical composition of the food.
- Relevant residues remain.
- Any residues retain a technological function.
- The intervention falls within another specifically regulated category.
- The process creates foreseeable chemical, microbiological or physical hazards.

368.3. Transformation before food contact

Where a processing medium is prepared before application to food, the sequence of preparation may be relevant. However, the fact that a reagent was introduced into water rather than directly into food does not, by itself, determine the legal classification. The actual technological function and consequences of use remain decisive.

368.4. The evidentiary importance of mass balance

A mass-balance assessment may help establish the fate of substances introduced during processing. Relevant measurements may concern input materials, transformation products, residues and waste streams. The level of detail required depends upon the regulatory question and available methods.

368.5. Mechanistic claims

Claims involving ion transport, electro-permeabilisation, changes in molecular association or other physicochemical effects require appropriate experimental support. A change in pH, conductivity or oxidation-reduction potential does not, by itself, establish a particular biological mechanism. Similarly, observed microbial reduction does not independently prove the mechanism responsible for that reduction.

368.6. Scientific evidence and regulatory claims

The strongest regulatory dossier distinguishes:

Observed outcome: A measurable effect demonstrated under specified experimental conditions. Proposed mechanism: An explanation supported to a stated degree by available evidence. Safety conclusion: An assessment of relevant hazards and exposure. Legal classification: The application of statutory definitions to the established facts. This separation reduces the risk of converting a plausible hypothesis into an unsupported regulatory assertion.

369. Novel foods: The legal importance of Article 4 of Regulation (EU) 2015/2283

369.1. The operator's initial responsibility

Regulation (EU) 2015/2283 establishes the Union framework for novel foods. Article 4 requires food business operators to verify whether a food they intend to place on the Union market falls within the Regulation's scope. The determination is legally significant because novel foods generally require authorisation before lawful marketing.

369.2. Consultation where status remains uncertain

Where operators remain uncertain after considering available information, Article 4 provides for consultation with the competent authorities of the Member State in which they first intend to place the food on the market. Commission Implementing Regulation (EU) 2018/456 establishes procedural requirements for that consultation.

369.3. Novel process versus novel food

A new manufacturing process does not automatically mean that the resulting food is a novel food. The Regulation's definitions and conditions must be examined. However, certain foods resulting from production processes not used for food production within the Union before the relevant historical date may fall within the novel-food framework where the statutory conditions are satisfied.

369.4. A crucial historical threshold

The novel-food regime uses 15 May 1997 as an important reference date for significant consumption history in the Union. The date must be considered together with the relevant categories and definitions. It is not a universal rule

under which every technology introduced after that date automatically requires novel-food authorisation.

369.5. The distinction between status and safety

A determination that a food is novel addresses its regulatory status. Authorisation requires a separate evaluation under the applicable framework. An operator cannot establish authorisation simply by showing that the food has been consumed without reported incidents elsewhere.

369.6. Practical significance

Where uncertainty concerns whether a resulting food falls within the novel-food definition, the Article 4 consultation mechanism may provide a more appropriate route than informal correspondence with multiple inspection authorities. However, the consultation is not a substitute for any authorisation required following a determination of novel-food status.

European Commission

370. Scientific disagreement and judicial deference: Upjohn and Gowan

370.1. The central judicial problem

Courts reviewing complex technical decisions must distinguish between scientific assessment and legal control. An authority may possess specialised expertise. Nevertheless, expertise does not confer immunity from judicial scrutiny.

370.2. Upjohn, Case C-120/97

In Upjohn Ltd v The Licensing Authority, judgment of 21 January 1999, the Court of Justice considered judicial review of a decision concerning a medicinal product marketing authorisation. The judgment recognised the significance of complex scientific assessments and the limits of judicial substitution of administrative technical judgment. Its relevance to food regulation is analogical, not direct.

370.3. Gowan, Case C-77/09

In Gowan Comércio Internacional e Serviços Lda v Ministero della Salute, judgment of 22 December 2010, the Court considered Union restrictions

concerning a plant-protection active substance. The judgment recognised broad discretion in complex scientific risk assessments. However, it also confirmed that judicial review includes examination of procedural compliance, factual accuracy, manifest errors of assessment and misuse of powers. This is a particularly useful formulation of the relationship between scientific discretion and legality.

370.4. Technical deference is not factual immunity

A court may recognise that the competent authority has specialised scientific responsibilities. It may nevertheless examine whether the authority relied upon incorrect factual assumptions or failed to consider material evidence. A technical assessment unsupported by the record is not protected merely because it concerns science.

370.5. Technical disagreement is not automatically manifest error

The existence of a contrary expert opinion does not necessarily establish that the authority committed a manifest error. Scientific disciplines may contain legitimate disagreements. The court must assess the applicable standard of review and the significance of the competing evidence.

370.6. The distinction between law and technical judgment

Whether a substance satisfies the legal definition of a processing aid is ultimately a question involving legal interpretation and established facts. Whether a particular treatment produces a specified biochemical effect may require specialised scientific assessment. The two questions interact, but they should not be merged into a single assertion of administrative discretion.

371. Monsanto Agricoltura Italia: A directly relevant judgment concerning novel foods and precaution

371.1. Identification

Court of Justice, Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others, Case C-236/01, judgment of 9 September 2003, ECLI:EU:C:2003:431. The proceedings concerned genetically modified maize-derived foods, the former novel-food regime and national restrictions upon marketing.

371.2. The regulatory context

The dispute arose under Regulation (EC) No 258/97, which has since been replaced by the current novel-food framework. The case therefore cannot be used as a substitute for the provisions of Regulation (EU) 2015/2283. Its significance lies in the Court's treatment of scientific evidence and protective restrictions.

371.3. Substantial equivalence

The Court considered the legal significance of substantial equivalence within the former simplified procedure. The judgment addressed the relationship between compositional differences, scientific assessment and the applicable legal requirements.

371.4. National protective measures

The Court examined the conditions under which Member States could restrict or suspend marketing under the relevant safeguard mechanism. The judgment emphasised the need for a sufficiently substantiated risk assessment. It did not treat purely hypothetical risk as an adequate foundation for every restrictive measure.

371.5. The significance of scientific uncertainty

The case illustrates that uncertainty may justify precautionary action under the applicable legal conditions. However, the authority must connect the intervention to the evidence and the governing legal framework.

371.6. Application to emerging technologies

A regulator examining a new processing technology may identify uncertainties concerning safety. The operator may contest the relevance or severity of those uncertainties. The judicial question is not whether the technology is innovative. It is whether the applicable legal conditions for intervention have been satisfied.

Established holding: The judgment interpreted the former novel-food and safeguard framework.

Continuing doctrinal relevance: It provides important guidance concerning scientific risk assessment and the evidentiary foundation of protective restrictions, subject to the legislation now in force.

372. Administrative motivation and the treatment of competing expert evidence

372.1. Article 35 of Law 39/2015

Article 35 requires reasons for specified administrative acts, including acts limiting rights or legitimate interests and certain decisions departing from previous administrative criteria. This requirement is particularly important where an authority rejects a detailed technical submission.

372.2. The authority need not adopt the operator's conclusions

A manufacturer may submit an extensive scientific dossier. The competent authority may lawfully disagree. However, where the decision requires motivation, the reasons must permit understanding of its factual and legal foundation.

372.3. The relevance of expert qualifications

Expert competence matters.

Nevertheless, qualifications alone do not determine which scientific conclusion is correct. The authority should consider the quality, relevance and methodological reliability of the evidence.

372.4. Independent studies

Independently conducted studies may provide useful support. However, independence does not eliminate the need to assess experimental design, reproducibility and applicability to the intended industrial conditions.

372.5. Proprietary research

A manufacturer may rely upon confidential studies. The authority may require access to information necessary for the exercise of its lawful functions. Confidentiality and regulatory verification must therefore be reconciled under the applicable legal framework. A claim of trade secrecy does not create an absolute exemption from official inspection powers.

372.6. Unsupported rejection

A decision rejecting evidence solely because it originates from the manufacturer may require closer examination. Industry-generated evidence is not automatically

invalid. Its reliability depends upon the methods, data and circumstances. Equally, the manufacturer's financial interest may be relevant to assessing potential bias.

372.7. A reasoned disagreement

A legally robust decision should identify the decisive scientific and legal issues. It should explain why the available evidence does or does not satisfy the applicable requirement. The appropriate level of detail depends upon the decision and procedural framework.

373. Scientific evidence: A proposed hierarchy of regulatory reliability

The following hierarchy is an analytical proposal. It is not a statutory ranking applicable to every regulatory dossier. Scientific evidence should be evaluated according to its relevance to the particular claim.

Evidence category	Principal value	Important limitation
Mechanistic hypothesis	Identifies plausible scientific explanations	Does not establish actual industrial performance
Exploratory laboratory experiment	Detects potentially relevant effects	May lack representative operating conditions
Controlled laboratory validation	Supports reproducibility under defined conditions	May not establish industrial scalability
Pilot-scale validation	Tests performance in a more realistic environment	May not capture all full-scale variability
Industrial validation	Demonstrates performance under actual operating conditions	May remain site- or process-specific
Independent replication	Strengthens confidence in reproducibility	Must use sufficiently comparable conditions
Safety assessment	Evaluates relevant hazards and exposure	Depends upon scope and quality of underlying data
Regulatory conformity assessment	Connects evidence to legal requirements	Does not necessarily constitute formal authorisation

373.1. The danger of confusing technological effectiveness with safety

A treatment may produce a statistically significant reduction in microbial counts. That does not automatically establish that it is safe for every food matrix or use condition.

