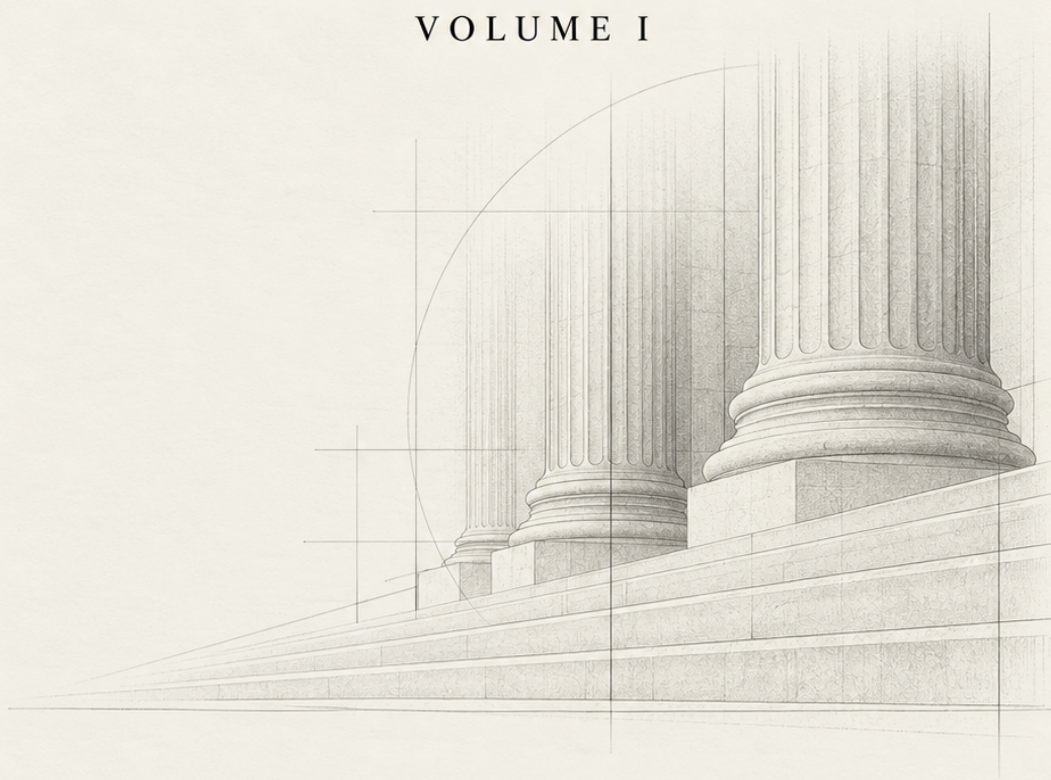


FOOD SAFETY ENFORCEMENT AND THE LIMITS OF ADMINISTRATIVE POWER

Legal Boundaries, Procedural Guarantees and
Judicial Control in the Spanish Food Industry

VOLUME I



José M. López, BSc, MD, PhD, LL.D (C)

A legal research monograph · Revised Edition, October 2026
Spanish Constitutional and Administrative Law · European Union Food Law

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Publication and research notice

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This work is a doctrinal and comparative study of the law governing official food controls. It is not an allegation that specific administrative authorities or officials have acted unlawfully, nor does it substitute for legal advice on particular facts. Legislative provisions and judicial decisions must always be read in their applicable temporal, sectoral and procedural context.

Legal materials have been considered as available on October 2026. The consolidated text of Royal Decree 562/2025 consulted for the sampling discussion includes the amendment published on 30 September 2026. Further updates, special regimes and transitional provisions may require separate treatment when this work is used in individual proceedings.

Abstract

Official food control is necessary for public health protection, consumer confidence and market integrity. Its constitutional legitimacy, however, depends not only on the public purpose served but on the competence, legal basis, factual and scientific justification, proportionality and procedural guarantees of each intervention. This volume develops a systematic account of the boundaries of food inspection in Spain under the Spanish Constitution, the general administrative-law framework and the European Union legislation governing official controls. It examines the duties of cooperation owed by food businesses alongside the enforceable rights of operators; the use and contestation of documentary and analytical evidence; the legal limits of precautionary and punitive action; and the availability of administrative and judicial remedies. It also identifies institutional reforms capable of increasing consistency and accountability without diluting the effectiveness of lawful enforcement.

Method and scope

The argument proceeds doctrinally, by distinguishing the source of each administrative power from the conditions governing its exercise and review. Constitutional provisions, legislation, judicial decisions, scientific concepts and

proposed analytical models are treated as distinct categories of authority. Hypothetical industrial examples serve to test legal propositions; they are not presented as empirical findings. The evaluation frameworks developed in the chapters are authorial research tools, not tests established by courts or regulatory instruments.

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 1

Constitutional Foundations and the Legal Structure of Official Controls

Public-health protection supplies the purpose of food safety inspection; constitutional and statutory law supplies its limits. This chapter establishes the legal framework against which particular exercises of official authority must be tested.

Introduction: The paradox of legitimate administrative power

Modern food safety systems depend upon public authorities capable of detecting non-compliance, investigating risks, verifying preventive controls and adopting effective corrective measures. Without such powers, the regulatory framework governing food production, processing, distribution and commercialisation would lack credible enforcement mechanisms. The legal necessity of official inspection is therefore beyond serious dispute. The constitutional difficulty emerges elsewhere. An administrative power may be legitimate in its origin, indispensable in its purpose and nevertheless unlawful in its specific exercise.

The distinction is fundamental. The existence of a statutory inspection mandate does not automatically establish that every instruction, demand, technical interpretation, access request, sampling decision or restrictive measure adopted by an inspector is legally justified. Nor does the presence of a genuine public health objective eliminate the obligation to respect the limits of the legal powers conferred. Within the Spanish constitutional system, administrative legitimacy is not derived exclusively from the importance of the public interest pursued. It also depends upon the legality of the means employed.

Consequently, the relevant question is not merely whether an intervention was intended to protect food safety, but whether the competent authority acted:

- Within the powers conferred upon it by law.
- For the statutory purposes justifying those powers.
- On a sufficiently established factual and technical basis.

- Through legally appropriate procedures.
- With due respect for proportionality and the rights of the affected operator.
- Subject to effective administrative and judicial scrutiny.

These conditions form the starting point of the present investigation. The analysis must also recognise an important asymmetry: public authorities exercise coercive powers in pursuit of collective interests, whereas food business operators ordinarily bear the immediate economic consequences of inspections, compulsory modifications, immobilisations and suspensions. That asymmetry does not establish administrative wrongdoing. It does, however, explain why legal systems impose special requirements upon the exercise of public powers. The constitutional function of these safeguards is not to weaken food safety enforcement. It is to ensure that coercive administrative intervention remains lawful, accountable and justified.

The constitutional architecture of food safety enforcement

Article 43: Public health as a constitutional justification for administrative intervention

Article 43 of the Spanish Constitution recognises the right to health protection and entrusts public authorities with organising and safeguarding public health through preventive measures and appropriate services. Its importance for food safety enforcement is substantial. Foodborne pathogens, chemical contaminants, undeclared allergens, fraudulent composition and failures in traceability can affect populations extending far beyond the premises of the individual food business. Accordingly, the protection of public health may require intervention before actual injury occurs.

However, Article 43 does not itself provide an unrestricted operational mandate to individual inspectors. Concrete inspection powers must be exercised through the applicable legal framework and by the competent authority. A distinction is necessary between the constitutional legitimacy of preventive intervention and the legality of an individual enforcement measure. The former explains why public authorities may intervene. The latter determines whether a particular intervention is lawful.

Article 38: Freedom of enterprise and its regulatory limitations

Article 38 recognises freedom of enterprise within the market economy. This freedom encompasses the constitutionally protected sphere of lawful economic initiative, although it does not confer immunity from regulatory obligations designed to protect health, consumers or other legitimate public interests. In the food industry, regulatory intervention may affect production methods, facility design, hygiene systems, supplier selection, product specifications and market access. Not every restriction constitutes a violation of Article 38. The relevant legal issue is whether the restriction is authorised, justified and proportionate in the circumstances.

For example, requiring an operator to eliminate an identified contamination hazard may constitute lawful enforcement. Requiring replacement of an adequately functioning industrial system solely because an inspector prefers another technical configuration raises a different legal question. The latter case demands examination of the applicable legal requirements, the evidence supporting the inspector's assessment and the legal nature of the instruction. Importantly, freedom of enterprise does not guarantee the operator an unrestricted choice of technology where binding legislation prescribes particular methods or outcomes.

Nevertheless, where the regulatory framework permits alternative compliant solutions, the authority must distinguish an enforceable legal requirement from a preferred technical practice.

Article 9.3: Legal certainty and the prohibition of arbitrariness

Article 9.3 establishes several foundational guarantees, including legal certainty, responsibility of public authorities and the prohibition of arbitrariness. These principles acquire particular significance where administrative authorities interpret technically complex food legislation. A food business may be subject to numerous overlapping provisions governing microbiological criteria, hygiene, traceability, additives, contaminants, food-contact materials, labelling and official controls. Compliance frequently requires substantial investment and specialised expertise. Consequently, unpredictability in administrative interpretation may impose serious economic consequences.

Yet legal certainty does not mean that an authority can never change its interpretation or that every difference between inspectors constitutes arbitrariness. The relevant inquiry concerns whether an administrative decision has a legally defensible basis, follows an intelligible reasoning process and respects the applicable procedural guarantees. An inspector's technical conviction cannot, by itself, create a legal obligation that the regulatory framework does not establish. This proposition does not prevent the inspector from requiring evidence that a process achieves legally mandated safety outcomes. It means that the legal obligation and the technical means of demonstrating compliance must be distinguished.

Articles 103 and 106: Administration subject to law and judicial control

Article 103.1 requires public administration to serve the general interest objectively and to act in full submission to the law and the legal system. Article 106.1 establishes judicial control over administrative regulatory powers, the legality of administrative action and its conformity with the purposes justifying it. Together, these provisions establish an essential constitutional relationship. Public administration does not exercise authority merely because an official considers an intervention useful. Its authority derives from legally conferred powers exercised for legally recognised purposes.

Furthermore, administrative assessments are not categorically immune from judicial review merely because they involve technical expertise. Judicial scrutiny may examine the competence of the authority, factual premises, procedural compliance, legal interpretation, reasoning, proportionality and the existence of misuse of power. However, the precise intensity of judicial review may differ according to the nature of the administrative assessment and the applicable evidentiary record. The court's function is not necessarily to replace every specialised technical judgment with its own preferred technical solution.

It is to determine whether the administrative decision withstands the legal standards applicable to its adoption. These constitutional foundations are supported by the consolidated text of the Spanish Constitution.

European Union Law: Official control as a legally structured power

Regulation (EU) 2017/625 and the transformation of food inspection

Regulation (EU) 2017/625 constitutes a central legal instrument governing official controls across the fields falling within its scope. Its importance extends beyond the authorisation of inspections. It establishes a regulatory architecture addressing the organisation, performance, documentation, transparency and enforcement consequences of official controls. Article 9 requires official controls to be conducted regularly, on a risk basis and at appropriate frequencies. Article 14 identifies methods and techniques available for official controls, including inspection of premises, equipment, products, processes and relevant documentation.

Article 15 addresses obligations imposed upon operators in relation to official controls. Articles 137 and 138 govern action where non-compliance is suspected or established. These provisions must be interpreted together. The legal framework confers substantial inspection powers, but their exercise remains connected to the regulatory objectives and conditions established by the Regulation.

Risk-based inspection is not equivalent to unrestricted suspicion

Risk-based control constitutes a rational method for allocating enforcement resources. Authorities may legitimately consider the nature of the activity, relevant hazards, previous compliance history and other factors prescribed by the applicable framework. Nevertheless, the existence of a risk-based system does not mean that every suspicion automatically establishes a regulatory infringement.

Three situations require distinction:

Situation	Legal significance
Risk factor identified	May justify enhanced verification
Suspected non-compliance	May justify investigation and appropriate precautionary action

Situation	Legal significance
Established non-compliance	May justify corrective enforcement under applicable law

These categories should not be collapsed. A suspected infringement is not necessarily a proven infringement, and a precautionary measure is not automatically a sanction. Conversely, the absence of a completed infringement finding does not always prevent urgent protective action where the legal conditions for such action are satisfied. This distinction will become central when examining immobilisation, product withdrawal, operational suspension and emergency measures.

The operator's duty to cooperate

An academically credible analysis must recognise that Regulation (EU) 2017/625 also imposes substantial cooperation obligations upon operators. An operator cannot ordinarily defeat lawful inspection by invoking commercial confidentiality, operational inconvenience or disagreement with the authority's technical assessment. The scope of required cooperation must be determined by the applicable provisions and the circumstances of the control.

This produces an important legal balance:

The authority must not exceed its powers, and the operator must not obstruct their lawful exercise. Both propositions are necessary for an effective and constitutionally legitimate enforcement system.

The Spanish statutory framework: Competence, coordination and accountability

Law 17/2011, of 5 July, on Food Safety and Nutrition, provides an essential national legislative framework. Its Article 14 addresses the distribution of official control responsibilities among competent public administrations and their coordination. Article 16 concerns audits of official control systems, including the assessment of whether controls are effective and appropriate for achieving their regulatory objectives. These provisions introduce an important dimension often overlooked in disputes between inspectors and operators: the legal quality of an inspection system is itself a matter of public accountability.

Inspection performance should not be assessed exclusively through the number of infringements detected or sanctions imposed. It must also be evaluated in terms of legality, consistency, technical competence, proportionality and effective achievement of public health objectives. A particularly promising line of investigation concerns whether existing audit and supervision arrangements sufficiently detect unjustified divergences between inspectors, excessive documentary requirements or disproportionate enforcement decisions. This is a research question, not a finding that the Spanish system systematically suffers from those defects.

It will require examination of official audit documentation, administrative practice and relevant judicial decisions.

Towards a legal test for assessing inspection excesses

The first methodological contribution of this study is a **structured assessment of official inspection decisions**. It may be provisionally designated the Legality and Proportionality Assessment Framework for Official Food Controls (LPAF-OFC).

The framework would examine nine dimensions:

Dimension	Central legal question
Competence	Did the authority possess jurisdiction and legal powers?
Legal basis	What specific rule authorised the intervention?
Legitimate purpose	Was the measure directed towards the statutory objective?
Factual basis	Were the relevant facts adequately established?
Scientific basis	Was the technical assessment sufficiently justified?
Necessity	Was the intervention necessary to achieve its purpose?
Proportionality	Were the burdens justified in relation to the objective?
Procedure	Were applicable procedural guarantees respected?
Reviewability	Could the affected operator effectively challenge the decision?

These dimensions do not constitute a judicially established nine-part test. They are an analytical proposal derived from distinct requirements of constitutional, administrative and European Union law. Their precise legal significance will depend upon the type of administrative act, the powers

exercised and the governing legislation. The model's principal advantage is methodological, and *it prevents the assessment of inspection legality from being reduced to the inspector's technical opinion or the operator's commercial disagreement*. It requires the intervention to be examined as a legally structured decision.

Chapter conclusions

The first stage of this investigation supports five propositions.

First, food safety inspection is a legitimate and necessary exercise of public authority.

Second, the constitutional importance of public health does not eliminate legal limits upon administrative intervention.

Third, European Union law establishes substantial inspection powers while simultaneously structuring their exercise through risk-based controls, prescribed methods and enforcement conditions.

Fourth, the rights of operators and their duties of cooperation must be analysed together rather than treated as mutually exclusive.

Fifth, the legality of an inspection measure cannot be determined solely by its declared objective. It also depends upon competence, legal basis, factual justification, procedure and proportionality.

CHAPTER 2

Administrative Discretion, Technical Judgment and Judicial Review

Technical expertise informs the assessment of food-safety risks, but it does not replace legislative authority. The central issue is how courts and administrative bodies distinguish enforceable requirements from a preferred professional judgment.

The fundamental legal problem: Technical expertise does not confer unlimited legal authority

One of the most consequential questions in food safety enforcement concerns the relationship between the **technical expertise** of an official inspector and the **legal authority** of the administration employing that inspector. The distinction is not merely theoretical. Food inspection frequently involves highly specialised assessments concerning microbiological hazards, processing technologies, hygiene procedures, equipment design, analytical methodologies, shelf-life validation, environmental monitoring, food-contact materials and preventive control systems. Such assessments may require substantial scientific knowledge and professional experience.

However, technical expertise and legal authority operate on different normative planes. Technical expertise concerns the capacity to evaluate facts, risks and scientific evidence. Legal authority concerns the powers conferred upon a public body or official by the applicable legal system. An inspector may possess considerable technical expertise without being legally entitled to impose every measure considered technically preferable. Equally, a food business operator may possess superior knowledge of a particular industrial process without thereby acquiring the right to disregard lawful inspection requirements.

The legal system must therefore reconcile two legitimate interests: the authority's capacity to enforce food safety requirements effectively and the operator's right not to be subjected to obligations lacking sufficient legal justification. The distinction becomes particularly important where legislation

establishes performance-based obligations rather than prescribing a single technological solution. For example, Regulation (EC) No 852/2004 establishes general hygiene obligations and requires food business operators to implement procedures based on HACCP principles, subject to the Regulation's applicable provisions and flexibilities.

This framework does not ordinarily prescribe a unique technical solution for every conceivable industrial hazard. Instead, it frequently requires the operator to identify, prevent, eliminate or reduce relevant hazards through appropriate procedures. The authority may examine whether those procedures comply with the law and achieve the required protective objectives. Nevertheless, it does not follow that the authority may automatically substitute its preferred technological arrangement for a different solution that is demonstrably compliant. The central legal question is whether the inspector is enforcing a binding requirement or attempting to transform a technical preference into an administrative obligation.

That distinction must be resolved through the applicable legislation, the factual circumstances and the reasoning supporting the intervention.

Four legal categories that must not be confused

Spanish administrative law distinguishes several concepts whose confusion can produce serious errors in the assessment of inspection decisions.

Regulated administrative powers

A regulated power exists where the legal framework establishes the conditions and consequences of administrative action with sufficient precision that the authority has no genuine freedom to choose between legally permissible alternatives on the relevant point. For example, where a binding provision requires a particular legal consequence once specified conditions have been established, the authority must act within that prescribed framework. However, a power may contain both regulated and discretionary elements. The authority's competence, the purposes of the power and procedural obligations remain legally controlled even where some substantive choices are permitted.

Consequently, the classification of an entire inspection decision as either regulated or discretionary may be misleading. Its individual components must be examined.

Administrative discretion

Administrative discretion arises where the legal framework permits the competent authority to choose between several legally acceptable courses of action. Such discretion does not constitute freedom from legal control. Its exercise remains constrained by the statutory purpose, the relevant facts, general principles of administrative law and the prohibition of arbitrariness. In food safety enforcement, a degree of discretion may arise when selecting an appropriate corrective measure from several measures authorised by the applicable legislation.

For instance, Article 138 of Regulation (EU) 2017/625 requires competent authorities to take appropriate action in response to established non-compliance and identifies a range of possible measures. The selection must reflect the circumstances and the legal requirements governing that intervention. The existence of several possible measures does not entitle the authority to select the most burdensome option without adequate justification. Nor does proportionality necessarily require choosing the least restrictive measure in isolation from effectiveness. A less burdensome intervention that fails to address the relevant risk may not constitute a legally adequate alternative.

Indeterminate legal concepts

An indeterminate legal concept is defined as a statutory expression whose application requires assessment of particular and sometimes, specific circumstances. Food law contains numerous expressions requiring contextual evaluation, including concepts relating to suitability, adequacy, risk, necessity and the prevention of contamination. Their use does not automatically create administrative discretion. The interpretation and application of such concepts may be subject to judicial scrutiny, including examination of the facts and technical assessments upon which the decision rests. Nevertheless, uncertainty in the underlying scientific evidence can make judicial evaluation complex.

The fact that a concept is legally reviewable does not mean that its application always produces an uncomplicated or scientifically uncontested answer.

Technical judgment

Technical judgment concerns the assessment of specialised facts or scientific matters. It may be indispensable to the lawful exercise of inspection powers. But technical judgment is not itself an independent source of legal authority. Its legal significance depends upon the rule being applied and the purpose of the assessment. A microbiological result, for example, may establish a fact relevant to compliance. Whether that result constitutes an infringement, requires further investigation or justifies a particular measure depends upon the applicable legal criteria.

The scientific conclusion and its legal consequences must therefore be distinguished.

Judicial review of technical assessments: Neither unrestricted substitution nor immunity from scrutiny

A recurring difficulty in administrative litigation concerns the extent to which courts may review decisions founded upon specialised technical evaluations. The problem is especially acute in food safety disputes, where judicial proceedings may involve conflicting expert opinions, uncertainty concerning causal relationships or disagreements over analytical methods. Two extreme positions must be rejected. The first assumes that courts may freely substitute their own scientific preferences for those of competent authorities. The second assumes that administrative technical assessments are practically immune from judicial scrutiny.

Neither position adequately reflects the constitutional requirement of judicial control. Article 106.1 of the Spanish Constitution subjects administrative action to judicial review. That control may extend to the authority's competence, the existence and accuracy of relevant facts, the adequacy of reasoning, the legal interpretation adopted, procedural regularity and compliance with general legal principles. In technically complex cases, judicial review may require independent expert evidence. However, the intensity and form of that review must be assessed

in relation to the nature of the administrative decision and the applicable substantive framework.

The court does not become a food safety laboratory or an industrial engineering department. Its function is to determine whether the challenged administrative action is lawful. This includes evaluating whether the authority's technical conclusions have an adequate evidentiary foundation and whether the resulting legal consequences are justified.

The decisive proposition is therefore:

Technical complexity may affect the method of judicial review, but it does not eliminate the jurisdiction of the courts to examine administrative legality. This principle is particularly relevant when a disputed inspection decision imposes substantial economic consequences upon an operator. A compulsory production shutdown, product destruction or major industrial modification may require examination of both the technical premises and the legal proportionality of the intervention. The existence of technical disagreement alone does not establish administrative unlawfulness. Equally, the invocation of specialist expertise does not conclusively establish legality.

The principle of proportionality as a substantive limit on inspection powers

The principle of proportionality constitutes one of the most important legal constraints upon restrictive administrative intervention. Its significance in Spanish administrative law is not merely doctrinal. Article 4.1 of Law 40/2015 expressly requires public administrations, when imposing measures restricting rights or establishing requirements for economic activities, to apply proportionality, select the least restrictive measure, justify its necessity in the public interest and explain its suitability for achieving the intended purpose. Article 4.2 simultaneously recognises administrative powers to verify, investigate and inspect relevant circumstances within the applicable legal limits.