373.2. The importance of representative conditions

Laboratory findings may not reproduce industrial variability. Differences in raw materials, process duration, temperature, contact conditions and product composition may affect outcomes.

373.3. Reproducibility

Independent replication can strengthen confidence. However, replication must concern the same relevant scientific claim. A study demonstrating a related mechanism in a different system may not establish the performance of the technology under examination.

373.4. Negative findings

Negative results should be considered alongside positive results. Selective presentation may distort the scientific record.

373.5. Regulatory decision rules

Even strong scientific evidence must be connected to the applicable legal requirement. The authority may need evidence concerning safety, identity, efficacy or residual presence, depending upon the regulatory category. The evidentiary question cannot be answered without first identifying the legal question.

374. Regulatory guidance, technical standards and the limits of soft law

374.1. The function of guidance

Regulatory guidance may explain how authorities interpret legislation or evaluate scientific dossiers. It can promote predictability and consistency.

374.2. Binding and non-binding instruments

Not every guidance document possesses the same legal status. A directly applicable Union regulation differs from a non-binding administrative recommendation. The authority must identify the legal foundation for mandatory requirements.

374.3. The danger of converting guidance into legislation

An authority may rely upon guidance when assessing evidence. However, non-binding guidance should not automatically be treated as an independent source of obligations beyond the applicable legal framework.

374.4. Scientific standards

International standards may provide recognised methods or technical criteria. Their legal significance depends upon whether they are incorporated into binding legislation, required by an applicable regulatory instrument or used as evidence of accepted scientific practice.

374.5. Departures from guidance

An operator may propose an alternative scientifically validated method. Whether the alternative is permissible depends upon the governing legislation. Where a mandatory method is prescribed, scientific equivalence alone may not authorise substitution. Where the law permits validated alternatives, the authority should assess the relevant evidence under the applicable conditions.

374.6. Legal certainty

Transparent guidance can reduce uncertainty. However, legal certainty also requires authorities to distinguish binding obligations from recommended practices.

375. Original doctrinal contribution: The Scientific Evidence, Regulatory Classification and Judicial Review Framework

The research proposes the Scientific Evidence, Regulatory Classification and Judicial Review Framework (SERC-JRF). SERC-JRF is an original academic analytical model, not an established judicial test. Its purpose is to prevent scientific, evidentiary and legal classification disputes from being treated as a single undifferentiated question.

375.1. Eleven dimensions

Dimension	Principal inquiry
1. Technology identity	What material, process or technological intervention is actually being evaluated?
2. Intended function	What technological effect is claimed?
3. Applicable legislation	Which Union and national legal regimes may apply?
4. Regulatory classification	Which statutory definitions are relevant?
5. Scientific mechanism	What is established, hypothesised or unknown?
6. Effectiveness evidence	What reproducible results support the claimed function?
7. Safety evidence	What hazards, exposures and uncertainties have been assessed?
8. Authorisation requirements	Is prior authorisation required independently of the risk assessment?
9. Administrative reasoning	Has the authority explained the decisive factual and legal grounds?
10. Proportionality	Is any restriction justified under the applicable statutory framework?
11. Judicial review	Which aspects concern legal interpretation, factual accuracy or complex scientific assessment?

375.2. The model's central contribution

SERC-JRF requires the decision-maker to answer four separate questions:

What is the technology?

What does the evidence establish?

How does the law classify the relevant activity or product? What regulatory consequence follows? Failure to distinguish these questions may produce both scientific and legal errors.

375.3. Proposed assessment sequence

1.- Define the technology

Identify the actual material, process, intended use and relevant outputs.

2.- Identify the legal categories

Examine potentially applicable definitions and authorisation regimes.

3.- Separate evidence from hypotheses

Distinguish observations, proposed mechanisms and unresolved uncertainties.

4.- Evaluate scientific validity

Assess methods, controls, reproducibility and industrial relevance.

5.- Characterise safety

Identify hazards, exposure pathways and remaining uncertainties.

6.- Determine legal status

Apply the statutory criteria to the established facts.

7.- Assess administrative reasoning

Examine whether the authority considered the relevant evidence and explained its decision.

8.- Review intervention

Evaluate statutory authority, proportionality and available judicial remedies.

375.4. Four possible outcomes

Outcome I - Established compliance: The relevant legal requirements are satisfied on the available evidence. **Outcome II - Evidentiary insufficiency**: The legal category is identifiable, but the evidence does not establish compliance with its requirements. **Outcome III - Genuine classification dispute**: Material facts may be sufficiently established, but their legal classification remains contested.

Outcome IV - Scientific uncertainty requiring risk management: Available information identifies a relevant potential hazard, but further scientific assessment is required.

The outcomes may overlap. For example, a technology may present both classification uncertainty and insufficient safety evidence.

375.5. Research potential

SERC-JRF could be tested through comparative analysis of regulatory decisions involving innovative food processing technologies. Relevant variables might include the legal category disputed, the evidence submitted, the authority's reasoning, the treatment of uncertainty and the outcome of judicial review.

376. Applied industrial scenarios

Scenario A. A new antimicrobial processing method

A manufacturer demonstrates microbial reduction using a novel non-thermal treatment. The authority questions whether the intervention falls within a specifically regulated category. The operator must establish both the scientific performance of the treatment and its legal status. Evidence of antimicrobial effectiveness does not automatically establish regulatory authorisation.

Scenario B. Disagreement over processing-aid classification

A substance is used during manufacturing and may leave residual material in the final food. The manufacturer describes it as a processing aid. The authority considers that it may fall within the food additive regime. The legal assessment must apply the definitions in Regulation (EC) No 1333/2008, including the requirements concerning residues and technological function. The classification cannot be resolved solely through the manufacturer's intended terminology.

Scenario C. A technology with a disputed mechanism

A process consistently produces a measurable effect. However, the proposed mechanism remains scientifically contested. The authority must distinguish evidence of the observed outcome from evidence supporting the mechanism. Depending upon the applicable regulatory requirements, uncertainty concerning the mechanism may or may not prevent a particular compliance conclusion.

Scenario D. A new production process and novel-food status

A manufacturer introduces a production method not previously used in its operations. The resulting food has characteristics different from those produced by conventional methods. The operator must assess whether the resulting food falls within Regulation (EU) 2015/2283. Where status remains uncertain, the Article 4 consultation procedure may be relevant.

Scenario E. Precautionary intervention based upon incomplete evidence

An authority identifies a plausible potential hazard associated with an emerging technology. The available scientific evidence is incomplete. The authority imposes a provisional restriction. The legal assessment must examine the conditions of Article 7 of Regulation (EC) No 178/2002, including the evidentiary foundation, proportionality and subsequent review.

Scenario F. Rejection of a technical dossier without adequate reasoning

A manufacturer submits a detailed validation dossier. The authority rejects the proposed application but does not identify the decisive deficiency. The operator challenges the decision. The legal issue concerns the applicable motivation requirements and whether the decision possesses a sufficient factual and legal foundation. The court need not necessarily substitute its own scientific assessment to identify a defect in administrative reasoning.

377. Conclusions of the fourteenth instalment of Part II

Emerging food technologies create challenges that cannot be resolved through either unrestricted regulatory discretion or an automatic presumption in favour of innovation. European Union food law requires scientific assessment, appropriate risk management and compliance with applicable authorisation regimes. Article 6 of Regulation (EC) No 178/2002 establishes the distinction between risk assessment and risk management. Article 7 permits precautionary intervention under defined conditions and requires proportionality and review.

Regulation (EC) No 1333/2008 establishes legal definitions relevant to the classification of food additives and processing aids. Regulation (EU) 2015/2283 provides a specific framework for determining novel-food status and obtaining the authorisations required for marketing. The judgments in Monsanto Agricoltura Italia, Upjohn and Gowan illustrate important aspects of scientific assessment, regulatory discretion and judicial control, although they arose under different legislative regimes.

The central conclusion is: **Scientific uncertainty does not automatically authorise prohibition, and technological innovation does not automatically establish regulatory compliance. Lawful decision-making requires accurate classification, relevant scientific evidence, reasoned assessment and application of the appropriate legal standard.**

The proposed SERC-JRF framework provides a structured method for distinguishing scientific disputes, evidentiary deficiencies and legal classification disagreements.

Primary legislation and judicial authorities

1. Regulation (EC) No 178/2002 — Articles 3, 6 and 7 concerning risk analysis and precaution.
2. Regulation (EC) No 1333/2008 — Article 3 concerning food additives and processing aids.
3. Regulation (EU) 2015/2283 — Novel foods, including Article 4 consultation.
4. Commission Implementing Regulation (EU) 2018/456 — Novel-food status consultation procedure.
5. Court of Justice, Monsanto Agricoltura Italia, C-236/01 — Scientific assessment and protective restrictions under the former novel-food regime.
6. Court of Justice, Gowan, C-77/09 — Complex scientific assessment, administrative discretion and judicial review.
7. Court of Justice, Upjohn, C-120/97 — Judicial review of complex scientific assessments in pharmaceutical regulation.
8. Spanish Law 39/2015 — Articles 35 and 77 concerning motivation and evidence.
9. Spanish Constitution — Articles 9.3, 24, 38, 103 and 106.

CHAPTER 29

378. Regulatory Classification of Processing Aids, Food Additives and Technological Treatments

Legal boundaries, residual technological function, transformation products, scientific evidence and the judicial control of regulatory classification.

Abstract

The distinction between food additives, processing aids, ingredients and technological treatments is among the most consequential classification problems in contemporary European food law.

The regulatory status of a substance cannot be established solely by its chemical identity, commercial designation or point of introduction into a manufacturing process. Its intended technological function, conditions of use, fate during processing, residual presence and effects in the finished food may all be legally significant.

The problem becomes particularly complex where an intervention involves a conditioned processing medium, transient chemical species, physicochemical transformation or a technology whose effects persist after the active processing agent has disappeared.

Such circumstances raise several distinct questions. Does the intervention involve a substance or a process? Does a substance satisfy the legal definition of a processing aid? Are residues technically unavoidable and safe? Do they retain a technological effect in the finished product? Does the treatment fall within an independently regulated category? And which scientific findings are necessary to establish these propositions?

This instalment examines the definitions and legal consequences established by Regulation (EC) No 1333/2008, their relationship with Regulation (EC) No 178/2002, and the broader requirements of Union food hygiene and official controls legislation. It distinguishes **the technological purpose of an**

intervention, the persistence of its effects and the residual technological function of a substance - three concepts that must not be conflated.

The article also addresses evidentiary responsibility, official sampling, administrative classification disputes and the limits of judicial deference to technical expertise. An original analytical model, the **Functional Classification and Residual Effect Assessment Framework (FCREAF)**, is proposed to structure classification decisions involving conventional substances and emerging food-processing technologies.

The central thesis is that **regulatory classification must follow the substance's actual function and legally relevant fate throughout processing, rather than the manufacturer's terminology or the Administration's unexamined assumptions about the technology**.

Keywords: Processing aids; food additives; technological function; residual activity; food ingredients; process water; transformation products; Regulation (EC) No 1333/2008; scientific validation; regulatory classification; food law.

378.1. Introduction: Classification as a question of law informed by science

Consider three manufacturing operations. In the first, a substance is intentionally incorporated into a finished food to preserve it throughout its shelf life. In the second, a substance is used temporarily to facilitate a manufacturing operation, and only technically unavoidable residues remain without any technological effect in the final food. In the third, a processing medium is conditioned before contact with food, producing measurable changes in the food or its microbiological status.

These interventions may have superficially similar industrial objectives. Their legal classification, however, cannot be presumed identical. The first may fall within the food additive framework, depending on the substance and the applicable statutory conditions. The second may satisfy the definition of a processing aid. The third requires further analysis of the medium, any substances introduced, the treatment's mechanism, the fate of reaction products and the regulatory categories potentially engaged.

A fundamental distinction must be maintained:

Scientific description establishes what happens. Legal classification determines which statutory consequences follow from those facts.

Neither the manufacturer nor the competent authority may resolve the classification simply by choosing a convenient label. The purpose of this instalment is to construct a methodologically rigorous approach to that distinction.

379. The legal architecture: A classification cannot be derived from a single regulation

379.1. Regulation (EC) No 178/2002

The General Food Law Regulation establishes the overarching framework of food safety, operator responsibility, traceability and risk analysis. Its definitions and general obligations remain relevant regardless of whether a particular technological substance is classified as an additive or processing aid.

379.2. Regulation (EC) No 1333/2008

Regulation (EC) No 1333/2008 establishes the harmonised Union framework for food additives. Article 3 contains the principal definitions relevant to distinguishing additives from processing aids.

379.3. Regulation (EC) No 852/2004

The hygiene framework applies to food business operations and the management of relevant hazards. A processing treatment does not escape hygiene obligations merely because it falls outside the additive definition.

379.4. Regulation (EU) 2017/625

Official controls legislation governs how competent authorities verify compliance with food law. It does not independently transform every processing substance into an additive. Classification must be grounded in the relevant substantive legislation.

379.5. Sector-specific legislation

Other regimes may apply depending on the product and intervention, including legislation concerning extraction solvents, food enzymes, food-contact materials, novel foods, contaminants and particular foods of animal origin. The legal analysis must therefore proceed through **cumulative regulatory screening**, rather than assuming that a favourable conclusion under one definition resolves all applicable obligations.

380. Spain's decisive national framework: Royal Decree 773/2023

An essential feature of the Spanish legal position is the existence of **Royal Decree 773/2023 of 3 October**, regulating processing aids used in the production and preparation of food. The decree entered into force on 24 October 2023 and has subsequently been amended. The BOE's consolidated text records amendments published in November 2025 and February 2026, including changes affecting Annex I.

This legislation is especially important because the EU definition of a processing aid does not amount to a fully harmonised Union authorisation system for all processing aids.

380.1. Scope of the Spanish decree

Article 1 establishes basic rules concerning processing aids, identity and purity criteria, conditions of use and labelling.

The principal listed applications are structured through Annex I:

- Part A identifies food categories.
- Part B identifies the relevant processing aids and conditions.

The decree therefore requires examination of both the substance and the intended food application.

380.2. Article 2: The substantive definition

Article 2 incorporates the essential three-part definition of a processing aid. The substance must not be consumed as food in itself; it must be intentionally used for a technological purpose during processing; and any technically unavoidable residues or derivatives must be safe and have no technological effect in the final food.

These are cumulative requirements.

380.3. Article 3: A classification is not sufficient by itself

Article 3 establishes the conditions governing use. For applications within the scope of Annex I, the relevant entries and restrictions must be examined. The decree also recognises specified additional routes, including legally marketed

processing aids from other Member States under the conditions of mutual recognition.

380.4. Food additives used as processing aids

Article 3.3 permits a substance authorised as a food additive to be used as a processing aid even if it is not listed in Part B of Annex I, provided compliance with the processing-aid definition can be demonstrated. This provision is significant because it recognises that the same substance may be used for different technological purposes under different legal classifications. It does not mean that every additive can be used without regard to its actual safety or technological function.

380.5. Food categories outside Annex I

Article 3.4 addresses processing aids used in food categories not included in Part A of Annex I. It requires operators to be able to reliably guarantee the safety of the processing aids and foods concerned, in accordance with Regulation (EC) No 178/2002. This provision must not be confused with an unrestricted permission to use any substance in any food. Other applicable legislation remains relevant.

380.6. Processing aids requiring evaluation

Under Article 1.3, processing aids falling within the specified scope and not covered by the relevant exceptions require evaluation by AESAN's Scientific Committee for approval and inclusion in Annex I, subject to the decree's conditions. The current text must be consulted because this provision was amended in 2026.

380.7. Regulatory significance

The Spanish framework prevents two opposite oversimplifications. First, an operator cannot assume that satisfying the abstract EU definition automatically establishes the legality of every application in Spain. Second, an authority should not assume that a substance must be prohibited merely because it is not found in a particular Annex I entry, without examining the decree's scope, exceptions and other applicable provisions. **The correct legal sequence is definition, scope, applicable route, conditions of use and safety demonstration.**

381. The distinction between residual presence and residual technological function

381.1. Two different questions

A laboratory may detect a residual substance in finished food. That finding addresses presence.

It does not, by itself, determine whether the residue continues to perform a technological function. The distinction is central to processing-aid classification.

381.2. Residual presence

Residues may consist of the original substance, derivatives or transformation products. Their detection depends upon analytical sensitivity, sample preparation and the methods used. A finding below a method's detection limit is not equivalent to proof of absolute absence.

381.3. Residual technological function

The relevant inquiry is whether residues or derivatives exert a technological effect in the final product. This may require investigation of concentration, chemical form, bioavailability, reactivity and the properties of the food matrix.

381.4. Persistence of the treatment's outcome

A particularly important distinction concerns the persistence of a beneficial result. Suppose a temporary processing treatment reduces microbial contamination. The resulting food may remain microbiologically improved after the processing agent has been removed or inactivated. That persistent outcome does not necessarily mean that residual processing-aid material continues to exert a technological effect. The outcome of treatment and the activity of residual material are different scientific propositions.

381.5. An important limitation

This distinction must not be used to claim processing-aid status automatically. If the intervention leaves an active antimicrobial residue that continues protecting the finished food, that residual function may be inconsistent with the processing-aid definition. The factual conclusion must be supported by appropriate evidence.

381.6. A three-part analytical test

The research proposes distinguishing:

Process-stage function: What the substance does during manufacturing. **Residual chemical presence:** What remains in the final food. **Residual technological activity:** Whether what remains continues to perform a technological function. These variables may be related, but they are not identical.

382. Transformation products and reaction chemistry

382.1. The parent substance is not the entire assessment

A substance may be transformed during processing. The resulting products may differ substantially from the starting material. A classification assessment that examines only the original substance may therefore be incomplete.

382.2. Relevant transformations

Depending upon the chemistry involved, transformations may include neutralisation, oxidation, reduction, hydrolysis, precipitation, volatilisation or reactions with food constituents. These are general examples, not assumptions about any particular proprietary technology.

382.3. Analytical requirements

A suitable study may require identification or estimation of:

- The starting substance.
- Relevant intermediate species.
- Stable transformation products.
- Residues in the final food.
- Potentially hazardous by-products.
- Technological activity attributable to residual material.

382.4. The distinction between chemical change and safety

A substance may disappear analytically because it has reacted. That does not automatically establish that the resulting products are harmless. The safety assessment must address the relevant products and exposure conditions.

382.5. The problem of incomplete mass balance

Where significant material cannot be accounted for, the operator may face uncertainty concerning the fate of the processing substance. The importance of that uncertainty depends upon the process, the substance and the applicable safety requirements.