The two provisions must be read together. The authority possesses inspection powers, but those powers do not eliminate the constraints governing restrictive intervention. A structured proportionality assessment generally examines three interconnected questions. **Suitability:** Is the measure capable of achieving the

legitimate objective? **Necessity:** Is there an equally effective, legally available alternative that imposes a lesser restriction?

Proportionality in the strict sense: Does the importance of the public interest served justify the intensity of the interference? Consider a food processing establishment in which an inspector identifies a defective sanitation procedure affecting one production line. Depending upon the nature and extent of the risk, proportionate measures might include targeted corrective action, intensified verification, temporary suspension of the affected line or broader operational restrictions. A complete factory shutdown may be lawful where the risk cannot be effectively controlled through narrower measures.

Conversely, a shutdown affecting independent, compliant production areas may require particularly careful justification where the identified hazard is demonstrably confined. The legal analysis cannot be resolved abstractly. It requires assessment of the hazard, its possible propagation, the available preventive measures, the evidence and the relevant statutory powers. A further distinction is essential: proportionality does not authorise the continuation of unsafe food production merely because stopping it would be economically expensive. The severity of economic consequences is relevant to the proportionality assessment, but it does not override the legal requirement to protect public health.

The inviolability of business premises: Article 18.2 of the Spanish Constitution

Corporate premises and constitutional protection

Article 18.2 of the Spanish Constitution protects the inviolability of the domicile. Spanish constitutional jurisprudence recognises that legal persons may also benefit from this protection. However, the constitutional protection afforded to companies is not identical in scope or intensity to that enjoyed by natural persons in their private homes. In Constitutional Court Judgment STC 69/1999, of 26 April, the Court distinguished premises connected with corporate management or the custody of reserved business documentation from ordinary commercial or operational spaces not possessing those characteristics.

This distinction is particularly relevant to food factories, where administrative offices, management departments, laboratories, archives, warehouses and production areas may coexist within the same industrial complex. The fact that all these areas belong to the same company does not necessarily mean that each enjoys identical constitutional protection. Equally, the fact that a company conducts industrial activities does not deprive it of constitutional protection over qualifying premises.

Access to production areas and access to constitutionally protected premises

Food inspectors may possess extensive statutory powers to access premises, examine equipment, inspect production processes and verify compliance. Regulation (EU) 2017/625 establishes corresponding operator cooperation obligations. Nevertheless, those powers must be reconciled with the constitutional regime governing entry into protected premises.

The legal assessment should distinguish:

Type of area	Principal legal consideration
Production line	Statutory inspection and access powers
Raw-material warehouse	Inspection powers and the particular function of the premises
Quality-control laboratory	Inspection powers, confidentiality and the activities conducted
Corporate management offices	Potential constitutional domicile protection
Restricted business archives	Potential constitutional protection and confidentiality
Personal devices or communications	Separate privacy, data-protection and other applicable safeguards

This classification is illustrative, not conclusive. The constitutional status of a particular space depends upon its actual function and the relevant jurisprudential criteria, not simply the label assigned to it by the company.

Consent and judicial authorisation

The validity of consent to enter constitutionally protected corporate premises is an especially important issue. In STC 54/2015, of 16 March, concerning tax inspection, the Constitutional Court examined entry into corporate premises and the requirements for valid consent. The judgment emphasised the significance of adequate prior information concerning the nature and scope of the proposed intervention. It also distinguished an administrative authorisation from the judicial authorisation required where the constitutional guarantee applies and no valid consent or other constitutionally recognised justification exists.

Although this decision arose in the tax enforcement context, its constitutional reasoning is relevant to examining entry into protected corporate premises in other administrative sectors. Such application must, however, account for the specific statutory regime governing food inspection. It would be incorrect to conclude that food inspectors invariably require judicial authorisation to enter any industrial establishment. It would be equally incorrect to conclude that statutory inspection powers permit unrestricted entry into every corporate space.

The legally relevant distinction concerns the constitutional nature of the premises, the existence of valid consent, the applicable statutory powers and the requirements governing judicial authorisation.

Practical implications for food business operators

A company confronted with an inspection involving potentially protected premises should distinguish **cooperation** with lawful official controls from **consent to an intrusion** whose legal basis or scope is disputed. It may be appropriate to request identification of the officials, clarification of the inspection's purpose and documentation of the legal authority relied upon. Where the scope of access raises a genuine constitutional issue, the company should seek immediate legal advice and preserve a contemporaneous record of the circumstances. However, refusal of access must not be treated as a routine defensive strategy.

Unjustified obstruction of lawful official controls may itself constitute an infringement and may expose the operator to enforcement consequences. The

legally defensible approach is informed cooperation, coupled with preservation of the operator's rights.

Administrative inspection and the obligation to provide reasons

A further distinction must be made between inspection activities, findings recorded during an inspection and administrative decisions imposing legal consequences. Not every technical observation constitutes an immediately enforceable administrative act. Nor does every inspection note require the same formal reasoning as a decision restricting production or imposing a sanction. The applicable duty to provide reasons depends upon the legal nature of the measure and the governing procedural framework. Article 35 of Law 39/2015 identifies categories of administrative acts requiring motivation, including certain acts limiting subjective rights or legitimate interests and acts involving discretionary powers.

This requirement is particularly significant when an authority adopts a decision with substantial operational or economic consequences. A sufficiently reasoned decision should permit the affected operator to understand the factual and legal basis of the intervention and, where appropriate, challenge it effectively. In technically complex cases, a purely formulaic invocation of food safety may be inadequate where the specific risk, alleged infringement or basis for the selected measure remains unexplained. Nevertheless, the required degree of detail must be assessed in context, particularly where urgent protective intervention is legally justified.

The authority's obligation is not to produce an academic treatise before every action. It is to comply with the applicable legal standard of motivation and to provide a reviewable justification for the measure adopted.

A critical distinction: Inspection irregularity, unlawfulness and administrative liability

Not every procedural defect renders an inspection or subsequent decision invalid as well as not every unlawful administrative act generates a right to compensation. And not every excessive or erroneous decision establishes personal misconduct by the inspector. These distinctions are indispensable to a

rigorous legal analysis. An inspection may contain an irregularity that has no invalidating effect.

A decision may be voidable because it infringes the applicable legal framework. A more serious defect may satisfy the statutory conditions for nullity. Separately, administrative liability for damage requires examination of its own legal prerequisites, including the existence of compensable injury and the relevant causal relationship. Personal disciplinary or criminal responsibility demands additional legal elements that cannot be presumed from the annulment of an administrative decision. This separation is essential.

The legal consequences of an inspection defect depend upon the nature of the infringement, the affected rights, the governing procedural rules and the conditions established for each form of responsibility. A defensible study of administrative excess must therefore resist the temptation to describe every disputed inspection as abuse of authority or every annulled decision as evidence of criminal wrongdoing.

The emerging doctrinal thesis: Scientific authority must remain legally accountable

The preceding analysis supports a broader conclusion in the sense that modern food safety enforcement increasingly depends upon specialised scientific and technological assessments. That dependence is justified by the complexity of contemporary food production. However, technical specialisation creates a potential accountability problem where the authority's scientific assessment is treated as effectively conclusive without adequate examination of its assumptions, methodology or legal consequences. The appropriate response is not to weaken scientific expertise.

It is to strengthen the connection between expertise, evidence, reasoned decision-making and judicial review.

A legally robust inspection system should therefore be capable of explaining:

- The specific legal requirement being enforced.
- The factual or scientific evidence relevant to compliance.
- The reasoning connecting that evidence to the alleged deficiency.

- The legal basis and proportionality of the corrective measure.
- The available mechanisms for challenging the decision.

This is particularly important in disputes involving **innovative food technologies, non-standard processing methods, novel ingredients or alternative systems** for achieving regulatory performance objectives. Innovation does not exempt operators from compliance, but regulatory enforcement should not treat unfamiliarity with a technology as proof of unlawfulness. The authority may legitimately require sufficient evidence of compliance, including validation where legally required. What it must not do is replace legal analysis with unsupported assumptions concerning the acceptability of an industrial process.

Chapter conclusions

This chapter establishes six further propositions.

First, administrative discretion, technical judgment and indeterminate legal concepts are distinct legal categories.

Second, technical expertise does not independently confer regulatory authority.

Third, technical assessments are subject to judicial scrutiny, although the nature and intensity of that scrutiny depend upon the applicable legal and evidentiary framework.

Fourth, proportionality constitutes a substantive constraint upon restrictive administrative measures.

Fifth, corporate premises may benefit from constitutional protection, but the scope of that protection varies according to their actual function.

Sixth, legal irregularity, invalidity, administrative liability and personal misconduct must be analysed separately.

These conclusions reinforce the central thesis of this study: official food controls are legitimate only when the exercise of administrative power remains connected to its legal foundations, statutory purposes and applicable safeguards.

CHAPTER 3

Compulsory Cooperation, Documentary Evidence and Confidentiality

An official inspection may move from preventive supervision to evidence-gathering with sanctioning consequences. This chapter analyses what operators must disclose, what authorities may demand and which procedural safeguards survive compulsory cooperation.

The transformation of inspection into an evidentiary process

Official inspection is often described as a technical activity directed towards verifying regulatory compliance. That description is correct but incomplete. An inspection may also constitute the initial phase of a process through which the Administration collects evidence, reconstructs potentially unlawful conduct and establishes the factual basis for subsequent enforcement. A single inspection may produce several legally distinct consequences. It may identify a deficiency requiring corrective action.

It may reveal circumstances justifying precautionary measures. It may produce evidence supporting administrative sanctioning proceedings. In more serious cases, it may disclose facts potentially relevant to criminal liability. The transition between these functions is particularly important because the legal safeguards applicable to ordinary regulatory supervision are not necessarily identical to those governing punitive proceedings. Spanish constitutional law recognises that administrative sanctioning proceedings are subject to fundamental guarantees derived from Article 24 of the Constitution, with the adaptations required by their administrative nature.

However, it would be legally inaccurate to conclude that every routine inspection automatically constitutes a sanctioning procedure or that every inspection question triggers the complete set of guarantees applicable to an accused person. The legal nature of the activity must be determined by its actual purpose, the powers exercised and the consequences of the information obtained.

The essential analytical distinction is therefore between:

Regulatory verification: Examination of compliance with existing legal obligations. **Administrative investigation:** Collection and assessment of information concerning possible infringements. **Sanctioning proceedings:** Formal exercise of the Administration's punitive powers under the applicable procedural regime. **Criminal investigation:** Investigation of conduct potentially constituting a criminal offence under the relevant criminal-procedure framework. These functions may be connected, but they are not legally interchangeable.

The distinction becomes especially consequential where the Administration compels the production of documents or obtains statements that are subsequently used to establish liability.

The statutory foundation of compulsory cooperation

Article 15 of Regulation (EU) 2017/625

Article 15 of Regulation (EU) 2017/625 establishes obligations of operators in connection with official controls. Within its scope, operators must provide competent authority staff with access to relevant equipment, means of transport, premises, other places under their control, computerised information-management systems, animals and goods, documents and other relevant information, as provided by the Regulation. Operators must also assist and cooperate with competent authorities in the performance of official controls and other official activities. These obligations are not merely recommendations. They form part of the binding European Union framework governing official controls.

Accordingly, a food business operator cannot ordinarily refuse a lawful request for required traceability records, relevant HACCP documentation or other legally accessible information simply because disclosure may reveal non-compliance. However, the existence of a general cooperation obligation does not resolve every question concerning the permissible scope of a specific request. The authority must still act within its legal powers and respect applicable constitutional and procedural guarantees.

The relevant legal inquiry concerns the relationship between the requested information and the purposes of the control, the authority's competence, the legal basis for compulsory disclosure and any specific safeguards applicable to the material concerned.

Article 14: Inspection methods and techniques

Article 14 identifies a broad range of methods and techniques available for official controls. These include examination of operators' controls, inspection of equipment and facilities, examination of relevant documents and records, interviews and other verification methods. The breadth of these powers reflects the complexity of food supply chains. A modern inspection may require examination of production records, supplier qualifications, laboratory results, environmental monitoring, digital traceability systems, sanitation programmes, equipment maintenance and process validation.

Nevertheless, a statutory list of inspection methods should not be interpreted as an unlimited authorisation to demand any information concerning the operator's commercial activities. The request must remain connected to the lawful purposes of official control and comply with any applicable restrictions. The distinction between relevant regulatory information and unrelated commercial information is particularly important in diversified companies operating across several industrial sectors.

For example, an inspection concerning the microbiological safety of a specific food-processing line does not automatically justify unrestricted access to every commercial negotiation, unrelated research project or confidential business strategy held by the company. Conversely, information initially appearing commercially sensitive may be legitimately relevant where it is necessary to verify traceability, ingredient composition, process compliance or another legally controlled matter. The assessment must therefore be substantive rather than based solely upon the company's classification of information as confidential.

The legal limits of documentary demands

Three categories of information

For analytical purposes, information requested during official inspection may be divided into three categories.

Category	Examples	Principal legal issue
Legally required regulatory records	Traceability, mandatory hygiene records, relevant monitoring results	Duty to maintain and provide access
Existing information relevant to compliance	Technical studies, validation data, process records	Legal relevance and scope of inspection powers
Information created through compelled explanation	Statements, admissions, reconstructed narratives	Potential self-incrimination and procedural safeguards

This classification is methodological rather than statutory. The legal treatment of each item depends upon its actual nature, the applicable legislation and the context in which disclosure is required. The distinction between pre-existing records and compelled statements is especially important.

Mandatory records cannot ordinarily be withheld merely because they are incriminating

Food legislation frequently requires operators to create, maintain and preserve information demonstrating compliance. Regulation (EC) No 178/2002 establishes traceability requirements under Article 18. Regulation (EC) No 852/2004 requires operators to implement and maintain procedures based on HACCP principles, subject to its applicable provisions. These requirements serve preventive and supervisory purposes. Their effectiveness would be substantially undermined if operators could refuse to disclose legally required records whenever those records might reveal an infringement.

Accordingly, the privilege against self-incrimination cannot be treated as a general exemption from regulatory recordkeeping or lawful inspection. However, the use of such material in subsequent punitive proceedings may raise additional questions, particularly concerning the manner in which it was

obtained and the applicable procedural guarantees. A legally rigorous analysis must therefore distinguish the duty to produce records from the admissibility and evidentiary use of material obtained through compulsion.

The right against self-incrimination in administrative sanctioning proceedings

Constitutional foundation

Article 24.2 of the Spanish Constitution recognises the rights not to testify against oneself and not to confess guilt. These guarantees are central to criminal proceedings and have relevance to administrative sanctioning proceedings through the constitutional principles governing punitive state action. Their application outside criminal proceedings requires careful attention to the nature of the procedure and the particular form of compulsion involved. The guarantee is not equivalent to an unrestricted right to remain silent in every interaction with an administrative authority. Nor does it necessarily prevent authorities from obtaining material that exists independently of the will of the person concerned.

The distinction between compelled testimony and pre-existing evidence has been developed extensively in European human-rights jurisprudence.

***Saunders v. United Kingdom*: The distinction between compelled testimony and independent material**

In *Saunders v. the United Kingdom*, judgment of 17 December 1996, the European Court of Human Rights examined the use in criminal proceedings of statements obtained under compulsory investigative powers. The Court identified the privilege against self-incrimination as an important component of the right to a fair trial under Article 6 of the European Convention on Human Rights. It also distinguished compelled statements from material existing independently of the will of the accused. The decision is particularly relevant where administrative investigators require an individual to provide explanations under threat of legal consequences and those explanations are subsequently used in punitive proceedings.

However, Saunders should not be interpreted as establishing that every compulsory documentary request is constitutionally impermissible. Its legal significance lies in the relationship between compulsion, the nature of the material obtained and its subsequent use.

Funke v. France and J.B. v. Switzerland

In *Funke v. France*, judgment of 25 February 1993, the European Court of Human Rights examined coercive measures used to compel the production of documents in customs proceedings. In *J.B. v. Switzerland*, judgment of 3 May 2001, the Court addressed compulsory documentary production in proceedings involving potential punitive consequences. These decisions illustrate that the distinction between documents and testimony is not always sufficient, by itself, to resolve a self-incrimination dispute. The degree of compulsion, the purpose of the request, the authorities' existing knowledge of the material and the punitive context may all be relevant. The jurisprudence therefore requires a contextual analysis.

Application to food inspection

Consider an inspector who requests production records showing that a required temperature limit was exceeded. The operator may be legally obliged to maintain and disclose those records. The possibility that the records establish non-compliance does not automatically extinguish the duty of cooperation. Now consider a different situation. The inspector requires a company representative, under threat of sanction for non-cooperation, to provide a written statement acknowledging that management knowingly authorised the production of unsafe food.

The second situation raises materially different constitutional questions. The requested statement is not merely a pre-existing regulatory record. It may constitute compelled testimonial material directly concerning potential liability. The legal assessment must consider whether the person is being compelled to make an incriminating statement, the nature of the proceedings and the consequences of refusal. The distinction is especially important when individual managers, technical directors or employees may face personal administrative or

criminal liability. A duty to provide access to regulatory evidence must not be confused with an unlimited duty to construct an admission of personal wrongdoing.

This proposition does not prevent lawful questioning, nor does it establish that every answer given during inspection is inadmissible. It identifies a constitutional boundary requiring case-specific examination.

The evidentiary status of official inspection reports

An inspection report is not an unchallengeable statement of truth

One of the most consequential legal misconceptions in administrative enforcement is the assumption that facts or conclusions recorded by an official inspector are automatically conclusive. Spanish administrative law does not establish such an unrestricted rule. Article 77.5 of Law 39/2015 provides that documents drawn up by officials legally recognised as authorities, observing the applicable formal requirements and recording facts personally established by those officials, have evidentiary value unless contrary evidence is produced. The provision therefore establishes a rebuttable evidentiary presumption, not an irrebuttable declaration of factual or legal correctness. Its operation requires several conditions.

First, the document must be prepared by an official possessing the relevant legally recognised status.

Second, the applicable formal requirements must be satisfied.

Third, the relevant statements must concern facts established by the official.

Fourth, the evidentiary effect remains open to contradiction.

These conditions are not interchangeable. An official report does not automatically acquire the same evidentiary force in relation to every statement it contains.

Directly observed facts, technical inferences and legal conclusions

A rigorous analysis should distinguish three categories of statements commonly found in inspection reports. Direct factual observations. These concern circumstances perceived or verified by the inspector through the performance of official duties. Examples include the existence of particular equipment, the absence of a required document when requested, a temperature reading obtained through a specified instrument or an observed condition of an industrial facility. Technical assessments. These involve scientific or professional interpretation of observed circumstances.

Examples include an assessment that an identified condition creates a contamination risk, that a sanitation process is insufficient or that an industrial system is incapable of achieving a required hygiene outcome.

Legal conclusions. These concern the classification of conduct under the applicable regulatory framework. Examples include the assertion that an operator has committed a specified infringement or that a particular production method is legally prohibited. The distinction is essential because Article 77.5 cannot reasonably be understood as conferring automatic, conclusive correctness upon every technical inference or legal interpretation contained in an official document.

A report may provide strong evidence of an observed fact while leaving substantial room for dispute concerning its scientific significance or legal consequences. For example, an inspector may accurately record that a processing line operated at a particular temperature. That observation does not necessarily establish, without further analysis, that the food produced was unsafe or that the operator infringed a specific legal obligation. The legal significance depends upon the applicable temperature requirements, process validation, product characteristics, measurement conditions and other relevant circumstances.

The danger of evidentiary circularity

A particularly problematic enforcement practice may arise where the Administration treats the inspector's conclusion as sufficient proof of the

underlying infringement merely because that conclusion appears in an official report.

Consider the following sequence:

- An inspector observes a particular industrial practice.
- The inspector considers the practice inappropriate.
- The report classifies the practice as non-compliant.
- The sanctioning authority relies upon the report's classification without independently examining the applicable legal requirement or technical evidence.

The potential defect is not the use of an inspection report as evidence. It is the substitution of an unsupported conclusion for proof of the constituent elements of the infringement. Administrative sanctioning requires establishment of the legally relevant facts and application of the correct legal standard. The evidentiary value of an official report cannot relieve the Administration of its responsibility to establish the infringement in accordance with the applicable procedural and constitutional guarantees.

The operator's right to challenge inspection findings

Article 77.1 of Law 39/2015 permits relevant facts to be established through legally admissible evidence. Article 77.3 limits the rejection of evidence proposed by interested parties to cases in which it is manifestly inappropriate or unnecessary, requiring a reasoned decision. Article 78 regulates the taking of evidence and includes provisions concerning notification of evidentiary activities and the possibility of appointing technical assistance. These provisions are particularly relevant where an operator contests an inspector's technical conclusions.

Potential evidence may include independent laboratory analyses, instrument calibration records, process-validation studies, expert reports, contemporaneous production data and documentation demonstrating the actual conditions under which the inspection took place. However, the right to propose evidence does not entail an unconditional right to have every requested test performed. The admissibility, relevance and necessity of the proposed evidence remain subject to

the governing procedural rules. Where the disputed evidence is decisive, the adequacy of the Administration's treatment of that evidence may become central to subsequent judicial review.

Written records of official controls and the right to obtain copies

Article 13 of Regulation (EU) 2017/625 requires competent authorities to prepare written records of official controls. Those records must identify the purpose of the controls, the methods applied, their outcome and, where appropriate, the measures required of the operator. Article 13.2 further provides for the operator to receive a copy upon request, subject to the exceptions established by that provision. This requirement has substantial legal importance. Written records contribute to traceability of administrative action, institutional accountability and the possibility of subsequent review.

They also help distinguish what an inspector actually observed from what was inferred, recommended or formally required. Nevertheless, the existence of a written record should not be confused with the existence of a complete administrative decision. A control record may document inspection activities without itself resolving every legal question arising from those activities. Equally, the operator's access to inspection records does not necessarily entail unrestricted access to every internal administrative document or information protected by other legal provisions.

Failure to record relevant circumstances

An incomplete inspection record may create significant evidentiary difficulties. For example, where an inspector alleges that an operator failed to comply with a verbal instruction, the absence of a reliable record of that instruction may complicate proof of its content, timing and legal basis. However, incomplete documentation does not automatically invalidate every subsequent measure. The legal consequences depend upon the applicable requirements, the importance of the omission and whether the defect affected the operator's rights or the legality of the decision.

The significance of contemporaneous objections

An operator may consider it necessary to record disagreement with an inspector's observations or conclusions. Such objections should be factual, precise and supported where possible by contemporaneous evidence. A useful distinction is between acknowledging receipt of a document and accepting the accuracy of its contents. The legal effect of signing an inspection record depends upon the document, the applicable procedure and the circumstances. It would therefore be incorrect to assert that signing always constitutes agreement or that refusal to sign automatically invalidates the report.

The appropriate course is to examine the legal function of the signature and preserve a clear record of any disagreement.

Business secrecy, confidential technical information and the limits of disclosure

The conflict between regulatory transparency and industrial confidentiality

Food businesses frequently hold information whose disclosure may affect their competitive position. Such information may include proprietary formulations, manufacturing parameters, process-validation methodologies, supplier relationships, industrial designs, experimental results and confidential research programmes. Some of this information may constitute **a trade secret** within the meaning of Directive (EU) 2016/943 and Spanish Law 1/2019 on Trade Secrets. However, trade-secret protection does not create a general exemption from official food controls. An authority may legitimately require access to confidential information where disclosure is necessary and legally authorised for verification of compliance.

The legal problem therefore concerns the conditions under which information may be obtained, used, retained and disclosed.

Three separate questions must be answered:

- Does the authority possess a lawful basis for accessing the information?
- Is the scope of access justified by the objectives of the control?

- What confidentiality obligations govern the information once obtained?

These questions should not be collapsed into a single debate about whether the material is commercially sensitive.

Article 8 of Regulation (EU) 2017/625

Article 8 establishes confidentiality obligations concerning information obtained by competent authorities in the performance of official controls and other official activities. Its provisions recognise the importance of professional secrecy while also accommodating legally justified disclosure and transparency obligations. This is significant because official inspectors may obtain access to information that would ordinarily remain inaccessible to competitors, customers or the general public. Such access is justified by the public function performed, not by any entitlement to use the information for unrelated purposes. Accordingly, confidentiality is not merely a matter of administrative courtesy.

It forms part of the legal framework governing the exercise of official control powers. Nevertheless, Article 8 does not establish absolute secrecy. Its exceptions and the interaction with applicable national and Union legislation must be examined before determining whether a particular disclosure is unlawful.

The specific problem of proprietary manufacturing technology

Consider an industrial operator employing a proprietary processing technology. The inspector requests the technical information necessary to verify that the process achieves the legally required safety outcome. The operator supplies validation studies, relevant analytical results and operating records. The inspector subsequently demands disclosure of the complete proprietary formulation and manufacturing know-how, notwithstanding the operator's contention that the compliance question can be resolved through less intrusive evidence. This situation raises a legitimate proportionality question.

It does not follow that the authority must accept the operator's proposed evidence as sufficient. The authority may require additional information where justified by the applicable legal framework. However, it should be possible to identify why the additional information is relevant and necessary for the regulatory purpose pursued. The legal entitlement to verify compliance should

not be confused with an unrestricted entitlement to acquire commercially valuable know-how unrelated to that verification. This proposition requires careful qualification: where the composition or manufacturing process itself determines regulatory compliance, access to otherwise confidential information may be indispensable.

The appropriate legal solution lies in **justified access accompanied by effective confidentiality safeguards**, rather than either unrestricted disclosure or absolute secrecy.

Digital inspection and the expanding boundaries of administrative access

The digitalisation of food production creates new legal questions that traditional inspection doctrine does not fully resolve. Modern industrial systems may contain electronic batch records, laboratory information-management systems, enterprise resource planning platforms, process-control databases, cloud-based traceability records and digitally stored research documentation. Article 15 of Regulation (EU) 2017/625 expressly contemplates access to relevant computerised information-management systems. However, access to a regulatory information system does not necessarily authorise unrestricted examination of every digital resource connected to the operator's infrastructure.

The legal assessment must consider the purpose of the inspection, the scope of the authority's powers, the relevance of the requested information and any additional protections applicable to personal data or confidential communications. Particular problems may arise where corporate and personal information coexist on the same device or where a single database contains both regulatory records and unrelated confidential information. A distinction must therefore be maintained between lawful access to required regulatory information and indiscriminate extraction of digital content.

The latter may raise additional questions under constitutional law, data-protection legislation and the applicable rules governing administrative evidence.

Digital evidence and integrity

Digital inspection also creates evidentiary challenges. The probative value of an extracted file may depend upon its provenance, completeness, integrity and relationship to the relevant production activity. An isolated spreadsheet, screenshot or database export may not adequately establish the circumstances under which the information was generated. Where digital evidence is disputed, relevant questions may include whether the extraction preserved necessary metadata, whether the record was subsequently modified and whether the material accurately represents the underlying industrial process. These issues do not automatically invalidate digital evidence.

They concern the reliability and weight of that evidence within the applicable legal framework.

The transition from administrative inspection to criminal investigation

A particularly sensitive legal boundary arises where official food controls reveal circumstances potentially constituting criminal offences. Such circumstances might concern serious conduct affecting public health, falsification of documents or other offences under the applicable criminal legislation. The discovery of potentially criminal conduct may trigger duties to communicate relevant information to the competent authorities. However, the transition from administrative supervision to criminal investigation must respect the procedural framework governing each activity.

A routine food inspector does not acquire unlimited criminal-investigative powers merely because suspected criminal conduct emerges during an inspection. Nor does the potential existence of criminal liability necessarily require immediate cessation of every lawful preventive food safety measure. The Administration may still need to address an ongoing risk to public health. The central legal difficulty concerns the collection and subsequent use of evidence, especially where administrative cooperation obligations are employed in circumstances involving potential criminal liability.

The European Court of Human Rights has repeatedly emphasised the importance of examining the nature and degree of compulsion, the available

procedural safeguards and the use subsequently made of the material obtained. In *Saunders v. the United Kingdom*, the use in criminal proceedings of statements obtained through compulsory investigative questioning was central to the finding of a violation of **Article 6. of the European Convention on Human Rights (ECHR)**, whose jurisprudence can be consulted and stored in the **HUDOC** database of the European Court of Human Rights (ECHR). This jurisprudence provides a foundation for examining whether information obtained during food inspection can subsequently be used against individual managers, employees or other potentially liable persons in the sense of a fair process/trial.

The answer cannot be reduced to a general rule that all administrative evidence is admissible or that all compelled evidence must be excluded. The legal analysis must consider the nature of the material, the circumstances of its acquisition, the procedural setting and the rights of the persons concerned.

Analytical framework: The regulatory evidence boundary

The preceding analysis suggests a further contribution to the proposed Legality and Proportionality Assessment Framework for Official Food Controls. We may designate it the **Regulatory Evidence Boundary Model (REBM)**. Its purpose is to distinguish **lawful regulatory verification** from potentially excessive or procedurally defective evidence gathering. Proposed analytical sequence

1. Legal authority

Identify the competent authority and statutory inspection power

2. Regulatory relevance

Determine the relationship between the information and the control objective

3. Nature of the material

Distinguish existing records, technical evidence and compelled statements

4. Applicable safeguards

Examine confidentiality, procedural rights and protection against self-incrimination

5. Evidentiary reliability

Evaluate provenance, integrity, methodology and opportunities for contradiction

6. Subsequent use

Assess whether use in corrective, sanctioning or criminal proceedings is legally permissible. This model is a proposed doctrinal instrument, not an established statutory or judicial test. Its value lies in preventing the assumption that information lawfully obtained for one administrative purpose may necessarily be used without further legal examination for every subsequent purpose. It also prevents the opposite error stated as treating every item of potentially incriminating regulatory evidence as protected from compulsory disclosure.

Chapter conclusions

The analysis supports several conclusions of particular relevance to food business operators and administrative authorities. The duty to cooperate with official controls is binding and extensive, but it must be exercised within the applicable legal framework. The production of legally required regulatory records is not equivalent to compelled testimonial self-incrimination. Official inspection reports possess evidentiary significance, but their contents are not universally conclusive. Directly observed facts must be distinguished from technical inferences and legal classifications.

The operator's ability to contest inspection findings constitutes an important component of procedural fairness. Commercial confidentiality does not prevent legitimate regulatory access, but it imposes legal obligations concerning the handling and disclosure of protected information.

Finally, the use of information obtained through administrative compulsion in subsequent punitive proceedings requires careful examination of the applicable constitutional and Convention guarantees.

Taken together, these conclusions establish an important proposition:

The effectiveness of official food controls depends not only upon the Administration's ability to obtain information, but also upon the legality, reliability and procedural integrity of the methods through which that information is acquired and used.

CHAPTER 4

Administrative Coercion, Informal Orders and Enforcement Powers

Inspection depends upon effective powers, including the capacity to compel compliance in cases prescribed by law. The legality of that compulsion depends on the legal form of the instruction, its enforceability and the means used to implement it.

Administrative coercion as a necessary but legally bounded instrument

Administrative inspection is not merely observational. Its effectiveness depends upon the existence of legal powers capable of overcoming resistance to lawful supervision. An inspection authority that could only make recommendations would often be unable to prevent the continued production or distribution of unsafe food. Consequently, European Union and Spanish legislation confer powers to investigate, require information, verify compliance and, where the relevant legal conditions are satisfied, adopt corrective or restrictive measures. These powers may affect commercial activity, production schedules, contractual commitments, inventory, industrial equipment and the economic viability of an establishment.

Their potentially serious consequences explain why coercive intervention must be legally structured. The essential constitutional distinction is between authority exercised through law and authority asserted through institutional position. A public official may legitimately demand compliance with an enforceable legal requirement. However, official status does not independently create substantive obligations. The inspector's professional assessment may be relevant to determining whether a statutory requirement has been breached. It cannot, without sufficient legal foundation, transform an optional practice into a mandatory industrial procedure.

Nor can an inspector lawfully use the prospect of sanctions to obtain compliance with a requirement that the competent authority lacks power to

impose. The relevant analysis must examine the actual legal content of the instruction, the authority issuing it, the circumstances justifying it and the consequences attached to non-compliance. This inquiry is particularly important in food production, where technical recommendations and legally binding requirements may be communicated during the same inspection.

The four categories of inspection communications

Inspection communications should be classified according to their legal nature rather than their terminology alone. For analytical purposes, four categories can be distinguished.

Category	Nature	Possible legal consequence
Technical observation	Description of a condition or practice	May support subsequent assessment
Recommendation	Proposed improvement without independent compulsory force	Normally does not itself establish an obligation
Formal requirement	Instruction issued under a legally applicable power	May create an enforceable duty
Restrictive or corrective decision	Administrative measure affecting operations, products or rights	May produce immediate legal effects subject to applicable safeguards

This classification is not a substitute for statutory analysis. A communication described as a recommendation may, in substance, operate as an enforceable instruction. Conversely, a statement recorded in an inspection report may merely document an observation without independently creating an obligation. The legal character of the measure must therefore be determined by its content, the powers exercised and its intended effects.

Technical observations

An inspector may record that an industrial surface exhibits deterioration, that a monitoring record is incomplete or that a sanitation procedure differs from an established internal protocol. Such observations may be relevant to regulatory compliance. However, the observation itself does not necessarily establish that

the operator has committed a legally defined infringement. The authority must connect the observed condition to the applicable regulatory requirement. A deteriorated surface, for example, may create a hygiene concern under the relevant provisions of Regulation (EC) No 853/2004.

The legal analysis must nevertheless consider the nature of the deterioration, the possibility of contamination, the applicable hygiene requirements and the measures necessary to restore compliance.

Recommendations

Inspectors may recommend improvements beyond the minimum required by law. Such recommendations can provide substantial value to operators. A recommendation might concern improved workflow, enhanced environmental monitoring, additional staff training or adoption of more sophisticated process-control equipment. The difficulty arises when the recommendation is presented as compulsory without identifying the legal basis for its enforceability. The distinction between recommended practice and legal obligation must remain explicit.

Binding requirements

A binding requirement presupposes a legal power authorising the authority to demand particular conduct. Its validity may depend upon competence, factual circumstances, legal basis, proportionality and compliance with applicable procedural requirements. Where the authority identifies established non-compliance, Article 138 of Regulation (EU) 2017/625 provides for appropriate action to ensure that the operator remedies the infringement and prevents its recurrence. The measures available depend upon the nature of the non-compliance and the applicable legal framework.

The existence of this enforcement power does not mean that every instruction issued during an inspection automatically constitutes a lawful Article 138 measure.

Restrictive measures

Some administrative measures directly interfere with ongoing industrial activity. Examples include product immobilisation, restrictions upon placing

goods on the market, suspension of specified activities and other measures contemplated by applicable legislation. Such measures may be justified where necessary to address non-compliance or protect public health. However, their restrictive effects make the legal basis, factual justification, procedural framework and proportionality of the intervention particularly important.

Verbal orders: Validity, documentation and enforceability

The written form as the general rule

Article 36.1 of Law 39/2015 establishes that administrative acts are generally produced in writing through electronic means, unless their nature requires or permits another more appropriate form of expression and recording. Article 36.2 specifically addresses administrative bodies exercising competence verbally and provides for written recording, where necessary, by the receiving official or the holder of the subordinate body, indicating the authority from which the instruction originates. These provisions are significant because they reject two simplistic assumptions.

First, **not every verbal administrative instruction is necessarily invalid.**

Second, **verbal communication does not eliminate the legal requirements governing the underlying act.**

The validity of a verbal instruction depends upon the applicable legal framework, the nature of the measure and the circumstances in which it is issued.

Emergency instructions

Food safety incidents may require immediate action. An inspector may encounter circumstances in which delaying intervention until completion of ordinary written formalities would create a serious risk to public health. In such cases, applicable legislation may permit **urgent protective action**. However, **urgency does not establish unlimited authority**. The competent body must still act within the powers conferred upon it, and the relevant measure must satisfy the legal conditions governing emergency intervention.

Where the law requires subsequent documentation, notification or formalisation, those requirements must be respected. A verbal instruction justified by genuine urgency should not be treated as equivalent to an informal recommendation communicated during an ordinary inspection.

The evidentiary problem of undocumented orders

Verbal instructions create potential *uncertainty concerning their content and legal consequences*. Disputes may arise over whether an instruction was actually issued, whether it was mandatory, the deadline imposed, the identity of the competent authority or the precise conduct required. For example, an inspector might orally instruct an operator to discontinue use of a particular processing method. If the operator later faces proceedings for non-compliance, the legal analysis may require proof of the instruction's content, legal basis and communication. The absence of written documentation does not automatically establish invalidity.

Nevertheless, it may create serious difficulties in demonstrating that an enforceable requirement existed and that the operator knowingly failed to comply.

A proposed documentation standard

A legally robust system should ordinarily distinguish in the inspection record:

- **The facts observed.**
- **The applicable legal provisions.**
- **The measures recommended.**
- **The measures formally required.**
- **The competent authority responsible for each requirement.**
- **The applicable deadlines and consequences.**

This is proposed as a standard of good regulatory administration. It should not be presented as a universally mandatory statutory checklist applicable to every inspection. Its value lies in improving transparency, legal certainty and the possibility of effective review.

Administrative enforceability and compulsory execution: A distinction with decisive legal consequences

The enforceability of an administrative act does not authorise unlimited material coercion

Spanish administrative law distinguishes the legal enforceability of an administrative act from the material mechanisms available to secure its execution. Article 98 of Law 39/2015 establishes the general rule of immediate enforceability of administrative acts, subject to statutory exceptions. Among those exceptions are suspension of execution and sanctioning decisions against which an administrative appeal remains available. This distinction is particularly important in food safety enforcement. A corrective measure adopted to protect public health may be immediately enforceable where the applicable legal framework so provides.

By contrast, a sanctioning decision is subject to the specific rules governing the enforceability of administrative penalties. The Administration cannot simply disregard these distinctions because an inspector considers immediate compliance desirable. Nor should a food business operator assume that filing an administrative appeal automatically suspends every restrictive measure. The legal consequences depend upon the nature of the decision and the applicable rules on suspension.

Article 97 (39/2015): The requirement of a prior administrative decision

Article 97 of Law 39/2015 establishes a particularly significant guarantee. Administrative authorities may not initiate material execution of decisions restricting private rights without a prior decision providing the legal foundation for that execution. The provision also requires notification of the decision authorising the material action to the interested party. This creates a legal boundary between a formal administrative decision and an official's unilateral physical intervention. For example, a decision lawfully ordering the immobilisation of a food consignment must be distinguished from an inspector's

attempt to impose equivalent restrictions without the necessary legal foundation.

Nevertheless, the provision must be interpreted alongside specific statutory regimes governing urgent protective measures. It would be incorrect to assume that Article 97 prevents all immediate intervention during an emergency. The relevant question is whether the action is supported by a valid legal power and complies with the procedural conditions applicable to that type of intervention.

The prohibition of *vía de hecho*

Spanish administrative law recognises the concept of *vía de hecho*, generally associated with material administrative action lacking the necessary legal basis or exceeding the legally authorised scope of execution. Its relevance to food inspection is substantial. Potential examples requiring examination include physical restrictions on production imposed without the legally required decision, interference with property beyond the authorised measure, or continued enforcement after the legal foundation for the intervention has ceased. However, not every procedural irregularity constitutes *vía de hecho*.

The concept has specific legal consequences and must be applied in accordance with the relevant legislation and jurisprudence. The distinction matters because Law 29/1998 regulating the contentious-administrative jurisdiction provides particular mechanisms for challenging material administrative action constituting *vía de hecho*. the available judicial remedies are addressed in Chapter 11.

The legally permitted mechanisms of compulsory execution

Article 100 of Law 39/2015 identifies *four* mechanisms of compulsory administrative execution. They are not interchangeable instruments available at an inspector's unrestricted discretion. Each operates under its own statutory conditions.

Enforcement against property

The administrative enforcement procedure against property applies to legally enforceable pecuniary obligations. It cannot be used to create a financial

obligation lacking the required legal foundation. In the food safety context, the distinction between an administrative fine, a recoverable enforcement cost and another pecuniary obligation is essential. Each may arise under different substantive and procedural rules.

Subsidiary execution

Article 102 permits subsidiary execution where the required action is not strictly personal and may be performed by someone other than the obligated party. The Administration may perform the action itself or through designated persons, at the obligated party's expense, subject to the applicable legal requirements. Potential food safety applications may include measures requiring the performance of specified material actions that the operator has failed to undertake. However, the existence of subsidiary execution powers does not automatically justify every intervention. The underlying obligation must be legally enforceable, and the chosen method must satisfy the relevant conditions.

Coercive fines

Article 103 permits coercive fines only where legislation authorises them and determines their form and amount. These fines are designed to secure compliance with an enforceable obligation. They are legally distinct from punitive administrative sanctions. The distinction has important consequences. A coercive fine is not necessarily a sanction merely because it imposes a financial burden.

Conversely, the Administration cannot avoid the guarantees of sanctioning law simply by describing a punitive measure as coercive. Its legal nature must be assessed by reference to its statutory foundation, purpose and operation. Article 103 expressly contemplates the compatibility of coercive fines with sanctions, but this does not dispense with the specific legal requirements governing either mechanism.

Direct compulsion against persons

Article 104 regulates direct compulsion against persons. Its application is subject to particularly strict conditions, including express statutory authorisation

and respect for human dignity and constitutional rights. It would therefore be legally unsustainable to infer a general power of physical coercion from the mere existence of official inspection authority. Any intervention affecting personal liberty or bodily integrity requires examination of its specific legal foundation and constitutional limits. The four mechanisms and their statutory conditions are established in Articles 100–104 of Law 39/2015.

Threats of sanction: Legitimate warning or improper coercion?

The legal function of a warning

A competent inspector may legitimately inform an operator of the consequences of failing to comply with applicable legal requirements. Such communication can improve compliance and prevent avoidable infringements. For example, informing an operator that refusal to provide legally required traceability information may constitute an infringement is not inherently abusive. The warning may accurately describe the legal consequences of non-cooperation. The problem arises where the threatened consequence is used to compel conduct that the Administration has no legal authority to require.

The distinction is therefore not between polite and forceful communication. It is between a warning grounded in applicable law and an attempt to obtain compliance through an unjustified assertion of punitive authority.

Three categories of enforcement pressure

Legitimate regulatory warning. An inspector identifies a legal obligation and accurately explains the consequences of non-compliance. The warning is connected to a lawful requirement and the applicable enforcement framework.

Potentially defective enforcement pressure. An inspector threatens sanctions to secure a technical modification without adequately identifying the legal obligation or communicates consequences disproportionate to the alleged infringement. **Potentially unlawful coercive conduct.** Official powers are deliberately invoked to compel conduct unrelated to legitimate regulatory purposes, retaliate against an operator or impose an obligation known to lack legal foundation. These categories are analytical. They do not constitute

independent statutory offences. In particular, a defective warning does not automatically establish criminal coercion, threats or prevarication. Any potential criminal responsibility requires satisfaction of the elements of the relevant offence, including its applicable subjective requirements.

The risk of conflating disagreement with obstruction

A significant problem may arise where an operator contests an inspector's legal interpretation or technical conclusion. Disagreement is not necessarily obstruction. A company may legitimately request identification of the applicable legal provision, submit contrary scientific evidence, seek clarification or challenge an administrative decision. These actions form part of the ordinary operation of administrative legality. However, disagreement does not suspend lawful inspection powers.

An operator who refuses access to legally required records or physically prevents a lawful control cannot automatically justify that conduct by asserting that the inspector's interpretation is incorrect. The relevant distinction concerns the operator's actual conduct and the legal obligation involved. Contesting an administrative requirement and obstructing its lawful execution are legally different activities. Whether particular conduct constitutes an infringement must be determined under the applicable statutory definition, with the corresponding procedural and evidentiary guarantees.

Obstruction of official controls: The need for a legally precise definition

The duty to cooperate is not a duty to agree

Article 15 of Regulation (EU) 2017/625 establishes cooperation obligations that may be essential to the effectiveness of official controls. An operator who deliberately prevents access to relevant facilities, conceals required records or obstructs legally authorised sampling may breach those obligations. However, the legal concept of obstruction must not be extended indiscriminately to every disagreement between the operator and the inspector. A technical director may challenge the interpretation of a microbiological result. A company may submit

evidence that an alternative process achieves the applicable hygiene requirements.

An operator may request that a disputed instruction be formally documented. Such conduct does not, merely by reason of disagreement, establish obstruction. The legal assessment must identify the specific cooperation obligation, the conduct alleged to violate it and the applicable infringement provision.