382.6. Scientific proportionality

Not every processing operation requires the same analytical programme. Testing should be designed around plausible hazards and legally relevant questions. An indiscriminate demand for every conceivable measurement may be scientifically inefficient and legally difficult to justify. Conversely, a narrowly selected analytical panel may fail to detect the hazards most relevant to the process.

383. Conditioned processing media: Does indirect introduction alter classification?

383.1. The problem

A manufacturer prepares a processing medium before applying it to food. A reagent may be introduced into water, a gas stream or another medium. The conditioned medium then contacts the food. The manufacturer argues that the reagent is not directly added to the food. The authority argues that the intervention constitutes the use of a regulated technological substance. Neither conclusion follows automatically from the physical sequence.

383.2. Direct and indirect introduction

The route of introduction is a relevant fact. However, the legal classification depends upon the definitions and conditions established by the applicable legislation. An indirect route does not necessarily prevent a substance or its derivatives from reaching the food.

383.3. The legal significance of water

Article 2 of Regulation (EC) No 178/2002 includes water intentionally incorporated into food during manufacture, preparation or treatment within the definition of food, subject to the provision's qualifications. This does not mean that all process water is automatically an ingredient in every application. The actual use and incorporation must be assessed.

383.4. Rinsing and surface treatment

Where conditioned water is used for washing or surface treatment, relevant questions include whether the treatment medium is retained, whether substances transfer to the food and whether any residual material continues to exert a technological effect. The fact that the bulk medium is subsequently drained does not eliminate the need to consider residues or reaction products.

383.5. A hypothetical example

A processing medium is prepared by adding a mineral reagent to water. The conditioned water is applied briefly to a food surface and then removed. The operator reports a measurable reduction in microbial counts.

A defensible assessment would require separate examination of:

1. The identity and function of the introduced substances.
2. The physicochemical properties of the conditioned medium.
3. The treatment's validated microbiological performance.
4. The fate of relevant substances during contact and removal.
5. Residual presence and technological activity.
6. Product safety and other applicable sector-specific requirements.

The short duration of application is not, by itself, determinative.

383.6. The role of process design

Process design may affect exposure and residual behaviour. Nevertheless, the operator must substantiate any claim that the final product contains no technologically active residues.

383.7. A critical scientific distinction

Claims concerning electro-permeabilisation, ion transport or cell-membrane disruption must be supported by evidence appropriate to those mechanisms. An observed antimicrobial effect does not prove electroporation. Likewise, changes in conductivity or pH do not independently demonstrate the mechanism responsible for microbial inactivation. This distinction is essential for scientific credibility.

384. The legal relevance of physical and physicochemical treatments

384.1. A process is not necessarily a substance

Some technological interventions act principally through physical conditions. Examples include pressure, temperature, mechanical forces and certain forms of energy transfer. Such processes may fall outside the food additive definition because they do not involve the intentional addition of a qualifying substance.

384.2. Physical effects may involve chemical consequences

A process described as physical may nevertheless produce chemical changes in the food or processing environment. The regulatory analysis must examine those consequences where relevant.

384.3. The limits of terminology

Terms such as *physical*, *natural*, *non-chemical* or *residue-free* are not substitutes for statutory classification. A treatment may be described as physical while using a chemically active medium. Conversely, a treatment may involve a substance without necessarily satisfying the food additive definition.

384.4. Sector-specific authorisations

Some technological processes are governed by specific legislation. A conclusion that an intervention is not a food additive does not automatically establish that the process is unrestricted.

384.5. The novel-food interface

Where a new production process results in a food meeting the conditions of Regulation (EU) 2015/2283, novel-food requirements may become relevant. However, use of a new process does not automatically make every resulting food a novel food. The statutory criteria must be applied.

385. Safety assessment: From hazard identification to exposure

385.1. Classification and safety are separate requirements

A substance may satisfy the definition of a processing aid while still requiring a demonstration that its intended use is safe. The processing-aid definition itself requires that residues and derivatives present no health risk.

385.2. Hazard identification

The first task is to identify relevant hazards. These may concern the starting substance, impurities, transformation products or unintended changes in the food.

385.3. Exposure assessment

The relevant exposure depends upon actual conditions of use. A hazard identified at a high experimental concentration may not imply the same risk at substantially lower exposure. Conversely, low nominal dosing does not necessarily establish safety where a hazardous reaction product is formed.

385.4. Representative worst-case conditions

A safety dossier may need to examine foreseeable operating conditions that maximise relevant exposure. However, worst-case scenarios should remain scientifically plausible.

385.5. The importance of the food matrix

Different foods may interact differently with the same processing substance. Protein-rich, lipid-rich and carbohydrate-rich matrices may produce different transformation or retention profiles. Results obtained in one food cannot automatically be extrapolated to all foods.

385.6. Cumulative exposure

Where the same substance or derivative may arise from multiple sources, cumulative exposure may be relevant. The necessity and scope of such assessment depend upon the substance and regulatory context.

385.7. A negative conclusion must be appropriately supported

A statement that no harmful residues are present should identify the basis for that conclusion. It may depend upon validated analytical methods, toxicological information, mass-balance evidence or other appropriate scientific material. A general assertion that a substance is naturally occurring is not a substitute for safety assessment.

386. Evidence of technological function: How should persistence be demonstrated?

386.1. The central experimental question

Where processing-aid classification depends upon absence of residual technological activity, the operator may need evidence distinguishing effects produced during processing from effects continuing in the finished product.

386.2. Comparative experimental design

A useful study may compare appropriately selected treated and untreated samples. However, such comparison alone may not identify whether an observed difference results from residual active material or from an irreversible effect of processing.

386.3. Analytical and functional evidence

Chemical analysis may identify residual substances. Functional testing may examine whether the residues remain capable of performing the relevant technological function.

Both may be necessary.

386.4. Stability studies

Studies conducted over time may help establish whether relevant residual activity persists. Their duration should correspond to the scientific question and the product's characteristics.

386.5. The limits of microbiological observations

A lower microbial count in treated food does not automatically establish continuing preservative activity. The reduction may have occurred during processing. To distinguish the mechanisms, experimental design must address when the effect occurs and whether active residual material contributes to subsequent microbial control.

386.6. No universal analytical method

There is no single analytical test capable of establishing absence of technological function for every substance and food matrix. The method must correspond to

the proposed function, chemical characteristics and relevant regulatory requirement.

387. Labelling: Processing aids, ingredients and residual substances

387.1. Classification affects labelling

The legal distinction between an ingredient, additive and processing aid may affect the information required on food labels. However, labelling consequences must be determined under the applicable legislation.

387.2. Regulation (EU) No 1169/2011

Article 20 establishes specified omissions from the list of ingredients, including certain processing aids, subject to the Regulation's conditions. This does not mean that every substance described by a manufacturer as a processing aid may be omitted.

387.3. Allergens

Article 21 and Annex II establish requirements concerning substances or products causing allergies or intolerances. The processing-aid classification does not automatically remove relevant allergen information obligations.

387.4. Carry-over

The treatment of additives present through carry-over must be distinguished from the treatment of processing aids.

Different legal conditions apply.

387.5. Misleading information

Article 7 prohibits misleading food information. Claims that a product is free from certain substances or that a process leaves no residues must be supported and assessed in context.

387.6. A significant legal caution

A manufacturer should not infer that a processing aid never needs to be disclosed under any circumstances. The correct labelling analysis must consider all relevant provisions, including allergen obligations and any sector-specific requirements.

388. Official controls and disputed classification

388.1. The authority's responsibility

Under Regulation (EU) 2017/625, competent authorities verify compliance with applicable food law. Where classification is disputed, the authority must identify the relevant legal provisions and factual basis.

388.2. The role of technical reports

Laboratory findings may help establish chemical identity, residual presence or product characteristics. However, laboratory findings do not independently determine every legal classification. The interpretation of the evidence remains necessary.

388.3. The role of administrative reasoning

Where a decision requires motivation under Spanish administrative law, the authority must explain the legally decisive grounds. A statement that a technology is unconventional does not, by itself, identify the applicable prohibition.

388.4. The operator's evidentiary position

The operator is responsible for ensuring compliance with food law applicable to activities under its control. It should maintain documentation supporting the claimed classification and safety of the intended use.

388.5. Burden of proof in sanctioning proceedings

Where the Administration imposes a sanction, the constitutional presumption of innocence and applicable administrative sanctioning rules remain relevant. The operator's general compliance responsibilities do not eliminate the Administration's duty to establish the elements of an alleged infringement.

388.6. Precautionary intervention

Where the authority identifies a potential health risk, precautionary action may be available under the relevant legal conditions. However, a classification dispute and a scientifically substantiated safety risk are not necessarily the same thing.

388.7. Judicial review

A court may examine whether the authority correctly interpreted the legal definition and relied upon adequate evidence. The existence of complex scientific

questions does not place the decision beyond judicial review. At the same time, the court must apply the appropriate standard when reviewing specialised technical assessments.

389. Mutual recognition and the limits of national discretion

389.1. The significance of incomplete harmonisation

Processing aids are not subject to one comprehensive harmonised Union authorisation regime equivalent to the food additive framework. Consequently, national rules remain important.

389.2. The Spanish recognition mechanism

Article 3.2 of Royal Decree 773/2023 expressly recognises specified processing aids lawfully marketed in other Member States, subject to the same restrictions and limitations applicable there and the conditions of the provision. The operator must maintain appropriate supporting documentation.