Obstruction and the principle of legality in sanctioning law

Article 25 of the Spanish Constitution provides a fundamental basis for the **legality of punitive state action**. In administrative sanctioning law, this principle is developed through the requirements governing statutory authorisation and the definition of infringements and sanctions. The Administration cannot punish conduct merely because it considers that conduct inconvenient or uncooperative. It must identify an applicable infringement and establish the legally required elements. Article 139 of Regulation (EU) 2017/625 requires Member States to establish penalties for infringements of the Regulation and ensure that they are **effective, proportionate and dissuasive**.

However, Article 139 does not itself constitute a complete catalogue of Spanish administrative infringements or automatically determine the sanction applicable to every alleged obstruction. The relevant Spanish statutory provisions and, where applicable, autonomous-community legislation must therefore be examined. This issue is especially important because a disputed request may concern information whose legal relevance is uncertain. The Administration must not simply presume that refusal of every request constitutes an independently punishable infringement.

A proposed distinction between resistance and legal contestation

The following analytical distinction may assist in evaluating contested situations.

Operator conduct	Preliminary legal assessment
Refusing access to mandatory traceability records	Potential infringement of cooperation obligations
Preventing legally authorised sampling	Potential obstruction
Requesting identification of the legal basis for a demand	Ordinarily legitimate legal contestation
Submitting an independent expert report	Exercise of procedural and evidentiary rights
Challenging a formal decision through available remedies	Legitimate exercise of legal rights
Refusing to comply with an enforceable measure solely because an appeal has been filed	Potential non-compliance, unless execution is suspended or another legal ground applies
Concealing or falsifying required information	Potentially serious infringement, depending on the applicable provisions

This table is not a determination of liability. The classification of conduct requires examination of the applicable legal framework, factual circumstances and procedural guarantees.

Deviation of power: When a lawful competence is exercised for an unlawful purpose

The concept of *desviación de poder*

The prohibition of arbitrariness (*interdicción de la arbitrariedad de los poderes públicos*) is not the only legal instrument available to challenge misuse of administrative authority. Spanish law expressly recognises *desviación de poder*. Article 70.2 of Law 29/1998 defines it by reference to the exercise of administrative powers for purposes different from those established by the legal system. Article 48.1 of Law 39/2015 also identifies ***deviation of power*** among the infringements capable of rendering an administrative act voidable. This doctrine is particularly relevant where the authority formally possesses the power exercised, but uses it to pursue an improper objective.

The legal defect therefore concerns the purpose of the intervention, not necessarily the absence of competence.

Potential applications in food inspection

Consider a hypothetical case in which an authority repeatedly inspects an establishment following a dispute between its management and an individual official. Repeated inspection is not inherently unlawful. A food business with a history of non-compliance may legitimately be subjected to *intensified controls*. However, if the evidence established that inspections were deliberately organised to retaliate against the operator rather than to pursue legitimate regulatory objectives, the situation could raise a question of *deviation of power*. The same reasoning may apply where enforcement powers are used to obtain unrelated commercial advantages, favour competitors or punish the exercise of procedural rights.

These examples are hypothetical. They do not establish that such practices are prevalent within Spanish food inspection services, although in the practice it seems that are turning a so-many frequent behaviour.

The evidentiary difficulty

Deviation of power may be difficult to establish because the improper objective is not always expressly documented. The existence of an unfavourable decision, a personal disagreement or a series of inspections is not sufficient by itself. The analysis may require examination of objective circumstances capable of supporting an inference that the statutory power was exercised for an unauthorised purpose. Relevant circumstances might include unexplained departures from established inspection criteria, inconsistent treatment of comparable operators, communications indicating an improper objective or patterns of action lacking a credible regulatory explanation. Nevertheless, each circumstance must be evaluated in context.

Differences in risk, compliance history, industrial activity or available evidence may legitimately explain different inspection frequencies or measures. The central legal question remains whether the power was exercised for the purpose established by law.

Precautionary measures, urgent intervention and the danger of disguised sanctions

Protective intervention must be distinguished from punishment

A recurring problem in administrative enforcement concerns measures that impose severe economic consequences but are legally characterised as *preventive* or *corrective*. A production suspension may cause greater financial damage than an administrative fine. However, the economic severity of a measure does not, by itself, determine whether the measure is punitive. Its legal classification depends upon its statutory foundation, purpose, conditions and operation. A measure designed to contain an identified food safety risk may be preventive even if it imposes substantial economic losses.

Conversely, a measure formally described as preventive may require scrutiny where its actual operation appears directed towards punishment rather than risk control. The distinction is essential because preventive and punitive measures are governed by different legal conditions and procedural guarantees.

Article 56 of Law 39/2015

Article 56 establishes the general framework for provisional administrative measures. It distinguishes measures adopted after commencement of proceedings from measures adopted beforehand in cases of urgent necessity. For measures adopted before proceedings begin under Article 56.2, the law requires confirmation, modification or withdrawal in the initiation decision within fifteen days; the measure loses effect if proceedings are not initiated within that period or the initiation decision fails to address it expressly. This is an important procedural guarantee.

However, the *fifteen-day rule* must not be indiscriminately extended to every precautionary measure adopted under sector-specific food legislation. The legal basis and relationship between the general and special regimes must be established in each case.

The obligation to justify the selected measure

Article 4 of Law 40/2015 requires proportionate intervention and justification of restrictive measures. In the context of official food controls, this obligation must be considered alongside Articles 137 and 138 of Regulation (EU) 2017/625. Article 137 addresses action where non-compliance is suspected. Article 138 addresses measures following established non-compliance. The distinction is important because suspicion and established infringement are different factual and legal situations.

An authority may be entitled to immobilise goods temporarily while investigating a credible suspected infringement. However, the legal basis for such immobilisation, its scope and its duration must remain connected to the conditions authorising it. Similarly, where established non-compliance requires *corrective* action, the authority must select legally appropriate measures having regard to the nature of the infringement and the relevant circumstances. The Regulation also provides procedural safeguards concerning written notification of decisions and information on appeal rights.

A hypothetical example: The suspension of an entire production facility

Suppose an inspection identifies contamination in a specific production line. The authority orders the suspension of the entire establishment. The legal assessment should examine whether the contamination could affect other production areas, whether common utilities or shared handling systems create a broader risk, whether the operator can demonstrate effective segregation and whether narrower measures would adequately protect public health. A complete suspension may be justified where the evidence supports a facility-wide risk. Conversely, where the hazard is demonstrably isolated and effectively controllable, the *proportionality* of an establishment-wide suspension may require further justification.

The question is not whether the measure causes economic damage. It is whether the measure is legally authorised, suitable, necessary and proportionate in relation to the relevant risk.

The legal protection of operators confronted with disputed inspection requirements

The existence of a dispute does not eliminate the operator's cooperation obligations. Nor does the authority's institutional position deprive the operator of procedural rights. A legally defensible response should preserve both objectives: continued compliance with lawful controls and effective protection against potentially unlawful intervention.

Identification of the measure

The first issue is determining whether the inspector has communicated an observation, recommendation, binding requirement or formal restrictive decision. This classification determines which procedural and substantive rules may apply.

Identification of the legal basis

Where a requirement is disputed, the operator should seek identification of the relevant legal provisions and the competent authority responsible for the decision. The purpose is not to obstruct inspection. It is to establish the legal foundation of the obligation.

Preservation of contemporaneous evidence

The operator should preserve relevant production records, inspection documentation, correspondence, technical assessments and evidence concerning the circumstances of the intervention. Where verbal instructions are disputed, contemporaneous documentation may be particularly important.

Technical contradiction

Where the disagreement concerns scientific or industrial matters, the operator should distinguish factual observations from technical interpretations. Independent analytical results, validation studies and expert opinions may be relevant. However, technical disagreement does not automatically suspend an enforceable administrative measure.

Administrative challenge and suspension

Article 117 of Law 39/2015 establishes that filing an administrative appeal does not generally suspend execution of the challenged act. Nevertheless, suspension may be requested under the statutory conditions, including circumstances involving harm that would be *difficult or impossible to repair* or reliance upon grounds of nullity. The provision also establishes a specific rule concerning failure to resolve a suspension request within one month, subject to its legal conditions. These mechanisms must be distinguished from judicial interim relief, which operates under the relevant provisions of Law 29/1998.

Preservation of the distinction between legal defence and obstruction

A company may challenge an administrative decision while continuing to comply with obligations that remain legally enforceable. This distinction is particularly important where non-compliance could create additional regulatory consequences. The operator's legal strategy should therefore be based upon the actual enforceability of the measure, not merely upon disagreement with its merits.

Analytical framework: The Administrative Coercion Legality Matrix

The preceding analysis permits development of a further component of the proposed assessment framework. **The Administrative Coercion Legality Matrix (ACLM)** is intended to distinguish lawful enforcement pressure from potentially defective or abusive administrative intervention.

Assessment criterion	Principal question
Competence	Was the instruction issued by a legally authorised authority?
Legal foundation	Does an applicable provision permit the requirement?
Nature of communication	Is it a recommendation, binding act or execution measure?
Factual justification	Are the circumstances supporting intervention established?
Legitimate purpose	Does the measure pursue the statutory regulatory objective?

Assessment criterion	Principal question
Proportionality	Is the selected intervention justified and appropriately limited?
Documentation	Have applicable recording and notification requirements been satisfied?
Enforceability	Is the obligation presently enforceable?
Coercive mechanism	Is the proposed method of compulsory execution legally authorised?
Procedural protection	Are the operator's applicable rights and remedies respected?

The matrix does not replace judicial analysis. It provides a systematic method for identifying the legal questions that must be resolved before an inspection instruction can be classified as lawful, defective or potentially abusive. Its value lies in resisting two errors. The first is assuming that every official instruction is lawful because it originates from an inspector. The second is assuming that every disputed instruction is unlawful because the operator disagrees with it.

Neither assumption is compatible with rigorous administrative-law analysis.

Conclusions of this chapter

This chapter establishes several propositions. Administrative coercion is indispensable to effective food safety enforcement, but its exercise requires legal authorisation. Verbal instructions are not categorically invalid, although their legal effects and documentation requirements must be carefully examined. The enforceability of an administrative act must be distinguished from the material mechanisms available to execute it. Coercive fines, punitive sanctions and corrective measures perform different legal functions.

Disagreement with an inspector does not automatically constitute obstruction, while disagreement does not excuse failure to comply with enforceable legal obligations. Deviation of power provides a legal basis for challenging the use of administrative powers for purposes different from those established by law.

Finally, precautionary intervention must remain connected to its protective purpose and satisfy the applicable legal conditions.

The broader doctrinal conclusion is that administrative authority cannot be measured solely by the intensity of the power exercised; its legitimacy depends

upon the legal foundation, purpose, necessity and procedural integrity of that exercise.

CHAPTER 5

Repeated Inspections, Selective Enforcement and Good Administration

Lawfulness cannot always be judged by examining an inspection in isolation. Repetition, selectivity and unequal treatment may reveal patterns that demand a fuller assessment of regulatory purpose and administrative consistency.

Introduction: Can individually lawful inspections produce a legally problematic pattern?

The exercise of administrative inspection powers is ordinarily examined through identifiable acts: an inspection visit, a documentary request, a sampling decision, an official report, a corrective requirement or a restrictive measure. This approach is necessary but not always sufficient. Administrative conduct may also be examined longitudinally. A succession of interventions may reveal relevant circumstances concerning the selection of operators, the consistency of technical criteria, the purposes pursued and the cumulative burden imposed upon a regulated establishment. Consider a hypothetical food manufacturer subjected to several inspections over a relatively short period.

Each visit is conducted by duly authorised officials. Each inspection concerns matters falling within the authority's regulatory competence. The operator receives inspection records and is permitted to submit observations. Taken individually, these circumstances may support the formal regularity of the interventions. Nevertheless, additional questions may arise if the inspections follow an unusual pattern, employ contradictory requirements, depart without explanation from ordinary risk-based selection criteria or appear connected to the operator's exercise of procedural rights.

The central legal difficulty is determining whether the overall pattern remains a legitimate expression of regulatory supervision or reveals a misuse of administrative powers. The distinction must be approached cautiously. A high frequency of inspections is not, by itself, evidence of harassment, discrimination or deviation of power. Food businesses presenting elevated risks, serious previous

non-compliance or unresolved corrective deficiencies may lawfully require intensified supervision. Conversely, the existence of formal inspection powers does not make their selection, frequency or exercise immune from legal scrutiny.

The relevant question is whether the pattern can be objectively explained by the statutory purposes governing official controls. this chapter therefore moves beyond the legality of isolated acts and examines the legal significance of administrative conduct considered as a sequence.

Risk-based inspection frequency: A legal obligation, not an unlimited prerogative

Article 9 of Regulation (EU) 2017/625

Article 9.1 establishes that competent authorities ***must*** perform official controls regularly, on a risk basis and at an appropriate frequency. The provision identifies several factors relevant to inspection planning, including the risks associated with the products and activities concerned, previous compliance history, the reliability of operators' own controls and information suggesting possible non-compliance. This creates a significant legal distinction. Inspection frequency is not required to be identical for every establishment.

A facility processing *ready-to-eat* foods with a history of serious microbiological deficiencies may legitimately receive more **intensive** supervision than a lower-risk establishment with a consistently satisfactory compliance record. Similarly, an emerging contamination incident or credible information indicating non-compliance may justify additional controls outside the ordinary inspection schedule. Consequently, a company's assertion that it has been inspected more frequently than a competitor is not sufficient to establish unequal treatment. The appropriate comparison requires examination of relevant risk characteristics.

Article 9.4 also establishes that official controls are generally performed without prior notice, subject to the exceptions provided. Article 9.5 requires authorities, as far as possible, to minimise administrative burdens and operational disruption without undermining the effectiveness of controls. These

provisions establish a balance between inspection effectiveness and the legitimate interests of operators.

Does Article 9 create a right to a particular inspection frequency?

No. Article 9 does not establish a universal numerical ceiling on inspections. Nor does it entitle an operator to demand that the competent authority refrain from further controls merely because a recent inspection found no infringements. An authority may possess legitimate reasons to conduct additional inspections. However, the absence of a numerical limit does not imply that frequency is legally irrelevant.

The pattern of inspections may be examined in relation to the risk-based objectives of the Regulation, the applicable national framework and the general principles governing administrative action. A sequence of controls that appears disproportionate or inconsistent with the authority's stated selection criteria may justify closer scrutiny. That scrutiny does not necessarily require disclosure of every confidential element of inspection planning, particularly where disclosure could undermine control effectiveness. Nevertheless, the Administration's selection and exercise of inspection powers remain subject to legality and judicial review.

The significance of previous compliance history

Article 9.1 expressly identifies the operator's past record as a relevant factor. This has two important consequences.

First, a history of established non-compliance may justify intensified supervision.

Second, the authority should not ignore relevant evidence demonstrating effective corrective action and sustained compliance.

The Regulation also recognises the relevance of the reliability and results of operators' own controls. Accordingly, an effective risk-based system should distinguish a persistent non-compliant operator from one that has implemented and demonstrated effective corrective measures. This does not create an automatic entitlement to reduced inspection frequency. It means that previous

compliance history and the reliability of controls are legally relevant factors in the authority's assessment.

Selective enforcement and the constitutional principle of equality

Article 14 of the Spanish Constitution

Article 14 establishes the constitutional **principle of equality** before the law (Principio de igualdad ante la Ley). Its application to administrative enforcement requires careful distinction between genuinely comparable situations and circumstances that justify different treatment. Equality does not require authorities to treat operators with materially different risk profiles identically. Nor does it require an authority to reproduce an unlawful practice merely because another operator has previously benefited from insufficient enforcement. The constitutional principle cannot ordinarily be invoked to demand equality in illegality.

However, unjustified differences in administrative treatment may raise questions under the principles of *equality, objectivity and prohibition of arbitrariness*.

The problem of comparable operators

Consider two food manufacturers operating within the same autonomous community. Both manufacture equivalent products, use comparable technologies and possess similar compliance histories. One operator is repeatedly required to implement costly technical modifications, while the other is permitted to continue operating under apparently equivalent conditions. The existence of different treatment does not automatically establish unlawfulness. Relevant differences may exist in production volume, process validation, facility design, microbiological results or other technical circumstances.

A legally meaningful comparison requires controlling for such variables. Only then can the analysis determine whether the different treatment has an objective and reasonable justification.

Selective enforcement as an evidentiary problem

A claim of selective enforcement must identify more than an unfavourable administrative outcome. Relevant evidence may include comparable inspection records, documented differences in technical criteria, administrative correspondence, established inspection policies and the authority's stated reasons for intervention. The operator must also account for legitimate differences in risk and compliance circumstances. A statistically unusual pattern may support further investigation, but statistical disparity alone does not necessarily establish unlawful discrimination or deviation of power. The evidentiary question is whether the observed difference is legally relevant and insufficiently justified.

Administrative harassment: A useful descriptive concept requiring legal precision

The absence of a single general statutory category

The expression *administrative harassment* may describe *repeated or oppressive official conduct*. However, it should not be treated as a single, universally defined infringement under Spanish administrative law. Depending upon the circumstances, the conduct may instead engage distinct legal categories:

- Arbitrariness.
- Deviation of power.
- Disproportionate administrative intervention.
- Unlawful discrimination.
- Breach of procedural guarantees.
- Administrative liability for compensable damage.
- Disciplinary misconduct or, exceptionally, criminal offences.

Each category has its own legal requirements. The use of a broad descriptive expression must not replace the identification of a specific legal defect.

The cumulative-effect problem

A significant doctrinal question arises where no single inspection is obviously unlawful, but the cumulative pattern imposes an exceptional burden. For example, an operator may experience repeated documentary requests, **overlapping inspections and inconsistent technical requirements**. Each intervention might possess an identifiable legal basis. Nevertheless, the cumulative consequences may raise questions concerning administrative coordination, necessity and proportionality. Article 9.5 of Regulation (EU) 2017/625 is particularly relevant because it expressly addresses the administrative burden and operational disruption associated with official controls.

The provision does not establish an absolute prohibition on cumulative inconvenience. It does, however, provide a normative basis for examining whether the organisation and performance of controls unnecessarily burden operators. A cumulative assessment should therefore consider whether the same regulatory objectives could reasonably have been achieved through better coordination without impairing inspection effectiveness.

Repetition as possible evidence of an improper purpose

Repeated inspections may become relevant to a claim of deviation of power where they form part of a broader evidentiary pattern. For example, the timing of inspections following protected procedural activity may be a circumstance worth examining. However, temporal proximity alone is not proof of retaliation. A convincing analysis requires additional evidence capable of linking the administrative intervention to an improper objective. The inquiry must distinguish coincidence, legitimate risk-based action and intentional misuse of authority.

The right to good administration: Spanish and European dimensions

Article 41 of the Charter of Fundamental Rights

Article 41 of the Charter recognises the right to good administration, including impartial and fair treatment, reasonable time, the right to be heard in

the circumstances covered, access to the file subject to legitimate confidentiality interests and the obligation to give reasons. An important legal qualification is necessary. Article 41 is expressly addressed to the institutions, bodies, offices and agencies of the European Union. It should not be presented as a provision directly imposing, in identical terms, every one of its obligations upon Spanish regional or national inspection services.

Nevertheless, the principles of good administration also have significance through general principles of Union law, applicable sectoral provisions and national administrative law. Furthermore, Article 51 of the Charter determines when Member States are bound by the Charter in implementing Union law. The relationship between Article 41, the general principles of Union law and national administrative obligations must therefore be analysed carefully rather than assumed as it was stated by European Union Agency for Fundamental Rights.

Good administration under Spanish law

Article 3 of Law 40/2015 establishes general principles governing public administration. These include *objectivity, transparency, good faith, legitimate expectations, responsibility, effectiveness and appropriate use of public resources*. The provision also recognises principles concerning coordination, administrative simplicity and rationalisation of procedures. These requirements provide an important domestic legal foundation for evaluating administrative conduct beyond the formal validity of isolated decisions. The question is not merely whether an inspector possesses authority.

It is also whether that authority is exercised in a manner consistent with the institutional obligations governing public administration.

Good administration and scientific impartiality

Scientific impartiality is particularly important in food safety enforcement. Inspectors may legitimately disagree with an operator's technical conclusions. However, the evaluation of evidence should not depend upon personal hostility, commercial preferences or predetermined assumptions concerning the operator. An authority should be capable of examining relevant technical evidence, identifying deficiencies in that evidence and explaining the basis for its

conclusions. This does not mean that an operator's expert report must prevail whenever it contradicts the inspector.

It means that disagreement should be resolved through reasoned evaluation rather than the mere invocation of official status. The quality of technical reasoning is therefore an important component of good regulatory administration.

Legitimate expectations and inconsistent administrative criteria

The doctrine of *legitimate expectations*

The principle of *legitimate expectations* protects legally relevant reliance upon certain forms of administrative conduct. In Spanish law, Article 3.1.e of Law 40/2015 expressly recognises *good faith* and *legitimate expectations* among the principles governing administrative action. However, legitimate expectations do not establish an unconditional right to preserve an unlawful situation. Nor do they prevent authorities from changing technical criteria where the applicable law, scientific evidence or relevant circumstances justify doing so. The doctrine must be applied with particular caution in food safety matters, where public health obligations may require intervention despite previous administrative tolerance.

Previous inspections without objections

Suppose an establishment has operated for several years under a documented processing system. Successive official inspections have not identified deficiencies concerning that system. A new inspector subsequently concludes that the process is non-compliant and requires substantial modification. Does the history of previous inspections prevent the new requirement? Not necessarily.

The absence of previous objections does not conclusively establish that the process was legally compliant. Earlier inspections may have failed to detect a defect. The legal requirements may have changed. New scientific evidence may demonstrate that previously accepted controls are insufficient. However, the previous administrative history may remain relevant.

It may help explain the operator's conduct, the reasonableness of its reliance and the circumstances surrounding the new requirement. The authority should be able to identify the legal and factual reasons supporting its changed assessment.

The distinction between changed interpretation and changed law

Four situations must be distinguished.

Situation	Legal consequence requiring analysis
New binding legislation	Compliance with the new legal requirements
New scientific evidence	Reassessment of risk and adequacy of controls
Correction of a previous administrative error	Legality of correction and any relevant reliance interests
Change in inspector preference without changed legal or technical circumstances	Need to examine the justification and legal basis of the new demand

This distinction is especially important in sectors using innovative processing technologies. An inspector may encounter a process that differs from conventional industry practice. Unfamiliarity alone does not establish non-compliance. Nevertheless, the operator must demonstrate compliance with the applicable regulatory requirements, including any necessary validation. The proper question is whether the process satisfies the law, not whether it resembles the inspector's preferred industrial model.

Retaliatory inspections and the exercise of procedural rights

The right to challenge administrative action

Food business operators may submit allegations, contest technical findings, request access to relevant records and pursue available administrative or judicial remedies. The exercise of these rights is part of the legal framework governing administrative supervision. An authority may not lawfully use its inspection

powers for the purpose of punishing an operator merely because the operator has exercised those rights. However, the exercise of a procedural right does not immunise the operator from subsequent lawful inspection. The relevant issue is the purpose and legal justification of the intervention.

A hypothetical sequence

Consider the following scenario. A food manufacturer challenges a corrective requirement and obtains its annulment. Shortly afterwards, the establishment receives several additional inspections. The inspections concern matters that had previously attracted little attention. The operator alleges retaliation.

This sequence may justify examination, but it does not establish deviation of power without further evidence. The authority may possess legitimate reasons for additional controls. The operator would need to examine the timing, selection criteria, inspection objectives, compliance history, internal administrative records where legally accessible and any evidence suggesting an improper purpose. The fact that an operator successfully challenged an earlier decision does not prevent the authority from exercising its lawful regulatory responsibilities. Equally, the authority cannot use those responsibilities as an instrument of retaliation.

The evidentiary significance of patterns

Patterns of administrative conduct may have evidentiary relevance. However, they must be interpreted against an appropriate factual baseline. For example, an increase in inspection frequency may coincide with an emerging food safety alert, a sector-wide control campaign or a change in the establishment's risk profile. Without examining those circumstances, the inference of retaliation may be unsustainable. A rigorous analysis should therefore seek both evidence supporting and evidence contradicting the alleged improper purpose.

This is particularly important because accusations of deliberate administrative harassment concern serious institutional misconduct. They should not be advanced as established facts without adequate evidence.

Institutional accountability and the supervision of inspectors

The responsibility of the competent authority

Inspection decisions are not merely personal acts of individual officials. They form part of an institutional system governed by legal duties concerning competence, coordination, supervision and accountability. Where an inspector adopts a technically or legally defective position, the relevant question may concern not only individual conduct but also the authority's procedures for reviewing and correcting such decisions. This distinction is important. A defective inspection finding may result from insufficient training, ambiguous guidance, inconsistent internal procedures or inadequate supervisory review.

These possibilities differ substantially from deliberate misuse of power. An effective system should be capable of identifying and addressing each category.

Internal review and quality assurance

Article 6 of Regulation (EU) 2017/625 establishes requirements concerning audits of competent authorities, including appropriate measures in light of audit results. This creates an institutional dimension to inspection accountability. Official control systems must not only examine food business operators. They must also evaluate the effectiveness and appropriateness of their own control activities. The legal significance of these audits should not be overstated.

Article 6 does not establish a general right for every operator to demand an individual audit of a particular inspector. Nevertheless, it demonstrates that the regulatory framework recognises the need for systematic evaluation of official control performance.

Proposed institutional indicators

A mature inspection quality-assurance system could examine:

- Consistency of findings between comparable inspections.
- Frequency and reasons for annulment of enforcement decisions.
- Quality of technical and legal reasoning.
- Timeliness of corrective action and administrative responses.

- Adequacy of inspection documentation.
- Repetition of previously corrected administrative defects.
- Effectiveness of internal complaint and review mechanisms.

These indicators are proposed as institutional performance measures. They are not presented as a mandatory list established by Regulation (EU) 2017/625. Their purpose would be to identify opportunities for improvement without equating every successful operator appeal with inspector misconduct.

Research framework: The Inspection Pattern Legality Assessment Model

The preceding analysis permits development of an additional component of the research framework. The proposed Inspection Pattern Legality Assessment Model (IPLAM) examines whether a sequence of official controls remains objectively connected to legitimate regulatory purposes. Its analytical structure contains eight dimensions.

Dimension	Assessment question
Frequency	Is the inspection frequency explainable by the relevant risk profile?
Selection	Were the operator-selection criteria legally relevant?
Consistency	Were comparable cases assessed through defensible criteria?
Purpose	Was each intervention directed towards a legitimate regulatory objective?
Technical foundation	Were findings supported by appropriate evidence?
Cumulative burden	Were avoidable operational disruptions minimised where possible?
Procedural fairness	Were applicable procedural rights respected?
Institutional review	Were concerns and identified defects appropriately examined?

The importance of cumulative assessment

The model's principal contribution is to distinguish the legality of individual interventions from the possible legal significance of their cumulative pattern. A sequence of inspections should not be considered abusive merely because it is frequent. Instead, the analysis should establish whether the frequency and intensity are reasonably connected to the applicable risk-based control

framework. Similarly, a difference in treatment between operators should not be considered discriminatory without establishing that the operators are materially comparable. The model therefore requires the investigator to consider alternative explanations before concluding that improper administrative conduct occurred.

A proposed evidentiary methodology

For research and litigation purposes, a longitudinal inspection record could include the date and duration of each visit, the competent authority, the stated inspection objective, the risk factors identified, the findings, the measures required and the outcome of any subsequent challenge. Where lawful access to appropriate comparative information exists, the record could also be examined against the inspection practices applied to comparable operators. The analysis should distinguish three evidentiary levels. Documented facts: Events and decisions established through reliable records. Reasonable inferences: Conclusions supported by identified facts but requiring assessment of alternative explanations.

Unverified allegations: Claims that have not yet been substantiated by sufficient evidence. This distinction is indispensable where allegations concern retaliation, deliberate harassment or institutional misuse of power.

Research implications and proposals for reform

The legal framework governing official food controls already contains important safeguards. The central research question is whether those safeguards are sufficiently operationalised in inspection practice. Several potential reforms merit examination.

First, competent authorities could improve the documentation of risk-based inspection selection criteria without disclosing information that would compromise control effectiveness.

Second, internal technical review mechanisms could help resolve significant disagreements concerning innovative industrial processes.

Third, inspection quality systems could systematically analyse annulled decisions and recurring inconsistencies.

Fourth, administrative authorities could develop clearer procedures for distinguishing mandatory corrective requirements from non-binding technical recommendations.

Fifth, supervisory systems could examine cumulative inspection burdens where several authorities exercise overlapping powers over the same establishment.

These proposals require evaluation of feasibility, cost, institutional competence and their potential effects upon food safety. They should not be assumed to improve regulatory performance without empirical assessment. A reform that increases administrative complexity without improving legal certainty or inspection quality may be counterproductive.

Chapter conclusions

This chapter establishes several important conclusions. Repeated inspections are not inherently unlawful. Their frequency must be examined in relation to the risk-based framework established by Regulation (EU) 2017/625. Differences in enforcement treatment do not necessarily establish discrimination. The constitutional principle of equality requires meaningful comparison between materially comparable situations.

Administrative harassment is a descriptive expression that must be translated into identifiable legal categories before legal consequences can be established. The principle of good administration provides a significant framework for assessing objectivity, consistency, fairness and institutional accountability. Legitimate expectations may be relevant where operators have relied upon previous administrative conduct, but they do not create a right to continue unlawful or unsafe practices.

Finally, a sequence of administrative acts may warrant cumulative examination where the overall pattern raises credible questions concerning purpose, proportionality or consistency.

The central doctrinal conclusion is:

The legality of official food control depends not only upon the existence of inspection powers, but also upon the objective, consistent and proportionate manner in which those powers are exercised over time.

CHAPTER 6

Administrative Silence, Inaction and Procedural Delay

Food control is time-sensitive: delay can damage perishable goods, interrupt supply and make subsequent remedies ineffective. The chapter examines the separate legal consequences of silence, inactivity, expiry and delayed decision-making.

The neglected counterpart of administrative excess: Failure to act

Discussions concerning excessive food inspection powers commonly focus upon intrusive visits, disproportionate corrective requirements, unsupported technical conclusions or unjustified restrictions on industrial activity. These matters are important, but they represent only one dimension of administrative legality. A second dimension concerns situations in which competent authorities fail to act when the legal system requires action. Administrative inactivity may arise in different forms. An authority may fail to resolve an application within the applicable statutory period.

It may fail to respond to a legally relevant request. It may delay the verification necessary to determine whether immobilised products can be released. It may fail to review an existing restrictive measure despite materially changed circumstances. It may omit a legally required enforcement action. Or it may fail to execute a final administrative decision whose implementation is mandatory.

These situations are not legally equivalent. The failure to respond to an informal technical consultation, for example, cannot automatically be equated with failure to decide a formally initiated administrative procedure. Similarly, a delay in laboratory analysis does not necessarily constitute unlawful inactivity merely because it causes commercial inconvenience. The legal assessment must first identify the obligation allegedly breached. That obligation may arise from a statutory time limit, a procedural duty to decide, an enforceable administrative act, a specific regulatory obligation or another legally binding source.

Without identifying such an obligation, the analysis risks confusing administrative inefficiency with legally actionable inaction. The distinction is central to this chapter.

The *duty to issue* an express administrative decision

Article 21 of Law 39/2015: The Administration cannot simply decline to decide

Article 21.1 of Law 39/2015 establishes the *general obligation to issue and notify an express decision in administrative proceedings*, irrespective of how they were initiated, subject to the exceptions provided by law. The obligation persists even where the proceedings terminate through circumstances such as prescription, withdrawal, expiry or disappearance of their subject matter. The provision is fundamental because it distinguishes the legal duty to decide from the substantive outcome of the decision. An authority may lawfully reject an application. It may determine that an operator has failed to satisfy the applicable requirements.

It may conclude that an authorisation cannot be granted. But where the statutory duty to decide applies, the Administration cannot substitute indefinite silence for a legally reasoned resolution. This is particularly significant in food-related proceedings where regulatory uncertainty may prevent an operator from investing, manufacturing, importing or commercialising products. The obligation to decide is not merely an aspiration of administrative efficiency. It is a binding procedural requirement.

The general *duration* of administrative proceedings

Article 21.2 provides that the maximum period for notifying an express decision is determined by the legislation governing the particular procedure. As a general rule, *that period may not exceed six months* unless a statutory provision or applicable European Union law establishes a longer period. Where the governing legislation does not establish a maximum period, Article 21.3 provides a default period of three months. The starting point differs according to how proceedings

are initiated. For proceedings initiated *ex officio*, the period ordinarily runs from the initiation agreement.

For proceedings initiated at the interested party's request, it runs from the date on which the application enters the electronic register of the administration or body competent to process it. These general rules must be examined alongside applicable special legislation. It would be legally incorrect to assume that every food safety registration, industrial authorisation or official control procedure must be resolved within three months. The specific procedure must first be identified.

Suspension and extension of time limits

Articles 22 and 23 of Law 39/2015 regulate *suspension* and *exceptional extension* of the maximum period for resolving and notifying decisions. These mechanisms are not interchangeable. **Suspension** may occur in legally defined circumstances, such as the need to obtain certain mandatory reports or require the interested party to remedy deficiencies. **Extension** is subject to its own exceptional statutory conditions and requires appropriate justification. The Administration cannot lawfully transform a general shortage of personnel or ordinary administrative inconvenience into an unlimited suspension of proceedings.

Equally, an operator cannot automatically allege unlawful delay where the statutory period has been validly suspended. The proper analysis requires reconstructing the procedural chronology. For this purpose, the relevant dates include initiation, documentary requests, notifications, suspension decisions, receipt of reports, extensions and final notification. A chronological reconstruction is often more legally useful than a general allegation that the Administration has taken too long.

Administrative silence: A legal fiction with differentiated consequences

The function of administrative silence

Administrative silence serves to attach legal consequences to the failure to issue a decision within the applicable period. It does not eliminate the Administration's general obligation to resolve proceedings. Nor does it operate identically across all procedures. Spanish administrative law distinguishes *positive* silence, *negative* silence and the consequences of *failure to resolve* proceedings initiated *ex officio*. These categories must be examined separately.

Positive silence in proceedings initiated by the interested party

Article 24.1 of Law 39/2015 establishes positive silence as the general rule for proceedings initiated at the interested party's request, subject to the statutory and European or international-law exceptions. Where positive silence lawfully applies, expiry of the relevant period may produce an administrative act granting the request. Article 24.2 gives positive silence the legal character of an act terminating the procedure. Article 24.3 further limits the Administration's subsequent express decision to confirmation of the act produced through positive silence.

However, these rules cannot be interpreted without regard to the applicable substantive legislation and the limits on acquiring rights contrary to essential legal requirements. Article 47.1.f of Law 39/2015 identifies a ground of nullity concerning express or presumed acts contrary to the legal system through which faculties or rights are acquired without satisfying essential requirements. Consequently, positive silence must not be treated as a mechanism for obtaining unrestricted permission to undertake activities that remain subject to binding food safety requirements.

Negative silence

Where negative silence applies, expiry of the period allows the interested party to pursue the relevant administrative or judicial remedies. Article 24.2 expressly distinguishes the effects of negative silence from those of positive silence. A

presumed rejection does not necessarily constitute a substantive administrative determination that the application is legally unfounded. Its principal function is to prevent administrative inaction from indefinitely blocking access to review. The Administration remains obliged to issue an express decision, subject to the applicable legal framework.

A critical warning concerning food authorisations

The legal effects of silence must be determined procedure by procedure. For example, an application concerning registration of a food establishment may be governed by rules different from those applicable to approval of establishments requiring prior authorisation under Regulation (EC) No 853/2004. Likewise, a request for an official certificate, a novel food authorisation or an administrative determination concerning a particular product may operate under different statutory arrangements. It is therefore unsafe to assert that failure to respond automatically permits an operator to begin manufacturing, importing or marketing a regulated product.

Administrative silence does not provide a universal substitute for compliance with food legislation. Before relying upon silence, the operator must identify the precise procedure, its governing legislation, the applicable period and the legally prescribed effects.

Proceedings initiated *ex officio*: Expiry, adverse measures and sanctions

Article 25 of Law 39/2015

Article 25 establishes the consequences of failure to resolve proceedings initiated *ex officio* within the applicable maximum period. In proceedings capable of producing adverse or burdensome effects, including sanctioning proceedings, expiry may result in *procedural “caducidad” (Expiration of procedure by the pass of time)*. This consequence must be distinguished from the negative silence applicable to certain proceedings initiated at the interested party's request. The distinction is fundamental. A sanctioning procedure cannot simply remain pending indefinitely without regard to the statutory time limits.

However, determining whether expiry has occurred requires examination of the applicable procedural regime, the relevant dates and any legally permitted suspension or interruption.

***Caducidad* is not equivalent to substantive exoneration**

The expiry of sanctioning proceedings by the pass/consumption of time, does not necessarily establish that the operator committed no infringement. It means that the particular proceedings have suffered the procedural consequence established by law. Article 95.3 of Law 39/2015 expressly provides that expiry does not, by itself, produce prescription of the actions available to the Administration or the individual. Where the infringement has not prescribed and the applicable legal requirements are satisfied, the Administration may in principle initiate new proceedings. Nevertheless, the expired procedure cannot simply be treated as if it had remained valid.

The distinction between *expiry* of proceedings and *prescription* of the underlying infringement is essential.

The importance of procedural classification

Not every administrative intervention constitutes sanctioning proceedings. An order requiring correction of a hygiene deficiency may be preventive or restorative rather than punitive. A decision suspending production to address a current food safety risk may have a protective purpose. The legal consequences of procedural delay therefore depend upon the nature of the proceedings. It would be incorrect to apply the rules governing sanctioning expiry indiscriminately to every official control measure.

Equally, the Administration cannot avoid applicable procedural guarantees merely by attaching a non-punitive label to a measure whose actual nature is sanctioning. The classification must be determined by its statutory foundation, purpose and legal effects.

Prolonged immobilisation of food products: The conflict between public health and procedural delay

Immobilisation as a protective measure

Food safety authorities may possess powers to restrict the movement or marketing of products where the applicable legal conditions are satisfied. Such measures may be necessary to prevent potentially unsafe food from reaching consumers. The legitimacy of immobilisation does not depend exclusively upon the existence of a final sanctioning decision. Preventive intervention may be justified before the Administration has completed its investigation. However, the continuation of a restrictive measure raises a distinct legal question.

A measure justified at its inception may become legally questionable if its factual basis disappears, its duration becomes unjustified or the authority fails to undertake necessary verification. The legality of adoption and the legality of continued maintenance must therefore be examined separately.

The changing factual basis of precautionary intervention

Consider a hypothetical food business whose consignment is immobilised following a laboratory finding suggesting possible contamination. Further analysis is required to establish whether the product complies with applicable criteria. The authority may initially possess a legitimate basis for preventing distribution. However, the legal position may change if subsequent evidence excludes the suspected hazard. Similarly, prolonged delay in obtaining results may require examination of whether the Administration has acted with appropriate diligence.

The authority is not necessarily obliged to release a product merely because analysis has taken longer than anticipated. If a credible and legally relevant risk remains unresolved, continued restriction may still be justified. Nevertheless, the authority must not treat the original suspicion as an indefinitely sufficient explanation without considering subsequent evidence and the continuing necessity of the measure.

***Perishability* as a legally relevant circumstance**

The *perishable nature of food products* creates particular and sometimes specific difficulties. An immobilisation lasting several days may destroy the commercial value of products with short shelf lives. The resulting economic consequences may be irreversible even where the measure is later withdrawn. This does not automatically make immobilisation unlawful. Public health protection may require restrictions despite substantial economic loss.

However, *perishability* may be relevant when evaluating the urgency of verification, the proportionality of the measure and the adequacy of administrative diligence. A risk-based control system should recognise that unnecessary delay can itself create material consequences. The legal analysis should therefore consider whether the authority could have obtained reliable evidence more promptly, whether less restrictive arrangements were legally and technically available and whether the measure was reviewed as relevant information emerged.

Judicial protection against prolonged restrictions

An operator affected by an enforceable administrative decision may seek judicial review under the applicable procedural conditions. Law 29/1998 provides for interim judicial measures intended to preserve the effectiveness of the eventual judgment. Articles 129 and 130 establish the general framework, while Article 135 addresses circumstances of particular urgency. The availability of interim relief does not mean that courts must suspend food safety restrictions whenever an operator demonstrates economic damage. The court must assess the statutory requirements and the competing interests, including the protection of public health.

Where the underlying measure addresses a credible serious risk, that public interest may weigh strongly against suspension. Nevertheless, the availability of judicial interim protection is essential where administrative restrictions threaten to produce irreversible consequences before final judgment.

Failure to execute favourable administrative decisions

A distinct form of administrative inactivity

A particularly serious problem arises where an administrative authority *fails to execute* a final decision that establishes a concrete obligation. This differs from *failure to resolve* an application. The Administration has already adopted a decision, but the corresponding legal obligation remains unfulfilled. For example, an authority may issue a final decision requiring a particular administrative action and subsequently fail to implement it. The legal analysis must establish whether the decision is final, whether it imposes a sufficiently concrete obligation and whether the relevant execution requirements have been satisfied.

Article 29.2 of Law 29/1998

Article 29.2 establishes a specific remedy where the Administration *fails to execute its final acts*. Affected persons may request execution. If execution does not occur within one month of the request, the statutory conditions permit contentious-administrative proceedings. This remedy must be distinguished from the broader action against *administrative inactivity* established in Article 29.1. The two provisions concern different legal situations and establish different preliminary requirements.

The distinction between administrative inactivity and disagreement with a decision

Article 29 cannot be used indiscriminately to replace ordinary appeals against administrative decisions. Its application depends upon the existence of the particular legally enforceable obligation contemplated by the provision. Where the dispute concerns whether an authority correctly rejected an application, the appropriate route may instead involve challenging the express or presumed decision. Where the Administration has a concrete obligation to act and fails to perform it, the action against inactivity may become relevant. Correct classification of the dispute is therefore essential.

Judicial review of administrative inactivity

Article 29.1 of Law 29/1998

Article 29.1 addresses cases where the Administration is obliged to perform a concrete service or action in favour of one or more determined persons under a general provision not requiring implementing acts, or under an administrative act, contract or agreement. The persons entitled to that performance may request compliance. If the Administration fails to perform the obligation or reach an agreement within three months, the statutory conditions permit contentious-administrative proceedings. The provision does not establish a general judicial remedy for every instance of administrative delay. Its application requires a sufficiently concrete obligation of the kind contemplated by law.

Judicial relief under Article 32

Article 32.1 permits a claimant challenging inactivity under Article 29 to seek a judicial order requiring the Administration to fulfil its obligations in the legally established terms. This is significant because the remedy is not confined to a declaration that the Administration has acted improperly. Where the legal conditions are satisfied, the court may order performance of the obligation. However, judicial intervention cannot ordinarily be used to compel a particular discretionary outcome where the applicable law leaves the competent authority a lawful margin of decision.

The court may require the Administration to comply with its legal duties without necessarily substituting its own technical or administrative judgment for every decision entrusted to the authority.

Administrative silence and inactivity are not interchangeable

The distinction between silence and inactivity is fundamental. Administrative silence concerns the legal consequences of failure to resolve proceedings within the prescribed period. The action against inactivity under Article 29 concerns failure to perform certain concrete obligations. An operator must identify the appropriate legal route. Using the wrong procedural mechanism may create admissibility problems and delay effective judicial protection.

This is particularly important in disputes involving authorisations, registrations, official certificates and product restrictions.

Public liability for *administrative delay*

The constitutional and statutory framework

Article 106.2 of the Spanish Constitution establishes the constitutional foundation for public liability arising from the functioning of public services, subject to the conditions established by law. Articles 32–34 of Law 40/2015 develop the general statutory framework. In broad terms, liability requires examination of legally compensable damage, its causal relationship with the functioning of the public service and the other statutory conditions. Administrative delay may form part of the factual basis of a liability claim. However, delay does not automatically establish an entitlement to compensation.

The need to establish legally compensable damage

A food business may experience financial loss because an authorisation was delayed, a consignment remained immobilised or an administrative decision was not executed. The existence of loss is relevant but insufficient by itself. The operator must establish the legally required elements of liability. These may include the actual occurrence of damage, its economic evaluation, the causal relationship with the administrative conduct and the absence of a legal duty to bear the particular injury. Where the loss concerns anticipated profits, additional evidentiary difficulties may arise.

A projected commercial opportunity is not necessarily equivalent to a sufficiently established loss of profit. The assessment must distinguish documented economic consequences from speculative expectations.