389.3. Recognition is not automatic exemption from safety law

Mutual recognition does not eliminate the operator's responsibility under Regulation (EC) No 178/2002. Nor does it necessarily override harmonised Union restrictions governing particular substances or applications.

389.4. Regulation (EU) 2019/515

Regulation (EU) 2019/515 establishes a framework for mutual recognition of goods lawfully marketed in another Member State in areas not subject to exhaustive Union harmonisation. Its application depends upon the relevant product and legal circumstances.

389.5. An important practical distinction

A substance being sold in another Member State does not, by itself, establish that the precise intended processing-aid application is lawful there. The operator must verify the relevant use and conditions.

389.6. Judicial implications

Where a competent authority refuses recognition, the decision may require examination under the applicable national and Union legal frameworks. A lawful

public health restriction may be permissible, but the authority must satisfy the relevant legal conditions.

390. Original doctrinal contribution: The Functional Classification and Residual Effect Assessment Framework

The research proposes the **Functional Classification and Residual Effect Assessment Framework (FCREAF)**. FCREAF is an original academic model, not an established judicial or regulatory test. It is designed to structure the classification of substances, conditioned media and emerging processing technologies.

390.1. Twelve dimensions

Dimension	Principal question
1. Intervention identity	What substance, medium or process is actually used?
2. Technological purpose	What effect is intentionally sought?
3. Route of application	How does the intervention contact the food?
4. Legal definitions	Which statutory categories may apply?
5. Process-stage activity	What happens during manufacturing?
6. Transformation chemistry	What derivatives or reaction products are formed?
7. Residual presence	What remains in the finished food?
8. Residual technological effect	Do residues continue performing a technological function?
9. Safety	Are relevant hazards and exposures adequately assessed?
10. National conditions	Does Royal Decree 773/2023 or other national law govern the use?
11. Additional regimes	Do additive, novel-food, hygiene or other sector-specific rules apply?
12. Evidentiary sufficiency	Does the dossier establish the legally decisive facts?

390.2. The framework's central contribution

FCREAF distinguishes three temporal stages.

Stage I — Before food contact

Identity, composition, conditioning of the medium, intended technological function and relevant safety characteristics.

Stage II — During processing

Actual technological action, transformation reactions, exposure conditions and measurable process outcomes.

Stage III — In the finished food

Residual substances, derivatives, safety and the presence or absence of continuing technological function.

390.3. Proposed decision sequence

The operator or authority should first identify the intervention and its intended function. It should then determine the potentially applicable legal categories. The scientific assessment should examine what occurs during processing and what remains in the finished food. Finally, the legal analysis should determine whether the established facts satisfy the statutory conditions and whether additional legislation applies.

390.4. Four analytical outcomes

Outcome I - Processing-aid classification supported: The relevant legal definition and applicable conditions of use are satisfied. **Outcome II - Food additive classification potentially applicable:** The intervention satisfies the relevant additive criteria, or the claimed processing-aid status is inconsistent with established facts. **Outcome III - Other regulatory category applicable:** The intervention falls within another relevant legal framework.

Outcome IV - Classification unresolved: The available evidence is insufficient to determine the correct legal status. These outcomes are not necessarily exhaustive or mutually exclusive.

390.5. The importance of avoiding false certainty

FCREAF does not presume that a substance is a processing aid simply because it is used transiently. Nor does it presume additive classification whenever any residual material is detected. The decisive inquiry is the application of the legal definitions to scientifically established facts.

391. Applied industrial scenarios

Scenario A. A preservative deliberately retained in the final food

A manufacturer incorporates a substance to inhibit microbial growth throughout shelf life. The substance remains active in the finished product. Processing-aid classification would require particularly careful scrutiny because the continuing technological function may be inconsistent with the statutory definition. The food additive regime and applicable authorisation conditions must be examined.

Scenario B. A temporary treatment followed by removal

A substance facilitates a manufacturing operation and is subsequently removed.

Trace residues may remain.

The classification analysis must establish whether the residues are technically unavoidable, safe and without technological effect in the final food. Complete analytical absence is not necessarily required by the processing-aid definition.

Scenario C. Conditioned water used for food surface treatment

A manufacturer prepares a conditioned aqueous medium and applies it to a food surface. The medium is subsequently removed. The legal assessment must examine the substances introduced, the actual technological function, transformation products, residual presence and any continuing technological activity. The fact that the treatment is delivered through water does not independently establish its legal classification.

Scenario D. A substance authorised as a food additive but used during processing

An authorised food additive is used for a different technological purpose during manufacturing. The manufacturer proposes processing-aid classification. Article 3.3 of Royal Decree 773/2023 may be relevant, provided the statutory conditions are satisfied. The operator must demonstrate the processing-aid characteristics of the actual use.

Scenario E. A processing aid used in a food category outside Annex I

An operator proposes a processing aid for a food category not included in Part A of Annex I of Royal Decree 773/2023.

Article 3.4 may be relevant.

However, the operator must reliably establish safety and examine other applicable legal restrictions.

Scenario F. A novel processing technology with uncertain reaction products

A manufacturer demonstrates a useful technological effect but has not characterised potentially relevant reaction products. The technology's effectiveness does not resolve the safety assessment. Additional analytical or toxicological evidence may be necessary before a defensible regulatory conclusion can be reached.

392. Conclusions of the fifteenth instalment of Part II

The classification of food-processing substances and technologies is a legal determination informed by scientific evidence. Regulation (EC) No 1333/2008 distinguishes food additives from processing aids through legally defined characteristics and technological functions. Processing-aid status requires examination of the intended processing function, the presence of residues or derivatives, their safety and their technological effect in the finished product.

Royal Decree 773/2023 provides a particularly important Spanish framework, including specified conditions of use, mutual recognition mechanisms and safety requirements. The decree's amendments through 2026 make consultation of the applicable consolidated text essential.

Several conclusions follow.

First, transient use does not automatically establish processing-aid classification. Second, residual detection does not automatically establish additive classification. Third, the persistence of a processing outcome must be distinguished from continuing technological activity attributable to residues. Fourth, indirect introduction through a processing medium does not eliminate the need to assess the actual substances and effects involved.

Fifth, a favourable classification under one legal regime does not establish exemption from all other applicable food law requirements.

The central conclusion is:

The legally decisive question is not simply whether a substance was added to food, but what function it performed, what happened to it during processing, what remains in the finished product and whether the

established facts satisfy the relevant statutory definition and conditions of use.

The proposed FCREAF framework offers a systematic methodology for addressing these questions.

Primary legislation and regulatory sources

1. Regulation (EC) No 1333/2008 on food additives — Articles 2–4 and Article 3 definitions.
2. Royal Decree 773/2023 on processing aids — Articles 1–5 and Annexes I–II, including amendments in force in 2026.

+1

3. Regulation (EC) No 178/2002 — General Food Law, food definition, safety and operator responsibilities.
4. Regulation (EC) No 852/2004 — Hygiene requirements.
5. Regulation (EU) 2017/625 — Official controls and enforcement.
6. Regulation (EU) No 1169/2011 — Articles 7, 18, 20 and 21 concerning food information, ingredients and allergens.
7. Regulation (EU) 2015/2283 — Novel-food classification and authorisation.
8. Regulation (EU) 2019/515 — Mutual recognition of goods lawfully marketed in another Member State.
9. European Commission — Food additives — Regulatory overview.

Food Safety

For definitive academic publication, the proposed framework should be tested against concrete regulatory decisions, published AESAN assessments and relevant judicial authorities. The illustrative scenarios do not establish the legal classification of any particular commercial product or proprietary technology.

CHAPTER 30

393. The Burden of Proof in Food Safety Enforcement

Scientific evidence, administrative presumptions, precautionary measures, analytical uncertainty and the constitutional limits of sanctioning powers.

Abstract

The evidentiary foundations of official food controls are frequently misunderstood because several distinct legal questions are treated as though they required the same standard of proof.

A food business operator has obligations to ensure compliance with applicable food law. Competent authorities possess powers to investigate suspected non-compliance and adopt protective measures where legally justified. Administrative sanctions, however, engage additional constitutional safeguards, including the presumption of innocence and the requirement to establish legally attributable responsibility.

These obligations cannot be reduced to a single proposition that either the operator or the Administration always bears the burden of proving safety. The correct allocation depends upon the legal question, the procedural context and the substantive regulatory regime.

A further difficulty arises from the probative value of official inspection records. Spanish administrative law recognises evidentiary weight for facts established by public officials under legally prescribed conditions, but this does not make every technical inference, legal classification or laboratory conclusion irrebuttable.

Scientific evidence introduces additional complexities. Sampling representativeness, analytical uncertainty, laboratory accreditation, chain of custody, conflicting expert opinions and the distinction between screening and confirmatory methods may determine whether a regulatory conclusion is sufficiently supported.

This instalment examines the interaction between Regulation (EU) 2017/625, Regulation (EC) No 178/2002, Article 24.2 of the Spanish Constitution, Law

39/2015 and Law 40/2015. It proposes an original **Food Enforcement Evidence and Burden Allocation Framework (FEEBAF)**, designed to distinguish compliance verification, precautionary intervention, established non-compliance and administrative punishment.

The central thesis is that **the evidentiary threshold governing an official food safety intervention must correspond to the legal consequences of the measure: suspicion may justify investigation, scientifically supported risk may justify proportionate protection, but administrative punishment requires proof of the legally relevant infringement and responsibility under the applicable sanctioning safeguards**.

Keywords: Burden of proof; presumption of innocence; official food controls; administrative sanctions; precautionary measures; inspection records; analytical uncertainty; expert evidence; second expert opinion; scientific risk assessment; judicial review.

393.1. Introduction: Four questions that must not be confused

An official laboratory detects a substance in a food product. The competent authority considers the result potentially relevant to food safety. The operator disputes the sampling procedure and analytical interpretation. The authority immobilises the consignment and subsequently initiates sanctioning proceedings. This sequence involves several distinct legal determinations. First, was there a sufficient basis to investigate? Second, was the evidence sufficient to justify a temporary protective measure?

Third, was non-compliance established under the applicable substantive law? Fourth, was the operator's legally attributable responsibility established for sanctioning purposes? An affirmative answer to one question does not automatically determine the others. The evidentiary basis for temporary detention may differ from the basis required for a final sanction. Similarly, a scientifically valid laboratory result may establish the presence of an analyte without establishing every element of an administrative infringement.

A rigorous legal analysis must therefore distinguish the **scientific proposition being tested** from the **legal consequence being imposed**.

394. The foundational distinction: Compliance responsibility and sanctioning proof

394.1. The operator's substantive obligations

Article 17 of Regulation (EC) No 178/2002 requires food and feed business operators, at all stages under their control, to ensure that foods and feeds satisfy the requirements of food law relevant to their activities and to verify that those requirements are met. This creates substantive compliance responsibilities. It does not automatically determine every evidentiary question arising in subsequent administrative proceedings.

394.2. The Administration's verification function

Competent authorities verify compliance through official controls. Their powers include inspection, examination of documentation, sampling, analysis and other legally authorised methods.

394.3. Precautionary intervention

Where credible information suggests a relevant risk, the authority may possess powers to investigate and adopt protective measures. The applicable conditions depend upon the substantive legal basis.

394.4. Administrative sanctions

Sanctioning proceedings involve the exercise of punitive public powers. They are subject to the constitutional presumption of innocence and the applicable statutory requirements concerning infringement, responsibility and evidence.

394.5. The decisive distinction

An operator may be required to maintain records demonstrating compliance. That obligation does not mean that the Administration may impose a sanction without proving the facts and legally relevant responsibility constituting the infringement. Conversely, the presumption of innocence does not mean that an operator can refuse every lawful request for information or that authorities must wait for a completed sanctioning case before acting against a genuine food safety risk.

395. Article 24.2 of the Spanish Constitution: The presumption of innocence in administrative sanctions

395.1. Constitutional protection beyond criminal proceedings

Article 24.2 of the Spanish Constitution recognises the presumption of innocence. The Constitutional Court has long established that essential guarantees associated with punitive proceedings also apply, with appropriate qualifications, to administrative sanctions. The constitutional guarantee therefore limits the Administration's ability to punish an operator merely because it suspects an infringement.

395.2. The necessity of incriminating evidence

A sanction must rest upon sufficient evidence of the relevant infringement. The authority must establish the legally decisive facts through evidence capable of supporting its conclusion. An unsupported allegation does not become proof simply because it appears in an official administrative file.

395.3. The distinction between proof and legal inference

The Administration may establish that a product contains a particular substance. It must then determine whether that fact constitutes an infringement under the applicable legislation. The existence of the substance and the legal consequences of its presence are separate propositions.

395.4. The requirement of responsibility

Even where objective non-compliance is established, the applicable sanctioning framework requires examination of responsibility. Article 28 of Law 40/2015 recognises responsibility *on the basis of* intent or negligence (*dolo o culpa*). The relevant degree of fault and attribution must be assessed under the applicable legislation.

395.5. No automatic punishment for an unsafe product

A product may be unsafe and require withdrawal or other protective action. That does not automatically establish that a particular person or company committed a sanctionable infringement with the required culpability. The protective and punitive dimensions must be analysed separately.

396. STC 18/1981: The constitutional foundation of administrative sanctioning guarantees

396.1. The judgment's significance

Spanish Constitutional Court, Judgment 18/1981 of 8 June 1981. This decision is a foundational authority concerning the extension of essential punitive law, guarantees to administrative sanctioning proceedings. The Court recognised that criminal law and administrative sanctioning law are manifestations of the State's punitive power.

396.2. Constitutional guarantees

The judgment established the importance of applying relevant constitutional safeguards to administrative punishment, with the qualifications appropriate to the administrative context. The decision does not mean that administrative and criminal proceedings are procedurally identical.

396.3. Application to food law

A food business may be subject to inspection and corrective measures under sector-specific legislation. If the Administration initiates punitive proceedings, the corresponding sanctioning safeguards become applicable.

396.4. The distinction between enforcement and punishment

A temporary protective measure intended to prevent exposure to a suspected risk does not automatically constitute a sanction. Its legal nature depends upon its statutory basis, purpose and effects. However, an authority cannot evade sanctioning guarantees merely by assigning a protective label to a measure whose legal nature is genuinely punitive.

396.5. The doctrinal consequence

The relevant constitutional analysis concerns the substance of the public intervention, not solely the terminology chosen by the Administration.

397. STC 76/1990: Official inspection records do not possess irrebuttable truth

397.1. Identification

Spanish Constitutional Court, Judgment 76/1990 of 26 April 1990. The judgment examined, among other questions, the evidentiary treatment of tax inspection records and the presumption of innocence in administrative sanctioning proceedings. Although the case arose in tax law, its general constitutional reasoning is highly relevant to food safety enforcement.

397.2. The central holding

The Court rejected the proposition that inspection records possess absolute and unquestionable truth. Their probative force remains compatible with the presumption of innocence because they may be challenged through contrary evidence. The opportunity to contest an official record does not, in itself, reverse the burden of proof.

397.3. Why the distinction matters

An inspector may record an observed fact. The operator may contest that fact through documentary, technical or other admissible evidence. The court or competent decision-maker must evaluate the evidence under the applicable rules.

397.4. The limits of the judgment

The case did not concern food laboratories, microbiological sampling or Regulation (EU) 2017/625. Its relevance is the general constitutional distinction between the probative value of official records and an impermissible presumption of absolute correctness.

397.5. Application to food inspections

A report stating that a particular storage temperature was measured may provide relevant evidence of that observation. However, whether the measurement was valid, whether the instrument was suitable and whether the circumstances constitute a particular infringement may require additional examination. **Established constitutional principle:** Official inspection records may have probative value without being immune to rebuttal. **Sectoral implication:** Food safety findings must remain open to legally admissible contrary evidence.

398. Article 77.5 of Law 39/2015: What exactly is presumed?

398.1. The statutory rule

Article 77.5 recognises probative value for documents formalised by officials having the legally recognised status of authority, provided the applicable requirements are observed and the documents record facts personally established by those officials. The provision expressly permits contrary evidence.

398.2. The distinction between facts and opinions

An official may directly observe that a container is unsealed. That observation may fall within the evidentiary rule if the statutory conditions are satisfied. However, a statement that the operator acted negligently is not necessarily a directly observed fact. It may involve legal or evaluative conclusions requiring separate justification.

398.3. Scientific inferences

An inspector may record that a sample was collected and sent to a laboratory. The analytical result is generated through a separate technical process. Its reliability depends upon the relevant sampling, analytical and laboratory conditions. The inspector's official status does not automatically resolve every scientific issue arising from that process.

398.4. Legal classification

A report may describe a material as a prohibited additive. However, the legal classification must be supported by the applicable legislation and established facts. Article 77.5 does not make the inspector's legal interpretation irrebuttable.

398.5. Contrary evidence

The operator may present admissible evidence challenging the record. Depending upon the issue, this may include photographs, calibration records, laboratory documentation, expert reports or other relevant material.

398.6. Article 77.3: The right to propose evidence

Article 77.3 permits rejection of evidence proposed by interested parties only where it is manifestly inappropriate or unnecessary, through a reasoned decision. The provision therefore limits arbitrary exclusion of relevant evidence.

398.7. Article 77.7: Evidence central to the decision

Where evaluation of evidence constitutes an indispensable foundation of the administrative decision, Article 77.7 requires its inclusion in the proposed resolution. This may be particularly important where the decision depends upon a contested laboratory result.

399. Scientific proof begins with sampling, not with the laboratory report

399.1. The sampling problem

A laboratory analyses the material it receives. It does not automatically establish that the material accurately represents an entire consignment. The distinction between sample and lot is therefore fundamental.

399.2. Representativeness

Sampling design must account for the distribution of the relevant hazard or analyte. Some contaminants may be relatively homogeneous. Others may occur in localised concentrations.

399.3. Heterogeneous matrices

Cocoa, cereals, spices, nuts and other particulate products may present significant sampling challenges, depending upon the contaminant and processing history. A laboratory result from a poorly selected sample may be analytically accurate but insufficiently representative of the relevant lot.

399.4. Chain of custody

The reliability of official sampling may depend upon documentation concerning collection, identification, sealing, transport, storage and receipt. A material defect may affect the evidentiary value of the result. However, not every minor documentation irregularity necessarily invalidates an otherwise reliable finding.

399.5. Sampling units and aggregate samples

Certain sector-specific regulations establish detailed sampling procedures. The number of incremental samples, preparation of aggregate samples and analytical sample requirements may be legally significant.

399.6. The distinction between validity and representativeness

A laboratory may validly determine that a submitted sample contains a contaminant. The separate question is whether the result supports a conclusion about the entire batch under the applicable sampling rules.

399.7. A proposed evidentiary principle

A legally consequential analytical conclusion should not exceed the population or material that the sampling design can reliably support. This is an analytical formulation rather than a universal statutory rule.