Lawful intervention and compensable damage

A further complexity concerns damage arising from lawful administrative action. The Spanish system of public liability is not restricted in principle to cases involving unlawful administrative conduct. Nevertheless, the fact that a

lawful measure causes economic damage does not automatically make that damage compensable. The applicable statutory conditions remain decisive. In food safety cases, the operator's duty to bear restrictions legitimately imposed to protect public health may be relevant.

The question is whether the particular injury satisfies the legal requirements for compensation.

Causation in prolonged immobilisation cases

Suppose a perishable consignment loses its commercial value during an official immobilisation. The operator alleges that the authority delayed laboratory verification. The causal analysis must distinguish several possibilities. The product may have been unsafe and therefore incapable of lawful commercialisation. The product may have been compliant but legitimately detained pending necessary verification.

The authority may have prolonged the restriction beyond what was justified by the available evidence. Or the operator's own incomplete documentation may have contributed to the delay. These situations have different legal implications. A credible liability analysis must reconstruct the factual chronology and determine which losses are legally attributable to the Administration.

Analytical framework: The Regulatory Inaction and Delay Assessment Framework

The analysis permits development of a further component of the proposed legal assessment methodology. The *Regulatory Inaction and Delay Assessment Framework (RIDAF)* is designed to distinguish legally justified administrative processing from potentially unlawful delay, actionable inactivity and restrictions whose continued maintenance requires reconsideration.

Dimension	Assessment question
Legal duty	What specific obligation requires the authority to act?
Procedural classification	Is the matter an application, ex officio proceeding, enforcement decision or concrete duty to perform?
Applicable deadline	What period governs the obligation, including valid suspensions?

Dimension	Assessment question
Administrative conduct	What action has the authority taken, and when?
Justification	Are delays attributable to legally relevant circumstances?
Continuing restrictions	Does the factual and legal basis for the restriction remain valid?
Economic consequences	What damage is documented and causally connected to the conduct?
Judicial remedy	Which procedural mechanism is legally available?
Public liability	Are the statutory conditions for compensation satisfied?

The importance of procedural classification

The model's central contribution is to prevent the indiscriminate use of the term administrative inactivity. Failure to resolve an application, failure to execute a final act and failure to perform a concrete statutory obligation may require different legal remedies. Likewise, the expiry of sanctioning proceedings must not be confused with positive administrative silence. The framework therefore requires identification of the precise legal duty before evaluating the consequences of its breach.

A longitudinal approach to restrictive measures

The model also proposes evaluating restrictive measures over time. An intervention may be justified when adopted but become questionable as relevant circumstances evolve. This temporal dimension is particularly important for food products whose commercial value depends upon limited shelf life. The assessment should therefore examine not only the original decision but also the authority's subsequent diligence and the continuing necessity of the restriction. This approach does not establish an automatic right to release goods after a particular period.

It provides a structured method for evaluating whether continued intervention remains legally justified.

Conclusions of this chapter

The analysis supports seven principal conclusions.

First, the duty to issue express administrative decisions is a binding legal obligation, subject to the statutory exceptions.

Second, administrative silence operates differently depending upon the nature of the procedure and the applicable legislation.

Third, positive silence cannot be treated as a universal authorisation to conduct activities subject to food safety requirements.

Fourth, expiry of sanctioning proceedings does not necessarily extinguish the Administration's substantive enforcement powers where the underlying infringement has not prescribed.

Fifth, the legality of an initial restrictive measure must be distinguished from the legality of its continued maintenance.

Sixth, administrative inactivity may be challenged through specific judicial mechanisms, but those mechanisms require identification of the legally enforceable duty involved.

Seventh, administrative delay may contribute to public liability where the statutory conditions are satisfied, but economic loss or procedural delay alone does not automatically establish compensation.

The resulting doctrinal proposition is:

Public health protection requires administrative authorities to intervene when legally necessary, but it also requires them to decide, investigate, review and execute their obligations within the legal framework governing their powers. Administrative legitimacy therefore encompasses both the limits of intervention and the duties of action.

CHAPTER 7

Scientific Uncertainty, Precaution and the Limits of Technical Discretion

Food safety decisions frequently must be taken before scientific uncertainty is eliminated. A legally defensible response nevertheless requires a reasoned distinction among hazard, probability, evidentiary insufficiency and actual non-compliance.

Introduction: The paradox of precautionary administration

Food safety authorities must often decide whether intervention is justified before scientific evidence becomes conclusive. This is not an exceptional weakness of regulatory science. It is an inherent feature of preventive public health administration. Scientific knowledge develops through observation, experimentation, critical evaluation and revision. Regulatory decisions, by contrast, may need to be taken immediately. A suspected contamination event cannot always await the completion of a comprehensive scientific investigation.

Nor can a competent authority necessarily permit continued marketing of a potentially dangerous food product simply because uncertainty remains concerning the precise mechanism of harm. The legal system must therefore accommodate protective action under uncertainty. However, the existence of uncertainty creates a corresponding risk of administrative overreach. If every unverified possibility of harm were sufficient to justify prohibition, virtually any industrial activity could be restricted indefinitely. Conversely, if authorities were required to demonstrate harm with absolute scientific certainty before acting, preventive food safety regulation would become ineffective.

The *precautionary principle* attempts to reconcile these competing concerns. Its legal function is not to eliminate uncertainty. It is to establish conditions under which uncertainty may justify protective intervention. The central question is therefore not whether a risk has been proven beyond all scientific doubt. It is whether the available evidence establishes a sufficiently

credible basis for intervention and whether the measure selected is legally justified.

Hazard, risk and uncertainty: Three concepts that must not be confused

Hazard identification

A hazard is a biological, chemical or physical agent in food or feed, or a condition of food or feed, with the potential to cause an adverse health effect. This definition is established in Article 3(14) of Regulation (EC) No 178/2002. Hazard identification concerns the existence of a potential source of harm. Examples include *pathogenic microorganisms*, *chemical contaminants*, *allergens* and *foreign bodies*. However, the existence of a hazard does not necessarily establish the magnitude of risk under particular exposure conditions.

Risk

Article 3(9) defines risk by reference to the probability of an adverse health effect and the severity of that effect, consequential to a hazard. This distinction is fundamental. A hazardous substance may present materially different risks depending upon its concentration, exposure, route of intake and relevant population. Likewise, the presence of a microorganism may require interpretation in light of the organism concerned, its concentration, the characteristics of the food and the applicable microbiological criteria. The distinction does not mean that every hazard requires quantitative exposure modelling before intervention.

Certain legally established requirements operate through categorical prohibitions or specified microbiological limits. Where a binding rule establishes a particular compliance criterion, the legal consequences may follow from its infringement without requiring the authority to construct an entirely new risk assessment in each individual case.

Scientific uncertainty

Scientific uncertainty concerns limitations in the available knowledge, data, methods or understanding relevant to an assessment. It may arise from insufficient observations, methodological limitations, biological variability, incomplete exposure data or disagreement among qualified experts. Not all uncertainty has the same legal significance. Uncertainty concerning a minor parameter in an otherwise well-characterised process differs from uncertainty concerning the existence of a potentially severe hazard. Similarly, uncertainty generated by an operator's failure to provide legally required validation data must be distinguished from uncertainty arising despite a comprehensive and scientifically credible evidence base.

The regulatory response should therefore be informed by the nature and consequences of the uncertainty.

The danger of treating unfamiliarity as evidence

A particularly important distinction concerns the difference between scientific uncertainty and institutional unfamiliarity. An inspector may be unfamiliar with a proprietary process, a novel preservation technology or a non-conventional control system. That unfamiliarity may justify requesting relevant information or seeking specialist advice. It does not, by itself, establish that the process is unsafe or unlawful. Conversely, an operator cannot establish safety merely by describing its technology as innovative or proprietary.

Where the law requires validation or proof of compliance, the operator must provide adequate evidence. Novelty is neither proof of danger nor proof of safety. This proposition is central to the lawful regulation of technological innovation.

The precautionary principle under Regulation (EC) No 178/2002

Article 6: Risk analysis as the foundation of food law

Article 6 of Regulation (EC) No 178/2002 establishes that food law must be based upon risk analysis, except where that approach is inappropriate to the

circumstances or nature of the measure. The provision distinguishes risk assessment from risk management. Risk assessment must be based upon available scientific evidence and conducted independently, objectively and transparently. Risk management must take account of the results of risk assessment, relevant opinions of the European Food Safety Authority, other legitimate factors and, where applicable, the precautionary principle. This distinction is legally important because scientific assessment and regulatory decision-making perform different functions.

A scientific assessment may identify a plausible hazard, characterise uncertainty or estimate exposure. The competent authority must then determine which measures are legally appropriate. Scientific evidence informs that decision, but the decision also involves the applicable legal framework, the chosen level of health protection and the proportionality of available interventions. It follows that the existence of a scientific opinion does not automatically determine the precise administrative measure to be adopted. Equally, the authority cannot disregard relevant scientific evidence without an adequate basis.

Article 6 therefore establishes a framework of scientifically informed regulatory decision-making rather than unrestricted technical discretion.

Article 7.1: The 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. Several elements are legally significant.

First, the provision presupposes an assessment of available information.

Second, that assessment must identify a possible harmful health effect.

Third, relevant scientific uncertainty must remain.

Fourth, the measure must be directed towards achieving the applicable high level of health protection.

Fifth, the intervention is provisional pending further scientific information permitting a more comprehensive risk assessment.

These requirements are cumulative elements of the statutory framework, although their application depends upon the circumstances. The principle does

not require conclusive proof that harm will occur. However, neither does it authorise intervention founded exclusively upon unsupported conjecture.

Article 7.2: Proportionality and review

Article 7.2 adds two further requirements. Measures adopted under Article 7.1 must be proportionate and no more restrictive of trade than required to achieve the high level of health protection chosen within the Union, taking account of technical and economic feasibility and other legitimate factors. They must also be reviewed within a reasonable period, depending upon the nature of the risk and the scientific information required to clarify uncertainty and permit a more comprehensive risk assessment. This second requirement deserves particular emphasis.

Precautionary measures are not intended to become permanent restrictions merely because the Administration fails to complete the scientific assessment that originally justified them. However, provisional does not necessarily mean short-lived. The reasonable duration of a measure depends upon the nature of the risk, the scientific questions involved and the time genuinely required to obtain relevant information. A scientifically complex investigation may legitimately require considerable time. The legal problem arises where the authority maintains restrictions without adequate reassessment of their continuing necessity.

The duty of review therefore creates a temporal dimension to precautionary legality.

European judicial doctrine: Precaution does not legitimise hypothetical risk

Pfizer Animal Health SA v Council, Case T-13/99

The judgment of the Court of First Instance of 11 September 2002 in *Pfizer Animal Health SA v Council* is a foundational decision concerning precautionary regulation under scientific uncertainty. The proceedings concerned the withdrawal of authorisation for an antimicrobial feed additive amid concerns regarding antimicrobial resistance. The Court recognised that

preventive measures may be justified before the alleged harmful effects have fully materialised. It also accepted that scientific uncertainty does not necessarily prevent regulatory action. However, the judgment expressly distinguished scientifically grounded precaution from measures based upon a purely hypothetical conception of risk.

Paragraphs 142–143 are especially relevant. The Court recognised that precautionary action need not be supported by conclusive proof of the reality and seriousness of the risk, while rejecting intervention founded merely upon conjecture lacking scientific verification. The decision is significant for food inspection because it establishes a conceptual boundary between incomplete evidence and the absence of a credible evidentiary foundation. These are not equivalent circumstances. A plausible risk supported by relevant scientific information may justify intervention despite unresolved questions.

An unsupported assertion that an unfamiliar industrial process might be dangerous does not acquire legal sufficiency merely through invocation of the precautionary principle.

Scientific disagreement and regulatory discretion

Pfizer also illustrates the distinction between scientific assessment and risk management. The competent institutions may possess discretion in managing scientifically complex risks. Nevertheless, that discretion remains legally reviewable. The judgment does not establish that a regulatory authority must adopt the scientific opinion most favourable to the operator. Nor does it establish that scientific uncertainty always requires the authority to refrain from intervention.

Rather, it recognises the legitimacy of protective decision-making where the evidentiary and legal conditions are satisfied. The scope of discretion must therefore be distinguished from immunity from review.

Alpharma Inc. v Council, Case T-70/99

The companion judgment in *Alpharma Inc. v Council*, also delivered on 11 September 2002, addressed precautionary intervention concerning another antimicrobial feed additive. Its relevance lies in the treatment of scientific

uncertainty, risk assessment and institutional discretion. Together, Pfizer and Alpharma demonstrate that precautionary regulation may be lawful even where the scientific evidence remains contested. However, these decisions should not be interpreted as granting individual inspectors unrestricted authority to impose measures independently of the applicable statutory framework. Both cases concerned the exercise of regulatory powers within a particular Union legal regime.

Their general principles must be applied with attention to the competence and legal powers of the authority concerned.

Commission v Denmark: The prohibition of disproportionate restrictions unsupported by individualised risk assessment

Case C-192/01, judgment of 23 September 2003

In *Commission v Denmark*, the Court of Justice examined a Danish administrative practice restricting the marketing of foods enriched with vitamins and minerals unless the enrichment corresponded to a nutritional need of the Danish population. The Court recognised that Member States may possess discretion concerning the level of public health protection where relevant scientific uncertainty exists and the matter is not fully harmonised. However, that discretion remains subject to proportionality and the requirements of free movement. The Court rejected the systematic restriction because the Danish approach did not adequately establish and assess the actual risks associated with the products concerned.

Paragraphs 45–56 are particularly important. The judgment emphasises the *need for an assessment grounded in relevant scientific evidence and rejects purely hypothetical considerations as a sufficient foundation for restrictive measures*.

The significance for food industry enforcement

The judgment supports an important proposition. An *authority cannot automatically justify a restrictive measure by invoking public health* without examining whether the specific intervention is supported by the

relevant evidence and legal framework. However, the decision must not be generalised beyond its legal context without qualification. The case concerned restrictions upon the marketing of products lawfully produced or marketed in other Member States, in circumstances involving the free movement of goods and the degree of harmonisation of the relevant rules. Its reasoning does not imply that every food inspection measure requires a new, product-specific quantitative risk assessment.

Where binding harmonised legislation establishes a prohibition or mandatory criterion, the competent authority may enforce that requirement according to its terms. The distinction is between enforcing an existing binding rule and introducing or maintaining an additional restriction whose justification depends upon the existence of a particular health risk.

The danger of systematic prohibitions

The decision is especially relevant where an administrative practice effectively excludes an entire category of products or technologies without differentiating among relevant circumstances. For example, an authority might adopt an informal policy treating every non-conventional preservation process as unacceptable, irrespective of its demonstrated performance. If the applicable legislation permits alternative compliant methods, such a policy may require scrutiny. The legal question would concern whether the authority is enforcing an existing requirement or introducing an additional restriction without adequate legal and scientific justification.

The answer depends upon the precise legislative framework governing the technology concerned.

***Monsanto Agricoltura Italia*: Specific evidence and the limits of speculative precaution**

Case C-236/01, judgment of 9 September 2003

In *Monsanto Agricoltura Italia SpA and Others*, the Court of Justice examined protective measures concerning novel foods produced from genetically modified maize under the then-applicable Regulation (EC) No

258/97. The case addressed the circumstances in which a Member State could restrict or suspend marketing on public health grounds. The Court accepted the possibility of protective measures under scientific uncertainty. However, paragraph 106 rejected an approach founded merely upon unverified suppositions. Paragraph 107 required a risk assessment as complete as possible in the circumstances.

Paragraph 113 further explained the need for specific evidence allowing a reasonable conclusion, based on reliable scientific information, that protective intervention was necessary. The judgment therefore identifies a critical boundary: uncertainty may prevent definitive conclusions, but it does not eliminate the requirement for a rational evidentiary foundation.

The significance of the applicable regulatory context

The judgment interpreted a particular safeguard clause in legislation subsequently replaced by the current novel foods framework. It should not be cited as though Regulation (EC) No 258/97 remained the governing regime for novel food authorisations. Its continuing significance lies in the general reasoning concerning precaution, scientific uncertainty and the evidentiary foundation of protective intervention. The exact legal conditions governing a contemporary food technology must be determined from the legislation presently applicable to that technology. This distinction is essential to avoid transforming useful jurisprudential principles into inaccurate statements about current statutory powers.

The distinction between scientific uncertainty and regulatory non-compliance

One of the most important practical issues concerns the relationship between the precautionary principle and established legal requirements. These are not interchangeable foundations for intervention. Where a binding rule prohibits a substance, establishes a maximum contaminant level or requires prior authorisation, the authority may enforce that requirement without independently proving that every particular use will cause harm. The legal basis is the applicable rule. For example, where a product is subject to an established

maximum residue limit, compliance is determined according to the applicable legal and analytical framework.

An operator cannot ordinarily avoid that requirement by presenting a general argument that the particular exposure is unlikely to cause harm. Conversely, where no binding rule prohibits a processing method and the legal framework permits different means of achieving a required safety outcome, the authority must examine the actual compliance question. It cannot necessarily impose a preferred technology solely because it is conventional.

Performance-based obligations and technological neutrality

Regulation (EC) No 852/2004 contains numerous requirements concerned with hygiene outcomes and the prevention of contamination. Its HACCP-based framework recognises the importance of identifying hazards and establishing effective controls. This can permit different technical solutions where the applicable legislation does not prescribe a single method. However, technological neutrality is not absolute. Certain processes, products and establishments are subject to specific authorisation, approval or operating requirements.

A novel technology may also alter the legal status of a food or ingredient. For example, whether a product requires authorisation under Regulation (EU) 2015/2283 on novel foods depends upon the statutory criteria, including relevant history of consumption and the categories established by that Regulation. Accordingly, demonstrating that a process produces apparently safe food does not automatically resolve every regulatory classification question. Safety, legality and authorisation status must be analysed separately.

The legal danger of technological prescription without statutory foundation

Suppose an inspector requires a food manufacturer to replace an existing preservation process with a particular conventional treatment. The operator maintains that its alternative process satisfies the applicable hygiene requirements and supplies validation evidence. The authority may legitimately challenge the adequacy of that evidence. It may require further verification

where authorised. It may take appropriate action if the process fails to meet binding requirements or presents a legally relevant risk.

However, if the legislation permits alternative compliant processes, *the inspector's personal preference for a conventional technology does not automatically establish a legal obligation to adopt it*. The authority should identify whether its demand rests upon a specific mandatory technical requirement, established non-compliance, justified precautionary intervention or another applicable legal power. The distinction determines the legal validity of the instruction.

Scientific validation, microbiological criteria and the burden of demonstrating compliance

The operator's responsibility

Article 17 of Regulation (EC) No 178/2002 places primary responsibility for ensuring compliance with food law upon food and feed business operators within the businesses under their control. This responsibility has important evidentiary consequences. An operator cannot simply require the authority to prove that every aspect of an unvalidated process is unsafe before implementing legally required controls. Where food legislation requires validation, monitoring or demonstration of compliance, the operator must satisfy those requirements. However, this regulatory responsibility should not be confused with the burden of proving an administrative offence in sanctioning proceedings.

The obligation to demonstrate compliance and the presumption of innocence in punitive proceedings concern different legal questions.

Regulation (EC) No 2073/2005

Regulation (EC) No 2073/2005 establishes microbiological criteria and related obligations for specified foods and processes. Its legal significance extends beyond laboratory testing. The Regulation distinguishes *food safety* criteria from *process hygiene* criteria. These categories have different functions and consequences. A food safety criterion concerns the acceptability of a product or batch placed on the market.

A process hygiene criterion concerns the acceptable functioning of the production process and indicates when corrective action is required. The distinction is critical because an unsatisfactory process hygiene result does not necessarily have the same legal meaning as failure to satisfy an applicable food safety criterion. The precise consequences must be determined under the relevant provisions and Annex I. Article 3 also requires operators to take measures ensuring compliance with applicable microbiological criteria, including relevant shelf-life considerations.

As necessary, operators must conduct studies in accordance with Annex II, particularly for certain ready-to-eat foods capable of supporting the growth of *Listeria monocytogenes*.

Why a single laboratory result may be insufficient

A laboratory result can provide highly significant evidence. Nevertheless, its interpretation may depend upon sampling design, analytical method, sample integrity, measurement uncertainty, batch definition and the particular criterion being applied. A positive finding for a pathogen may justify immediate intervention under applicable legislation. However, the scope of that intervention must still be determined according to the relevant legal and factual circumstances. Similarly, a satisfactory result from one sample does not necessarily establish that an entire process is safe.

The European Commission expressly recognises that microbiological testing alone cannot guarantee food safety. European Commission This is particularly important where the operator relies upon an alternative preservation or decontamination technology. A defensible validation programme may require evidence concerning repeatability, worst-case operating conditions, relevant microbial hazards, process variability and the maintenance of effective controls. The specific studies required depend upon the process, product and applicable legislation.

Validation is not necessarily a demand to disclose every trade secret

A regulator may need access to confidential process information to verify compliance. However, the scope of disclosure should remain connected to the lawful purpose of the control. Where compliance can be adequately established through validated performance data, the necessity of demanding additional proprietary information should be assessed. Conversely, where undisclosed process parameters are indispensable to evaluating safety or compliance, confidentiality cannot automatically prevent lawful access. The appropriate legal response involves justified regulatory access and effective protection of confidential information.

Suspected non-compliance and established non-compliance: The significance of Articles 137 and 138

Regulation (EU) 2017/625 distinguishes between *suspected* and *established* non-compliance. Article 137.2 requires competent authorities to investigate suspected non-compliance in order to confirm or eliminate the suspicion. Where necessary, Article 137.3 contemplates intensified official controls and official detention of goods. Article 138 governs action following established non-compliance, including measures necessary to determine its origin and extent and to ensure that the operator remedies it and prevents recurrence. This distinction has substantial implications for scientifically uncertain situations.

A suspicion may justify investigation and appropriate protective action. However, suspicion should not automatically be treated as an established infringement. Nor should the absence of a final determination necessarily prevent proportionate interim protection where the legal conditions are satisfied. The regulatory response must therefore distinguish the evidentiary threshold supporting investigation from the requirements governing established non-compliance and sanctions. The authority should also avoid using precautionary measures as a substitute for completing the investigation required to determine whether the suspected infringement exists.

Precaution permits justified protection during uncertainty but certainly, it does not convert uncertainty into proof of infringement.