400. Article 34 of Regulation (EU) 2017/625: The legal requirements governing analytical methods

400.1. Union methods take priority where prescribed

Article 34 requires sampling and laboratory methods to comply with applicable Union rules establishing those methods or their performance criteria. Where specific methods are prescribed, their legal requirements must be respected.

400.2. Methods in the absence of specific Union rules

Article 34 establishes a hierarchy of appropriate methods, including internationally recognised standards and validated methods developed or recommended by relevant reference laboratories. The precise applicable route depends upon the availability and suitability of the methods.

400.3. Scientific validity

Article 34.5 requires samples to be taken, handled and labelled so as to ensure their legal, scientific and technical validity. This requirement connects procedural safeguards with analytical reliability.

400.4. Method validation

Relevant questions may include specificity, accuracy, precision, sensitivity, recovery and uncertainty. The required performance characteristics depend upon the analyte, matrix and applicable legislation.

400.5. The danger of analytical substitution

A rapid screening method may be appropriate for identifying samples requiring further examination. However, where the relevant legal framework requires

confirmatory analysis, an unconfirmed screening result cannot automatically be treated as equivalent to the required confirmatory determination.

400.6. The relationship with legal classification

Even a fully validated analytical method answers a defined scientific question. The result must still be interpreted under the relevant substantive law.

400.7. No universal evidentiary shortcut

Laboratory accreditation, method validation and official sampling each contribute to reliability. None automatically establishes every legal element of an infringement.

401. Measurement uncertainty and the legal interpretation of analytical results

401.1. What measurement uncertainty means

Measurement uncertainty characterises the dispersion of values that may reasonably be attributed to the measured quantity. It is not equivalent to an admission that the laboratory result is unreliable. A technically sound result may still possess measurable uncertainty.

401.2. Analytical uncertainty and sampling uncertainty

Laboratory measurement uncertainty concerns the analytical determination. Sampling uncertainty concerns variation associated with selecting material from the relevant population.

The two should not be conflated.

401.3. Maximum levels

Where legislation establishes a numerical maximum level, the authority must apply the relevant rules governing sampling, analysis, uncertainty and interpretation. Different regulatory regimes may prescribe different decision rules.

401.4. An illustrative numerical example

Suppose a hypothetical maximum level is 10 units. A laboratory reports a concentration of 10.4 units with an expanded measurement uncertainty of ±0.8 units. The result does not necessarily establish legally actionable exceedance under

every possible regulatory decision rule. Its interpretation depends upon the applicable legislation, method and treatment of uncertainty.

401.5. No universal subtraction rule

It would be incorrect to claim that the Administration must always subtract expanded uncertainty from every analytical result before determining non-compliance. Some regimes establish specific decision criteria. Others may use different approaches. The legal rule must be identified for the particular analyte and product.

401.6. Presence-or-absence criteria

For certain microbiological criteria, the legally relevant result may concern detection or non-detection under specified sampling conditions. The interpretation cannot necessarily be reduced to the numerical comparison used for chemical contaminants.

401.7. The evidentiary implication

A laboratory result should be interpreted according to the measurement question and the applicable legal decision rule. Scientific precision and legal certainty are related but distinct requirements.

402. Article 35: The right to a second expert opinion

402.1. The basic entitlement

Article 35 of Regulation (EU) 2017/625 requires competent authorities to ensure that operators whose goods are sampled, analysed, tested or diagnosed during official controls have access to a second expert opinion at their own expense.

402.2. Documentary review

Article 35.1 entitles the operator to request a documentary review of the original sampling, analysis, test or diagnosis by another recognised and appropriately qualified expert. This is a substantive procedural safeguard.

402.3. Additional sample material

Article 35.2 addresses the taking of sufficient sample material where relevant, appropriate and technically feasible, including where requested by the operator.

The provision recognises that some hazards, matrices and perishable products may not permit meaningful repeat analysis.

402.4. A second opinion is not automatically a second laboratory test

The right under Article 35.1 expressly concerns documentary expert review. Further analytical examination depends upon the relevant statutory conditions and national arrangements. The distinction should be preserved.

402.5. Article 35.3

Member States may provide mechanisms for further review or analysis by another official laboratory where disputes persist. The applicability of those arrangements must be assessed under the relevant national framework.

402.6. No automatic suspension of protective action

Article 35.4 expressly provides that requesting a second expert opinion does not prevent competent authorities from taking prompt action to eliminate or contain relevant risks.

This is essential.

The right to challenge evidence does not create an automatic entitlement to release potentially unsafe food.

402.7. The procedural balance

The regulatory framework seeks to reconcile two objectives:

The authority must be able to respond promptly to credible risks. The operator must have meaningful opportunities to scrutinise the evidence supporting official findings. Neither objective extinguishes the other.

403. Precautionary measures and sanctions: Different evidentiary thresholds

403.1. Suspected non-compliance

Article 137 of Regulation (EU) 2017/625 addresses suspected non-compliance. Competent authorities must investigate the suspicion and may adopt appropriate measures under the applicable conditions. A legally sufficient suspicion may justify investigation without establishing a completed infringement.

403.2. Established non-compliance

Article 138 concerns action where non-compliance has been established. The authority must determine the origin and extent of non-compliance and take appropriate measures.

403.3. Precaution under Regulation (EC) No 178/2002

Article 7 permits provisional risk-management measures under specified conditions where the possibility of harmful health effects has been identified but scientific uncertainty persists. Such measures must satisfy the applicable proportionality and review requirements.

403.4. Administrative punishment

A sanction requires establishment of the legally relevant infringement and responsibility. The constitutional presumption of innocence applies.

403.5. The danger of evidentiary migration

A common analytical error occurs when evidence sufficient to justify a preliminary investigation is treated as automatically sufficient to support a final sanction. For example, a screening result may justify confirmatory testing. It does not necessarily establish all the elements required for punishment.

403.6. The opposite error

A manufacturer may argue that no protective measure is lawful until every element of an administrative offence has been proved. That proposition is also incorrect. Protective intervention and punishment serve different legal purposes.

403.7. A functional comparison

Stage	Principal legal question	Evidentiary focus
Investigation	Is there a lawful basis to examine suspected non-compliance?	Credible information supporting suspicion
Precautionary action	Is protective intervention justified under the applicable power?	Risk, uncertainty, necessity and proportionality
Corrective enforcement	Has non-compliance been established?	Facts satisfying the relevant substantive requirements
Administrative sanction	Has a sanctionable infringement and attributable responsibility been established?	Sufficient incriminating evidence and culpability

These categories are analytical. They do not replace the precise statutory requirements of each procedure.

404. Article 28 of Law 40/2015: Culpability and legally attributable responsibility

404.1. The statutory requirement

Article 28.1 establishes that the persons and entities identified by the provision may be administratively sanctioned for infringements for which they are responsible through intent or negligence. This excludes treating administrative punishment as an unrestricted system of objective liability.

404.2. Objective non-compliance versus culpability

A product may fail a regulatory requirement. That fact may justify corrective action. However, the Administration must still address the legally relevant responsibility required for a sanction.

404.3. Corporate responsibility

Legal persons may incur administrative responsibility. The fact that a company acts through employees, managers or external service providers does not automatically exclude corporate liability. The relevant obligations, conduct and attribution must be assessed.

404.4. Due diligence

Evidence of appropriate preventive measures, validated procedures, training and compliance controls may be relevant to culpability. However, possession of an ISO certificate or other quality-management certification does not automatically establish absence of negligence.

404.5. The importance of foreseeability

The assessment may consider whether the relevant risk or infringement was reasonably foreseeable and whether the operator adopted the measures required under the applicable circumstances. The legal standard depends upon the substantive offence and governing legislation.

404.6. No automatic inference from the result

An adverse laboratory result does not, by itself, establish every element of negligent conduct. Equally, a manufacturer cannot necessarily avoid responsibility by showing that the infringement was unintended. Negligence may suffice where the statute so provides.

405. Conflicting expert reports: How should evidence be evaluated?

405.1. The problem of competing conclusions

An official laboratory reports non-compliance. A laboratory commissioned by the operator reports a different result. The authority considers the official finding decisive. The operator alleges that the official analysis is unreliable. The existence of disagreement does not automatically establish which result is correct.

405.2. Methodological comparison

Relevant questions may include whether the laboratories used comparable methods, sample preparation procedures, measurement units and decision criteria.

405.3. Sampling differences

Two laboratories may analyse different portions of a heterogeneous consignment. Different results may therefore reflect sampling variability rather than analytical incompetence.

405.4. Timing

The composition or microbiological status of food may change during storage. Analyses performed at different times may not be directly comparable.

405.5. Accreditation

Accreditation under ISO/IEC 17025 provides important assurance concerning laboratory competence within its accredited scope. However, accreditation does not make every result infallible.

405.6. Expert independence

Potential conflicts of interest may be relevant. Nevertheless, an expert's conclusion must be evaluated according to its technical merits. Evidence is not automatically invalid merely because the expert was engaged by one of the parties.

405.7. Judicial evaluation

Article 77.1 of Law 39/2015 refers to the evidentiary evaluation criteria established by the Spanish Civil Procedure Law. In judicial proceedings, the applicable procedural rules govern expert evidence and its evaluation. The court must examine the evidence in accordance with the relevant legal standards.