Judicial review of scientifically complex administrative decisions

The limits of judicial substitution

Courts reviewing food safety decisions may encounter complex scientific disagreements. The competent authority may possess specialised expertise and a legally recognised margin of assessment. However, scientific complexity does not eliminate judicial review. The reviewing court may examine whether the authority possessed competence, applied the correct legal framework, relied upon relevant evidence, respected procedural requirements and exercised its powers proportionately. Where the applicable legal regime confers broad scientific or regulatory discretion, judicial review must account for that discretion.

The court's role is not necessarily to replace the authority's technical assessment with its own preferred scientific hypothesis. Nevertheless, it may examine whether the administrative reasoning is sufficiently supported and whether material errors affect the legality of the decision.

The importance of independent expert evidence

Expert evidence may be indispensable where the dispute concerns industrial processes, microbiological interpretation or the validity of a risk assessment. A technically credible challenge should identify the specific scientific proposition being contested. General statements that the operator's technology is safe or that the inspector lacks expertise may have limited evidentiary value. A more rigorous challenge may demonstrate that the authority relied upon an inapplicable standard, misunderstood a validation study, used an unsuitable analytical method or failed to consider material evidence.

Similarly, an authority may legitimately reject an operator's expert conclusions where the evidence is incomplete, methodologically defective or inconsistent with binding regulatory requirements. The legal issue is the *quality and relevance of the evidence*, not the institutional identity of the expert alone.

Analytical framework: The Scientific Precaution Legality Framework

The present research proposes the **Scientific Precaution Legality Framework (SPLF)** as a structured method for assessing administrative restrictions justified by scientific uncertainty.

Dimension	Principal question
Legal authority	Does the competent authority possess the power exercised?
Regulatory context	Is the measure enforcing a binding requirement or addressing an uncertain risk?
Hazard identification	What potential adverse health effect has been identified?
Scientific foundation	What reliable evidence supports the concern?
Uncertainty	Which material scientific questions remain unresolved?
Risk assessment	Has the available evidence been evaluated appropriately?
Necessity	Why is intervention required before uncertainty is resolved?
Proportionality	Is the selected measure justified relative to the risk?
Review	When and how will the measure be reassessed?
Procedural protection	Can the operator challenge the evidence and legal consequences?

The framework is an original research proposal, not a statutory test or established judicial doctrine. Its principal contribution lies in requiring explicit separation of three regulatory situations: **Situation A** - Established legal non-compliance A binding requirement has been infringed. Enforcement must proceed under the applicable statutory conditions. **Situation B** - Scientifically plausible but unresolved risk

Protective intervention may be justified where the conditions of the applicable precautionary framework are satisfied. **Situation C** - Unsupported speculation or mere unfamiliarity Further inquiry may be appropriate, but unfamiliarity alone does not establish non-compliance or provide an unrestricted basis for prohibition. This distinction is particularly relevant to the regulation of innovative food technologies. It also provides a means of evaluating whether an administrative decision has improperly transformed scientific uncertainty into an assertion of established unlawfulness.

Chapter conclusions

The precautionary principle occupies a central position in European food law. It permits protective intervention where credible scientific concerns remain unresolved. However, its operation is legally bounded. Article 7 of Regulation (EC) No 178/2002 requires an assessment of available information, identification of possible harmful effects, relevant scientific uncertainty, proportionality and subsequent review. European jurisprudence confirms that authorities need not await conclusive proof of harm before acting.

At the same time, protective measures cannot properly rest upon purely hypothetical risks unsupported by relevant scientific evidence. The distinction between enforcing an established legal requirement and managing an uncertain risk is essential. So too is the distinction between the operator's responsibility to demonstrate regulatory compliance and the Administration's obligations when establishing an infringement or imposing sanctions. Innovative technologies may legitimately require rigorous validation. Nevertheless, regulatory unfamiliarity cannot be treated as an independent source of prohibition.

The central conclusion is therefore:

The precautionary principle authorises legally justified action in the presence of scientific uncertainty. However, it does not authorise the substitution of unsupported administrative assumptions for scientific assessment, statutory authority or proportionality. Verified primary legal and judicial references are exposed here:

- Regulation (EC) No 178/2002 — Articles 3, 6, 7 and 17.
- Regulation (EU) 2017/625 — Articles 137 and 138.
- Regulation (EC) No 853/2004 — Food hygiene and HACCP-based obligations.
- Regulation (EC) No 2073/2005 — Microbiological criteria.
- Regulation (EU) 2015/2283 — Novel foods.
- Pfizer Animal Health SA v Council, T-13/99, 11 September 2002 — Particularly paragraphs 142–143.

- *Alpharma Inc. v Council*, T-70/99, 11 September 2002.
- *Commission v Denmark*, C-192/01, 23 September 2003 — Particularly paragraphs 45–56.
- *Monsanto Agricoltura Italia*, C-236/01, 9 September 2003 — Particularly paragraphs 106–113.

CHAPTER 8

Legal Norms, Regulatory Guidance and Voluntary Standards

Technical recommendations and private certifications are important to industrial compliance, but their practical authority must not be confused with legal enforceability. The governing distinction is between binding norms and evidentiary or interpretive guidance.

Introduction: The invisible expansion of regulatory obligations

The contemporary food industry operates within a regulatory environment that extends far beyond legislation formally published in official journals. Food manufacturers must interpret European Union regulations, national legislation, autonomous-community requirements, official guidance, scientific opinions, technical standards and private certification criteria. These instruments frequently overlap. A single food manufacturing process may be assessed through binding hygiene legislation, HACCP principles, microbiological criteria, ISO-based management systems and customer-specific certification requirements. The resulting complexity creates a significant legal risk.

Requirements originating in different normative systems may be treated as though they possessed identical legal force. An inspector may refer to a technical recommendation as mandatory. A private certification requirement may be presented as a condition imposed by food legislation. An administrative interpretation may be applied as though it were an independently binding rule. Alternatively, an operator may incorrectly assume that a legal requirement becomes optional merely because it is also addressed in voluntary guidance.

The problem is therefore not the existence of technical standards. Such standards may substantially improve food safety, process consistency and regulatory compliance. The problem concerns their legal classification. The decisive question is not whether a requirement is technically reasonable, but whether the competent authority possesses a lawful basis for imposing it as a public-law obligation. This distinction is central to the rule of law.

It also protects the effectiveness of official controls by requiring inspectors to identify the correct legal foundation for their decisions.

The hierarchy of norms and the principle of legality

Constitutional foundations

Article 9.3 of the (CE) Spanish Constitution guarantees, among other principles, the hierarchy of legal norms, publicity of norms, legal certainty and the prohibition of arbitrariness. Article 103.1 requires public administration to serve the general interest objectively and act in accordance with the law and the legal system. These provisions establish the constitutional foundation for distinguishing legally binding obligations from recommendations, technical preferences and informal administrative criteria. The principle of legality does not prevent authorities from interpreting open-textured statutory requirements. Food hygiene legislation frequently uses concepts such as adequate, appropriate, effective or sufficient.

Such terms necessarily require technical assessment. However, interpretation must remain connected to the legal requirement being applied. An authority cannot simply create an entirely new substantive obligation through an inspection report where the applicable legal framework does not authorise it.

Article 128 of Law 39/2015

Article 128 of Law 39/2015 addresses the exercise of regulatory powers and the hierarchy of regulatory provisions. Its provisions reflect the principle that administrative regulations must operate within the limits established by superior legal norms. An individual inspection instruction does not possess the same normative status as a validly adopted regulation. Similarly, an internal administrative document cannot ordinarily alter a binding European Union regulation or impose obligations contrary to superior legislation. The relevant legal inquiry concerns the source of the obligation and the authority competent to establish it.

Publicity and legal certainty

The publication of binding provisions is an important component of legal certainty. An operator must be able to identify the legal rules governing its activity. This does not mean that every technical criterion used by an inspector must appear word for word in legislation. Where the law establishes a performance-based requirement, the Administration may need to evaluate technical evidence. Nevertheless, an unpublished administrative preference cannot automatically acquire the status of a generally binding legal rule.

The distinction becomes particularly important where different inspectors apply inconsistent criteria to equivalent industrial processes.

European Union regulations, directives and non-binding instruments

Article 288 TFEU/TFUE

Article 288 of the **Treaty on the Functioning of the European Union** distinguishes among regulations, directives, decisions, recommendations and opinions. Regulations are binding in their entirety and directly applicable in Member States. Directives bind Member States as to the result to be achieved, while leaving national authorities the choice of form and methods, subject to the applicable legal framework. Decisions are binding according to their terms. Recommendations and opinions have no binding force.

These distinctions are essential when identifying the source of food safety obligations. However, a non-binding instrument may still possess interpretative or evidentiary significance. The absence of binding force does not make a document legally irrelevant.

The legal significance of recommendations

The Court of Justice addressed the interpretative significance of recommendations in *Grimaldi*, *Case C-322/88*, judgment of 13 December 1989. The Court recognised that national courts must take recommendations into consideration, particularly where they assist in interpreting national measures adopted to implement them or supplement binding Union provisions. This does

not transform recommendations into regulations. Rather, it demonstrates that non-binding instruments may influence legal interpretation without independently creating the same obligations as binding legislation. The distinction is especially relevant to European Commission guidance on food hygiene and HACCP implementation.

Such guidance may assist inspectors and operators in understanding regulatory requirements. Its legal status must nevertheless be distinguished from that of the underlying regulations.

Administrative instructions and internal criteria under Spanish law

Article 6 of Law 40/2015

Article 6 of Law 40/2015 permits administrative bodies to direct the activities of hierarchically dependent bodies through instructions and service orders. This power is important for the organisation and consistency of official inspection services. Competent authorities may issue internal criteria concerning inspection priorities, documentation practices, allocation of responsibilities or the interpretation of regulatory requirements. However, *internal instructions and service orders must be distinguished from generally binding regulations*. An instruction addressed to inspectors does not, merely because it originates from their administrative hierarchy, create a new legal obligation for food business operators.

Article 6 also provides that instructions and service orders are to be published in the relevant official journal when a specific provision so establishes or when publication is considered appropriate because of their addressees or potential effects. The provision further states that failure to comply with such instructions or orders does not, by itself, affect the validity of administrative acts, without prejudice to any disciplinary responsibility that may arise. This latter rule concerns the internal effects of non-compliance with administrative instructions. It should not be confused with a general authorisation to disregard binding legislation. See Law 40/2015, Article 6.

The distinction between uniform interpretation and regulatory innovation

Administrative instructions may promote consistency. For example, an autonomous-community food safety authority may establish internal procedures for assessing sanitation records or documenting microbiological sampling. Such instructions can support **equal treatment** and **effective supervision**. The legal problem arises when an **internal criterion** is used **to impose a substantive obligation not established by the applicable legal framework**. Suppose an internal circular directs inspectors to require a particular commercial sanitation technology in every establishment of a specified category.

If binding legislation genuinely requires that technology, the circular may merely restate or operationalise the legal obligation. If legislation permits alternative compliant technologies, the circular may instead raise questions concerning competence, proportionality and the improper restriction of lawful technical choices. The issue cannot be resolved by examining the circular alone. It requires analysis of the underlying legal requirements and the scope of the authority's powers.

Unpublished criteria and legal certainty

An operator may encounter a requirement justified through reference to an internal administrative criterion that has not been made publicly available. The absence of publication does not necessarily render every application of the criterion unlawful. Some internal operational instructions may legitimately remain unpublished, particularly where disclosure would compromise inspection effectiveness. However, a purported generally applicable substantive obligation cannot ordinarily derive its binding force solely from an unpublished internal preference.

Where a restrictive administrative decision relies upon such a criterion, the authority must still identify the legally applicable obligation and provide the reasoning required by the relevant procedural framework.

The legal status of European Commission guidance

Guidance as an interpretative instrument

The European Commission frequently publishes guidance documents explaining the operation of food legislation. These materials may address HACCP implementation, good hygiene practices, microbiological controls, traceability and other regulatory matters. Their practical importance is considerable. Guidance can help operators understand complex requirements and support consistent enforcement across Member States. However, guidance does not automatically possess the same binding force as the regulation it explains.

Its legal status must be determined by reference to the nature of the instrument, its legal foundation and any relevant provisions incorporating its content.

Commission Notice 2022/C 355/01

A particularly relevant example is the Commission Notice of 16 September 2022 concerning food safety management systems, good hygiene practices and procedures based on HACCP principles. The Notice expressly addresses flexibility in implementing these systems and the relationship between food safety management systems and international standards. Its structure includes specific treatment of HACCP-based procedures, prerequisite programmes, good hygiene practices, flexibility and guides developed under Regulation (EC) No 852/2004.

The Notice is highly relevant to inspection disputes concerning whether a particular documentary arrangement, management structure or technical control must be implemented in one prescribed manner. Nevertheless, the Notice is guidance. It must be read alongside the binding requirements of Regulation (EC) No 852/2004 and other applicable legislation. An operator cannot disregard a mandatory requirement merely because guidance recognises flexibility. Conversely, an inspector should not treat every recommended practice in the Notice as an independently mandatory statutory obligation.

The meaning of flexibility

Flexibility does not mean absence of control. The legal framework permits adaptation of HACCP-based procedures to the nature and size of the food business, within the limits established by legislation. The objective is to achieve effective food safety management through arrangements appropriate to the relevant hazards and activities. This distinction is important because **excessive documentary requirements may impose substantial costs without necessarily improving food safety**. However, a simplified system must still adequately control the relevant hazards.

A company cannot rely upon flexibility to justify the absence of controls required by its actual operations. The legal assessment therefore concerns whether the chosen system satisfies the applicable obligations, not whether it reproduces a particular template.

HACCP: Binding principles, flexible implementation and the danger of documentary formalism

Article 5 of Regulation (EC) No 853/2004

Article 5 requires food business operators to establish, implement and maintain permanent procedures based on HACCP principles. The provision identifies the familiar elements of hazard analysis, critical control points, critical limits, monitoring, corrective actions, verification and appropriate documentation. These principles are legally significant. However, their implementation must be understood in relation to the nature and scale of the food business. Article 5.2(g) expressly refers to documents and records commensurate with the nature and size of the food business.

This wording is important. It does not eliminate documentation requirements. It requires the documentary system to be proportionate to the business concerned.

HACCP is not necessarily equivalent to a particular commercial management system

An operator may demonstrate HACCP compliance through a management system incorporating recognised international standards. However, the legal obligation to implement HACCP-based procedures is not, by itself, an obligation to obtain ISO 22000, IFS Food or BRCGS certification. These certification schemes may contain requirements that exceed the minimum established by food legislation. They may also organise compliance evidence in ways that facilitate inspection. Their use can therefore be advantageous without being universally compulsory.

The distinction between substantive control and documentary presentation

Suppose an inspector requires a manufacturer to reproduce its HACCP documentation in a specific format. The operator already possesses an effective, documented system that addresses the relevant hazards and satisfies applicable legal requirements. The inspector's preferred format may improve readability or consistency. However, unless the format is legally required or necessary to demonstrate compliance, the authority should distinguish a recommendation concerning presentation from an enforceable obligation. Conversely, an operator cannot defend materially incomplete HACCP documentation merely by asserting that its internal format is proprietary.

The decisive question is whether the required information exists, is adequate and can be verified. The law requires effective hazard control and legally appropriate documentation; it does not automatically require adoption of every administrative or commercial documentation template.

Guides to good hygiene practice under Regulation (EC) No 852/2004

Articles 7–9

Regulation (EC) No 852/2004 expressly recognises the development and dissemination of guides to good hygiene practice and HACCP implementation. Article 7 in other hand, encourages the development of national and Community guides. Article 8 establishes requirements concerning national guides. Article 9 addresses Community guides. These instruments can assist operators in implementing hygiene requirements and provide useful references for official controls.

However, Article 7 characterises the use of such guides by food business operators as voluntary. That qualification is fundamental. A guide developed through the procedures contemplated by the Regulation does not automatically become a universally binding regulatory code.

Voluntary use does not imply evidentiary irrelevance

A recognised guide may provide evidence of established industry practice. It may help an inspector evaluate whether an operator's control system is technically adequate. It may also assist a court in understanding the state of relevant professional knowledge. Nevertheless, the operator may be able to demonstrate compliance through alternative measures. The acceptability of those measures depends upon the applicable legal requirements and the evidence supporting their effectiveness.

An authority cannot necessarily reject an alternative merely because it differs from the guide. Equally, the operator cannot assume that any alternative is acceptable without demonstrating compliance.

A hypothetical sanitation dispute

Consider a manufacturer using a validated sanitation process that differs from a method described in a recognised industry guide. The inspector demands replacement of the process solely because the guide recommends another method. The legal assessment should determine whether the applicable

legislation mandates the recommended method. If it does, the operator must comply with the binding requirement. If the guide merely provides one recognised means of achieving a required hygiene outcome, the authority should examine whether the alternative process achieves the legally required level of control.

The inspector may challenge the adequacy of validation or monitoring. However, the mere existence of a different recommendation does not necessarily establish infringement.

Codex Alimentarius: International technical authority without automatic domestic binding force

The role of Codex

The Codex Alimentarius Commission develops international food standards, guidelines and codes of practice under the joint FAO/WHO programme. Its work is particularly significant for food hygiene, contaminants, additives, labelling and international trade. Codex standards may influence national legislation, international regulatory convergence and the interpretation of technical requirements. Their scientific and institutional significance is substantial. Nevertheless, Codex instruments do not automatically become directly enforceable Spanish legislation merely because they have been adopted internationally.

Their domestic legal effects depend upon the applicable Union and national legal framework.

The WTO dimension

Codex standards have particular relevance under the **World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures**. The SPS Agreement recognises relevant international standards and provides a framework governing the justification of sanitary and phytosanitary measures. However, the WTO significance of Codex does not mean that every Codex recommendation is directly enforceable against an individual Spanish food manufacturer. The relationship between international

standards, Union legislation and domestic enforcement requires separate legal analysis.

Codex as scientific evidence

Codex may provide a valuable technical reference. For example, its **General Principles of Food Hygiene** may assist in interpreting established hygiene concepts. However, an inspector citing Codex should distinguish whether the cited provision is incorporated into binding law, informs interpretation or represents a recommended practice. These categories produce different legal consequences.

ISO standards: Voluntary technical systems and their regulatory significance

ISO 9001 and ISO 22000

ISO 9001 establishes requirements for quality management systems. ISO 22000 establishes requirements for food safety management systems. Both can support industrial organisation, process consistency and systematic control. However, certification to these standards is not generally a universal statutory prerequisite for operating a food manufacturing establishment in Spain. Specific contractual arrangements, procurement conditions or sectoral rules may nevertheless make particular certification requirements relevant.

It is therefore necessary to distinguish general food law from specific legal or contractual obligations.

The difference between certification and regulatory compliance

A company may possess ISO 22000 certification and nevertheless infringe food legislation. Certification does not confer immunity from official controls. Similarly, a company may comply with applicable food legislation without holding ISO 22000 certification. The relationship between certification and compliance is evidentiary and organisational, not one of automatic equivalence. Certification may provide useful evidence concerning the existence of management procedures.

However, competent authorities remain responsible for assessing compliance with binding law.

The significance of accredited certification

Certification performed by an appropriately accredited body may provide additional confidence concerning the competence and independence of the assessment process. Nevertheless, accreditation and certification do not automatically transform private standards into legislation. Their legal effects depend upon the relevant regulatory or contractual framework. An inspector may take certification evidence into account. The inspector should not treat certification as conclusive proof of compliance or its absence as conclusive proof of infringement.

IFS Food and BRCGS: Private certification schemes versus public regulatory obligations

Their commercial importance

IFS Food and BRCGS Food Safety are widely used private certification schemes within food supply chains. Retailers, manufacturers and distributors may require suppliers to hold certification under one or more such schemes. These requirements may be commercially decisive. However, *commercial necessity must be distinguished from statutory obligation*. A customer may lawfully require certification as a condition of doing business, subject to the applicable contractual and competition-law framework.

That does not mean that every food manufacturer is legally required by public food law to obtain the same certification.

Private requirements may exceed legal minimums

Private certification schemes may include requirements concerning supplier approval, food safety culture, site security, documentation, traceability testing, internal audits and management review. Some requirements overlap with binding food legislation. Others may exceed statutory minimums. The overlap

creates potential confusion. An inspector may encounter a company that has voluntarily committed itself to more demanding controls.

Failure to satisfy one of those additional controls may constitute a certification non-conformity. It does not automatically establish a statutory food law infringement. The authority must identify the binding legal requirement allegedly breached.

The operator's own commitments may still matter

A further complication arises where a company incorporates private-standard requirements into its own HACCP or food safety management procedures. Suppose the operator's validated control system specifies a particular monitoring frequency. The company subsequently fails to perform that monitoring. The legal significance cannot be determined solely by asking whether the frequency originated in a private standard. If the monitoring is a necessary component of the operator's system for satisfying binding food safety obligations, its omission may be relevant to regulatory compliance.

However, the Administration must still establish the connection between the omitted control and the applicable legal requirement. A voluntary commitment does not automatically become legislation, but its incorporation into a legally required control system may make its performance relevant to assessing compliance. This distinction deserves particular attention in future judicial and doctrinal research.

AESAN guidance (National), autonomous-community (Regional) criteria and territorial consistency

Spain's food control system operates within a multilevel institutional structure. **European Union** law establishes substantial parts of the applicable framework. **National** legislation develops additional obligations and institutional arrangements. **Autonomous communities** exercise important competences concerning official controls. **Local** authorities may also possess relevant functions within their legally defined spheres of competence.

This structure can generate differences in inspection practice. Such differences are not necessarily unlawful. Authorities may encounter different risk profiles,

industrial conditions or factual circumstances. However, inconsistent interpretations of harmonised Union requirements can create legal uncertainty and potentially affect the internal market.

The role of AESAN materials

AESAN publishes technical information, interpretative materials and guidance relevant to food safety. These resources may assist operators and inspectors. However, their legal status must be determined individually. An AESAN document may reproduce binding legislation, explain regulatory requirements, provide scientific information or recommend a particular practice. Those functions must not be conflated.

The mere appearance of a requirement in an agency guidance document does not automatically establish that it possesses independent compulsory force.

Autonomous-community guidance

Regional authorities may adopt interpretative or operational criteria to organise official controls. Such criteria may promote consistency within their territorial jurisdiction. Nevertheless, the exercise of regional competence must respect the applicable hierarchy of norms and the limits established by Union and national legislation. A regional inspection service cannot ordinarily modify directly applicable Union requirements through an internal document. Nor can a regional technical preference automatically displace lawful alternatives permitted by the governing legislation.