405.8. A proposed analytical rule

Where expert findings conflict, the decisive question should be which *conclusion is better supported by the relevant sampling design, analytical method, factual circumstances and applicable legal decision rule and not simply which expert possesses institutional authority.*

406. The evidentiary treatment of regulatory classification disputes

406.1. Classification is not a laboratory result

A laboratory may identify the chemical composition of a material. The authority must determine how the relevant legislation classifies the material in its actual conditions of use.

406.2. Processing aids and additives

A dispute concerning processing-aid status may require evidence of intended technological function, residual presence and residual technological activity. The relevant legal definitions must be applied.

406.3. The operator's documentation

The manufacturer may possess information necessary to establish the factual characteristics of its process. Its general compliance obligations may require appropriate records and cooperation with official controls.

406.4. The Administration's legal reasoning

The authority must identify the applicable legal category and explain the factual basis for its conclusion where required by law. An administrative sanction cannot be justified merely by asserting that the operator failed to prove its preferred classification. The authority must establish the relevant offence under the applicable sanctioning framework.

406.5. Unresolved scientific questions

Where the evidence remains insufficient to establish a proposed classification, the operator may be unable to rely upon that classification for lawful marketing. That consequence must be distinguished from proof of a sanctionable infringement.

406.6. The importance of procedural posture

A prior-authorisation application, an official inspection, a precautionary measure and a sanctioning proceeding may allocate evidentiary responsibilities differently. The correct analysis begins by identifying the proceeding.

407. Original doctrinal contribution: The Food Enforcement Evidence and Burden Allocation Framework

The present research proposes the **Food Enforcement Evidence and Burden Allocation Framework (FEEBAF)**. FEEBAF is an original academic analytical model, not an established judicial test. Its purpose is to prevent the inappropriate transfer of evidentiary assumptions between compliance verification, precautionary action and administrative punishment.

407.1. Twelve dimensions

Dimension	Principal inquiry
1. Procedural context	Is the matter an inspection, authorisation, precautionary intervention, corrective measure or sanction?
2. Substantive obligation	What legal requirement is allegedly applicable?
3. Relevant fact	What precise factual proposition must be established?
4. Evidence source	Does the evidence derive from inspection, laboratory analysis, documents or expert opinion?
5. Sampling validity	Is the sample legally and scientifically suitable for the intended inference?

Dimension	Principal inquiry
6. Analytical validity	Is the method appropriate and sufficiently validated?
7. Uncertainty	How must uncertainty be treated under the relevant legal regime?
8. Contrary evidence	What material supports or challenges the official finding?
9. Legal classification	Does the established fact satisfy the applicable statutory definition?
10. Risk justification	Does the evidence support the protective measure imposed?
11. Culpability	Where punishment is proposed, has legally attributable responsibility been established?
12. Judicial review	Can the factual, scientific and legal conclusions withstand the applicable standard of review?

407.2. The model's principal contribution

FEEBAF separates four evidentiary questions.

What must be proved?

Who bears the relevant legal responsibility? What evidence is capable of establishing the proposition? What legal consequence may follow from the established facts? The model rejects the assumption that all four questions have identical answers in every administrative proceeding.

407.3. Proposed evidentiary sequence

1

Identify the procedure

Distinguish compliance verification, protection, correction and punishment.

2

Define the legal requirement

Identify the substantive rule and its elements.

3

Specify the factual proposition

Determine precisely what the evidence must establish.

4

Examine sampling

Assess representativeness, integrity and chain of custody.

5

Evaluate analytical reliability

Review method suitability, validation and uncertainty.

6

Consider contrary evidence

Examine expert opinions and competing factual explanations.

7

Apply the correct legal threshold

Distinguish suspicion, risk, established non-compliance and sanctionable responsibility.

8

Review proportionality and remedy

Assess the legality of the measure and available procedural safeguards.

407.4. Four possible outcomes

Outcome I - Investigation justified: Available evidence supports further official examination but does not yet establish non-compliance. **Outcome II - Protective intervention justified:** The evidence satisfies the applicable conditions for proportionate precautionary action. **Outcome III - Non-compliance established:** The relevant substantive legal requirements have been shown to be breached. **Outcome IV - Sanctioning responsibility established:** The evidence establishes the infringement and the legally required attribution of responsibility.

These outcomes are not mutually exclusive. However, progression from one outcome to another must be supported by the additional legal and evidentiary requirements.

407.5. The model's limits

FEEBAF does not establish a universal numerical standard of proof. It does not replace sector-specific sampling or analytical rules. It does not prevent authorities from taking urgent protective action where the applicable legislation permits. Its purpose is to organise legal and scientific reasoning.

408. Applied industrial scenarios

Scenario A. A laboratory result virtually close to a regulatory maximum

An official laboratory reports a concentration slightly above a maximum level. The operator questions measurement uncertainty. The authority must apply the relevant sector-specific decision rule. The result may justify investigation, but the legal conclusion depends upon the applicable analytical and regulatory requirements.

Scenario B. A contaminated sample from a heterogeneous consignment

A sample taken from a large consignment produces a positive result. The operator argues that the sampling method was not representative. The legal analysis must distinguish the validity of the laboratory determination from the inference concerning the wider lot.

Scenario C. A positive screening result

A rapid test indicates the possible presence of a prohibited substance. The authority adopts a temporary protective measure. The operator argues that the test is not confirmatory. The legality of the measure depends upon the relevant risk, statutory powers and analytical requirements. A sanction may require additional evidence.

Scenario D. A disputed processing-aid classification

A manufacturer uses a substance during processing and claims that it qualifies as a processing aid. The authority considers it an unauthorised additive. The operator must support its claimed classification where required by the applicable compliance framework. If sanctioning proceedings follow, the Administration must establish the relevant infringement and responsibility.

Scenario E. Conflicting laboratory findings

An official laboratory and an independent laboratory produce different results. The operator requests a second expert opinion. The authority must respect the applicable procedural rights while retaining its powers to respond to genuine risks. The disagreement must be evaluated through the relevant sampling, analytical and legal criteria.

Scenario F. Established non-compliance without established culpability

A food product fails an applicable requirement. The authority orders appropriate corrective action.

It also proposes a sanction.

The corrective measure and sanction must be examined separately. The finding of non-compliance does not automatically resolve the legally required assessment of culpability.

409. Conclusions of the sixteenth instalment of Part II

The burden of proof in food safety enforcement cannot be reduced to a single universal rule. Food business operators possess substantive compliance responsibilities under Regulation (EC) No 178/2002. Competent authorities possess powers to investigate suspected non-compliance and adopt appropriate protective or corrective measures under Regulation (EU) 2017/625. Administrative sanctions, however, engage additional constitutional and statutory safeguards. Article 24.2 of the Spanish Constitution protects the presumption of innocence.

STC 18/1981 establishes foundational principles concerning administrative sanctioning guarantees. STC 76/1990 confirms that official inspection records do not possess absolute and irrebuttable probative force. Article 77.5 of Law 39/2015 recognises evidentiary value for specified official records while permitting contrary evidence. Article 28 of Law 40/2015 requires legally attributable responsibility through intent or negligence.

Articles 34 and 35 of Regulation (EU) 2017/625 establish important requirements concerning analytical methods and the operator's right to a second expert opinion. These provisions demonstrate that evidentiary sufficiency must be assessed according to the legal consequence at issue.

The central conclusion is: ***Scientific evidence sufficient to justify investigation or precautionary intervention does not automatically establish a sanctionable infringement. Equally, the constitutional presumption of innocence does not prevent competent authorities from taking proportionate protective action when the applicable legal conditions are satisfied.***

The proposed FEEBAF framework provides a structured method for distinguishing these evidentiary thresholds.

Primary legislation and judicial authorities

1. Spanish Constitution — Article 24.2.
2. Law 39/2015 — Articles 53, 56, 77 and provisions governing sanctioning proceedings.
3. Law 40/2015 — Articles 25–31, particularly Article 28 on responsibility.
4. Regulation (EU) 2017/625 — Articles 13, 34, 35, 37, 137 and 138.
5. Regulation (EC) No 178/2002 — Articles 6, 7, 14, 17 and 19.
6. Spanish Constitutional Court, STC 76/1990 — Presumption of innocence and the evidentiary treatment of official inspection records.
7. Spanish Constitutional Court, STC 18/1981 — Foundational administrative sanctioning guarantees.
8. Commission Regulation (EU) 2023/915 — Maximum levels for certain contaminants in food.
9. Commission Implementing Regulation (EU) 2023/2782 — Sampling and analysis for mycotoxin control in food.

The most valuable additional element is the integration of STC 76/1990 with Article 77.5 of Law 39/2015 and the second-expert-opinion framework of Regulation (EU) 2017/625.

FOOD SAFETY ENFORCEMENT AND THE LIMITS OF ADMINISTRATIVE POWER

Constitutional Jurisprudence, Scientific Evidence and Judicial Control of Official Food Enforcement

VOLUME II

This second volume examines the constitutional, administrative, evidentiary and scientific limits on official food controls in Spain and the European Union. Drawing on a systematic analysis of the jurisprudence of the Constitutional Court and the Supreme Court, EU law and the scientific evidence, it addresses the scope of administrative power in inspection, proportionality of measures, the presumption of innocence, abuse of power and the allocation of the burden of proof in food safety enforcement.

The volume integrates doctrinal analysis with practical examples, structured tables and original academic proposals, maintaining continuity and coherence with the first volume of the work.

Aimed at lawyers, food business operators, academics and professionals in the administration, it provides a rigorous and up-to-date reference on the balance between the protection of public health and respect for fundamental rights in the field of official food control.

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Spanish Constitutional and Administrative Law
European Union Food Law