The problem of territorial fragmentation

A particularly difficult situation arises where an industrial process is accepted by one competent authority but challenged by another. The existence of different assessments does not necessarily establish illegality. The factual circumstances may differ. The authorities may possess different evidence. The legal status of the activity may depend upon specific territorial requirements.

Nevertheless, unexplained divergence in the interpretation of harmonised obligations can undermine legal certainty. A legally robust response requires

identification of the precise provisions applied and the reasons for the divergent conclusions.

When a voluntary standard becomes legally relevant

The distinction between binding and voluntary instruments is not absolute in every practical situation. A technical standard may acquire legal relevance through several mechanisms.

Mechanism	Legal effect
Express legislative incorporation	The incorporated requirements may become binding within the scope of the incorporating rule
Contractual adoption	The standard may create obligations between contracting parties
Regulatory evidentiary use	The standard may help assess compliance with binding requirements
Operator's own control system	Its provisions may become relevant to evaluating the adequacy or performance of legally required controls
Public procurement or specific authorisation conditions	Particular standards may be relevant where lawfully required under the governing framework
Voluntary certification	Compliance may establish private certification status without automatically proving statutory compliance

Legislative incorporation

Where legislation expressly incorporates a technical standard, the legal position changes. The incorporated provisions may acquire binding force within the scope and conditions established by the legislation. However, incorporation must be examined carefully. A legislative reference to a standard does not always mean that every provision of the standard becomes compulsory. The wording and legal function of the reference are decisive.

Contractual incorporation

A supply agreement may require IFS Food certification. Failure to maintain certification may then constitute a contractual breach. However, contractual breach and statutory food law infringement remain distinct. The same conduct

may sometimes have consequences under both systems, but each requires its own legal foundation.

Evidentiary relevance

Technical standards may provide evidence of recognised professional practice. They may assist experts in assessing the adequacy of a process. However, evidentiary relevance does not necessarily establish compulsory force. The Administration must still identify the applicable legal obligation and demonstrate why the evidence supports a finding of non-compliance.

The prohibition of regulatory substitution through inspection practice

The preceding analysis reveals a recurring legal risk. An inspector may begin with a legitimate objective, i.e.: verifying compliance with food safety legislation. The inspector then identifies a recognised technical standard. Finally, the inspector treats that standard as though it were the legal obligation itself.

This process may be described as *regulatory substitution*. The concept is proposed here as an analytical category rather than an established statutory doctrine. Regulatory substitution occurs where a non-binding technical instrument is treated as an independently enforceable legal requirement without adequate legal foundation. The problem is not the use of standards. It is the failure to distinguish the legal obligation from the technical means proposed for satisfying it.

Example: Mandatory certification without statutory foundation

An inspector informs a manufacturer that it must obtain IFS Food certification to continue operating. If no applicable legal provision requires such certification, the instruction may exceed the authority's powers. The operator may still be obliged to maintain an effective food safety management system. The authority may legitimately identify deficiencies in that system. However, the legal obligation to control hazards is not automatically equivalent to an obligation to purchase a particular private certification service.

Example: Mandatory use of a specified sanitation technology

An inspector requires a manufacturer to use a particular sanitation method because it appears in an industry guide. The operator uses a different validated method. If legislation permits alternative methods and the operator demonstrates compliance, the authority must establish why the alternative is inadequate before treating it as non-compliant. Conversely, where the alternative process fails to achieve required hygiene outcomes, the authority may lawfully demand corrective action.

Example: Excessive documentary demands

An inspector requires extensive documentation exceeding what is necessary to verify the operator's legally required controls. The operator may legitimately question the relevance and proportionality of the request. However, it cannot simply refuse every additional request because the documents are not expressly listed in legislation. Regulation (EU) 2017/625 grants authorities broad access to relevant information. The proper legal inquiry concerns the request's statutory foundation, relevance, scope and applicable safeguards.

Analytical framework: The Normative Status and Enforceability Test

The present research proposes the **Normative Status and Enforceability Test (NSET)** as a structured method for assessing inspection requirements derived from technical instruments.

Stage	Question
1. Source identification	Which instrument contains the disputed requirement?
2. Legal classification	Is it legislation, administrative guidance, a technical standard or a private contractual rule?
3. Incorporation	Has a binding legal provision incorporated the requirement?
4. Competence	Does the authority possess power to impose the measure?
5. Regulatory connection	Which statutory obligation is the measure intended to enforce?
6. Technical justification	Is the demanded practice necessary to establish or achieve compliance?

Stage	Question
7. Alternatives	Does the legal framework permit other technically adequate solutions?
8. Proportionality	Is the requirement justified in relation to its regulatory objective?
9. Procedural safeguards	Has the authority provided the legally required reasoning and review mechanisms?

This test is an original analytical proposal, not an established statutory or judicial test. Its central contribution is to separate three questions that are frequently confused: Is the technical practice advisable? Is the technical practice evidence of compliance? Is the technical practice legally compulsory?

The answers may differ. A practice may be scientifically advisable without being mandatory. It may provide strong evidence of compliance without being the only lawful method. It may also be legally compulsory where the applicable legislation expressly requires it. The legal analysis must identify which situation applies.

Chapter conclusions

The contemporary food industry is governed by a complex interaction of binding legislation, administrative guidance, technical standards and private certification systems. These instruments cannot be treated as legally interchangeable. European Union regulations and validly adopted national provisions establish binding obligations within their respective spheres. Guidance documents may assist interpretation and promote consistent enforcement. Codex Alimentarius standards may provide internationally recognised technical references.

ISO, IFS Food and BRCS schemes may support management systems, commercial assurance and contractual compliance. However, none of these functions automatically converts every voluntary technical requirement into an independently enforceable public-law obligation. The analysis also demonstrates that non-binding instruments are not legally irrelevant. They may acquire significance through legislative incorporation, contractual commitments, evidentiary use or their relationship to the operator's own control systems. The

critical task is therefore to identify the precise legal mechanism through which a requirement becomes relevant.

The central doctrinal conclusion is:

Official food controls may legitimately use technical standards to interpret, verify and substantiate compliance, but administrative inspection cannot silently replace binding law with voluntary guidance, private certification requirements or the personal preferences of individual inspectors.

CHAPTER 9

Official Sampling, Laboratory Evidence and Second Expert Opinions

Official samples and laboratory reports often determine the practical outcome of enforcement. Their legal value depends on the sampling regime, technical integrity of the analytical process and the operator's effective opportunity to obtain a second expert opinion.

Introduction: When scientific evidence becomes administrative power

Official laboratory evidence occupies a distinctive position in food safety enforcement. An analytical certificate may appear to provide a simple answer to determine if a substance is present or absent, a concentration exceeds a specified limit or a microbiological criterion has been satisfied or breached. Yet the transition from analytical result to legal conclusion is rarely as straightforward as it appears. A laboratory result is generated through a sequence of technical operations. The sample must be **collected, identified, preserved, transported, prepared and analysed**. The selected method must be suitable for the analyte, matrix and regulatory purpose. The result must then be interpreted under the applicable legal criterion.

Each stage may influence the reliability or legal significance of the final conclusion. This is particularly important where the administrative consequences are severe. An analytical finding may trigger restrictions affecting an entire production batch, multiple consignments or a complete manufacturing facility. The resulting intervention may be justified by public health concerns. Nevertheless, its legality depends upon the quality of the evidence and the statutory conditions governing the measure. Two opposite errors must therefore be avoided.

The first is treating an official laboratory certificate as legally unchallengeable merely because it originates from a public or officially designated laboratory. The second is assuming that every methodological imperfection automatically

destroys the evidentiary value of the analysis. Neither position is defensible. The appropriate approach requires an integrated examination of scientific reliability, procedural legality, evidentiary sufficiency and proportionality.

A decisive legislative development: Spain's Royal Decree 562/2025

A fundamental qualification is necessary before examining Spanish counter-analysis procedures. **Spain's traditional three-sample, three-analysis model is no longer the general framework governing official controls of food products.** Royal Decree 562/2025 of 1 July entered into force in July 2025 and established a national framework complementing Regulation (EU) 2017/625. This analysis uses its consolidated text as amended on 30 September 2026. The decree expressly repealed the application of Articles 15 and 16 of Royal Decree 1945/1983 to official controls of food products, while preserving certain provisions for other matters within the scope specified by its derogation clause.

This change is not a minor procedural amendment. It alters the legal analysis of official sampling, the availability of additional sample material and the procedures through which operators may challenge analytical findings.

The former three-sample system

Under the historical framework established by Royal Decree 1945/1983, the ordinary procedure contemplated three homogeneous sample units. The traditional sequence comprised an initial analysis, a contradictory analysis and, where the results differed, a third analysis intended to resolve the disagreement. The system was designed to preserve opportunities for technical contradiction. However, it also presented practical difficulties, particularly where samples were perishable, unstable or unsuitable for repeated analysis.

The legislative rationale for reform

The preamble to Royal Decree 562/2025 expressly identifies technological, scientific and administrative developments that had rendered elements of the previous framework obsolete. It also recognises that the traditional sequence of three analyses could unnecessarily prolong procedures. The reform seeks to align

Spanish procedures with the structure of Regulation (EU) 2017/625, including the right to a second expert opinion and the conditions governing further analysis. This change requires a conceptual adjustment. The operator's procedural protection must no longer be described simply as an unconditional entitlement to the historical three-analysis sequence.

Instead, the applicable rights must be identified under the current European and Spanish framework.

Temporal and sectoral application

The date on which the relevant control activity commenced may be significant. Royal Decree 562/2025 contains a transitional provision addressing activities initiated before its entry into force. Its scope also extends beyond food products to other areas of the agri-food chain. Consequently, a legal assessment must identify the controlled product, the nature of the official activity, its date and any applicable special or transitional rules. The use of the repealed food-control sampling provisions of Royal Decree 1945/1983 as though they remained generally applicable in October 2026 would produce a materially inaccurate legal analysis.

Article 34 of Regulation (EU) 2017/625: Sampling and analytical methods

Article 34 establishes the **European framework governing methods used for sampling, laboratory analyses, tests and diagnoses during official controls**. Where Union rules establish applicable methods, those methods govern the relevant activities. In the absence of such rules, the Regulation provides a hierarchy of methods, including internationally recognised methods and scientifically validated alternatives under the conditions established by the provision. This framework recognises that laboratory methodology is not a matter of unrestricted administrative preference. The analytical method must be appropriate to the regulatory purpose.

Method suitability

The suitability of a method depends upon the particular analytical question. A method developed for detecting a contaminant in a liquid matrix may not be appropriate for determining the same substance in a complex fatty or protein-rich food without suitable validation. Similarly, a method designed for qualitative detection cannot automatically be used to establish a precise quantitative concentration. The method's intended purpose, validated scope and relevant performance characteristics must therefore be considered.

The distinction between analytical validity and regulatory interpretation

A laboratory may correctly identify the presence of a substance. However, the legal consequence may depend upon whether that substance is prohibited, subject to a maximum limit, permitted under particular conditions or naturally present in the food. The analytical result and the legal classification are distinct stages. An inspector cannot establish an infringement merely by demonstrating the presence of a substance without identifying the applicable legal criterion. Conversely, where a binding rule prohibits the substance under the relevant circumstances, a properly established finding may be sufficient to support enforcement.

The decisive issue is the relationship between the analytical finding and the legal requirement.

Article 35: The right to a second expert opinion

A right recognised by Union law

Article 35.1 of Regulation (EU) 2017/625 requires competent authorities to ensure that operators whose animals or goods are subject to official sampling, analysis, testing or diagnosis have the right to a second expert opinion at their own expense. The minimum Union entitlement includes the possibility of requesting a documentary review by another recognised and appropriately qualified expert. This distinction is fundamental. A second expert opinion is not necessarily synonymous with a new laboratory analysis. The documentary review

may examine the sampling procedure, analytical method, laboratory records and interpretation of results without physically reanalysing the original material.

Article 35.2 addresses the collection of sufficient sample material where relevant, appropriate and technically feasible. Article 35.3 allows Member States to provide additional review arrangements where a dispute remains. Article 35.4 expressly preserves the authority's duty to take prompt protective action where necessary.

Spain's implementation: Article 29 of Royal Decree 562/2025

For the relevant official food-control procedures, Article 29 provides an important practical guarantee. Following notification of an unfavourable analytical result, **the operator may request a second expert opinion within ten working days**, calculated from the day following notification. The request may concern documentary review, a second analysis where sufficient sample material is available, or both. Where documentary review is requested, the operator must identify an appropriately qualified expert and provide the documentation demonstrating compliance with the applicable qualification requirements.

Where a second analysis is requested, the operator identifies an eligible official laboratory, subject to the conditions established by the decree. The detailed rules also address deficiencies in the application and opportunities for correction. These procedural requirements are important because a company may lose valuable opportunities to challenge evidence if it does not act within the prescribed period.

Documentary review under Article 30

Article 30 identifies categories of documentation that may be examined in the second expert opinion. These include sampling records, the legal basis for sampling, the sampling method, transport and conservation documentation, laboratory accreditation, official designation where relevant, analytical methods and the laboratory report. The provision is especially important because it permits technical scrutiny of the evidence-generation process. A dispute need not be limited to whether the numerical result is correct. It may concern whether

the sample was representative, whether the laboratory method was suitable or whether storage conditions could have affected the result.

Article 30 also establishes a period of ten working days from access to the relevant information for submission of the expert's optional, non-binding report. The decree attaches consequences to failure to submit that report within the prescribed period. Accordingly, the documentary-review procedure should be treated as a formal evidentiary opportunity requiring careful preparation.

Second analysis under Article 31

Where the relevant conditions are satisfied, Article 31 governs **the second analysis, test or diagnosis**. The competent authority assesses the suitability of the laboratory selected by the operator, including potential conflicts of interest. The laboratory must satisfy the applicable official-laboratory requirements. This is not an unrestricted entitlement to send the sample to any commercial laboratory chosen by the operator. The procedural guarantees operate within the system of official laboratory designation and suitability established by law.

Article 31(4) of Royal Decree 562/2025 expressly provides that, where a second analysis, test or diagnosis is performed under that provision, its result prevails over the first. This statutory effect must not be confused with the evidentiary position of an independently commissioned private test, which is assessed under the rules applicable to that evidence. The authority must consequently identify whether the contradictory procedure fulfils the conditions of Article 31 before determining the legal effect of competing results.

The right to additional sample material and its technical limits

Article 25 of Royal Decree 562/2025

Article 25 establishes the general sampling procedure for the relevant official controls. The provision requires written recording of sampling and appropriate measures to preserve the legal, scientific and technical validity of samples. It also addresses the collection of sufficient material to permit a second analysis. At or before sampling, the operator must be informed of the procedure and the possibility of requesting sufficient material for a second analysis. Where such

material is not collected, the circumstances and justification must be documented as prescribed.

These requirements provide an important safeguard against disputes arising only after the original sample has been consumed or destroyed.

Why a second sample is not always scientifically appropriate

The right to additional sample material is qualified by relevance, appropriateness and technical feasibility. Royal Decree 562/2025 expressly recognises circumstances in which obtaining sufficient material for a second analysis may not be appropriate. Examples include certain microbiological investigations, unstable or volatile analytes, and circumstances in which additional material would not adequately represent the original sampling event. These exceptions must not be treated as a blanket exemption for all microbiological sampling. The relevant technical and legal conditions must be examined.

For example, microorganisms may be distributed heterogeneously within a food lot. Two physically separate samples may therefore produce different results without either laboratory having committed an analytical error. In such circumstances, repeating the analysis on another portion of the product may not reproduce the evidentiary conditions of the original finding. The scientific problem concerns representativeness, not merely laboratory accuracy.

The evidentiary consequences of an unavailable second sample

Where additional sample material is unavailable for legally and technically justified reasons, the operator may still have access to documentary review and other applicable evidentiary mechanisms. The absence of a second sample does not automatically invalidate the initial analysis. However, the authority's compliance with applicable notification, sampling and documentation requirements may remain relevant. The legal assessment must distinguish justified technical impossibility from a failure to respect a safeguard that could reasonably have been implemented.

Representativeness: The difference between a sample and a production lot

A sample is not the same thing as the population from which it is taken. This elementary scientific distinction has major legal consequences. Official sampling frequently seeks to establish whether a production lot complies with a particular regulatory criterion. However, the relationship between the analytical result and the lot depends upon the applicable sampling plan.

Homogeneous and heterogeneous distributions

Some chemical constituents may be distributed relatively uniformly within a properly mixed product. Other hazards may be highly heterogeneous. Mycotoxins, for example, can occur in localised concentrations within agricultural commodities. Microbiological contamination may also be unevenly distributed. A sample may therefore fail to detect a hazard that is present elsewhere in the lot.

Conversely, a positive result may reveal contamination whose distribution throughout the lot remains uncertain. These possibilities do not mean that a positive finding lacks legal significance. The applicable legislation may prescribe sampling plans and decision rules that determine how results are interpreted. The legal question is whether the sampling was performed and interpreted according to the relevant framework.

The importance of lot definition

A dispute may arise concerning the boundaries of the affected lot. An authority may identify a positive sample and impose restrictions upon a wider quantity of goods. The operator may argue that the sampled material belonged to a distinct production batch. The legal analysis must examine traceability, manufacturing records, common raw materials, processing conditions, potential cross-contamination and the applicable regulatory definition of the lot. A narrow lot definition cannot be accepted merely because it reduces commercial losses.

Equally, an unnecessarily broad lot definition should not be adopted without examining the factual basis for extending the finding. The scope of restrictive measures must remain connected to the relevant risk and legal powers.

Chain of custody and sample integrity

The evidentiary function of traceability

A laboratory result can only support a particular enforcement conclusion if the analysed material can be reliably connected to the sampled product. The chain of custody therefore performs a critical evidentiary function. Relevant documentation may concern sample identity, collection time, responsible personnel, packaging, sealing, transport, receipt and storage. The specific records required depend upon the applicable legal and technical framework.

Preservation conditions

Food samples may change after collection. Microorganisms may multiply or decline depending upon temperature and other conditions. Certain chemical substances may degrade, evaporate or react. Consequently, preservation conditions may materially affect analytical validity. Where the disputed analyte is unstable, transport and storage records may be particularly important.

An operator challenging the result should identify the specific mechanism by which the alleged defect could have affected the finding. A general assertion that the sample was transported incorrectly may be insufficient.

Procedural defects and evidentiary consequences

A missing signature, incomplete transport record or discrepancy in sample identification may require examination. However, not every documentary defect has the same significance. A minor clerical error may be capable of explanation through other reliable records. A fundamental failure to establish sample identity may undermine the connection between the laboratory result and the product alleged to be non-compliant. The legal consequences depend upon the nature of the defect, the applicable rules and its effect upon the operator's rights or the reliability of the evidence.

Official laboratories, accreditation and technical competence

Article 37 of Regulation (EU) 2017/625

Article 37 establishes the framework for designating official laboratories. The provision requires, subject to specified exceptions, appropriate expertise, equipment, infrastructure, qualified personnel, impartiality and accreditation in accordance with EN ISO/IEC 17025. The scope of accreditation is particularly important. Accreditation should not be treated as a general declaration that every possible analysis performed by the laboratory is covered. The relevant question is whether the laboratory possesses the required competence and authorisation for the particular analysis, method and matrix, taking account of the permitted accreditation arrangements and statutory exceptions.

Accreditation does not establish infallibility

Accreditation provides important assurance concerning **technical competence** and **quality systems**. It does not establish that every individual analytical result is beyond challenge. Laboratory error, sample deterioration, method limitations and interpretative disagreement remain possible. Conversely, an operator cannot invalidate a result merely by asserting that accredited laboratories sometimes make mistakes. A credible challenge requires specific evidence relevant to the analysis concerned.

Official designation and private laboratory reports

An operator may commission analysis from a private laboratory. Such a report may provide valuable technical evidence. However, it does not automatically possess the same procedural status as an analysis performed by an officially designated laboratory under the applicable control framework. The legal significance of the private report depends upon its methodology, competence, sample comparability and procedural context. A private analysis may challenge an official result without necessarily replacing it.

The authority must assess the evidence according to the applicable legal standards.

Measurement uncertainty and regulatory decision-making

The scientific meaning of measurement uncertainty

Quantitative laboratory results are estimates obtained through measurement procedures. They are accompanied by uncertainty arising from relevant sources of variability. Measurement uncertainty does not mean that the laboratory lacks competence or that its result is unreliable. It describes the dispersion of values that can reasonably be attributed to the measurand under the applicable measurement model. The legal treatment of uncertainty depends upon the specific regulatory regime.

Some legislation prescribes how measurement uncertainty must be taken into account when determining non-compliance. Other regimes employ different decision rules. It would therefore be incorrect to assume that a universal uncertainty adjustment applies to every food safety analysis.

A hypothetical chemical contaminant result

Suppose a laboratory reports a concentration slightly above a regulatory maximum. The legal significance of that finding may depend upon the applicable analytical rules, recovery correction, expanded measurement uncertainty and decision criteria. If the relevant legislation requires a particular approach to uncertainty, the authority must apply it. A result numerically exceeding a maximum does not necessarily establish a legally actionable exceedance without consideration of the applicable decision rule. Conversely, measurement uncertainty cannot be invoked to disregard an exceedance where the governing legislation provides a different legally binding interpretation.

Microbiological results require different treatment

The interpretation of microbiological findings may involve sampling plans, acceptance numbers, detection limits and specified criteria. The statistical and biological issues differ from those associated with quantitative chemical measurements. A universal approach based upon subtracting analytical uncertainty would therefore be scientifically and legally inappropriate. The

correct interpretation must be determined from the applicable microbiological criterion and analytical framework.

Conflicting analytical results: Why disagreement does not automatically invalidate the first finding

Suppose an official laboratory detects a contaminant. A subsequent analysis commissioned by the operator does not detect it. The operator argues that the original result must therefore be erroneous. That conclusion does not necessarily follow. The samples may not be equivalent.

The analyte may be unevenly distributed. The methods may possess different detection limits. The samples may have undergone different storage conditions. Alternatively, one analysis may contain a genuine methodological or analytical error. The proper scientific inquiry must distinguish these possibilities.

The relevance of analytical comparability

A meaningful comparison should examine whether the laboratories analysed equivalent material using suitable methods and comparable analytical criteria. Different results obtained from different sample portions may not establish direct contradiction. This is especially important in microbiological testing and heterogeneous agricultural commodities.

The need for reasoned administrative assessment

Where the operator submits credible contradictory evidence, the authority should evaluate its relevance. The Administration is not necessarily required to accept the result most favourable to the operator. However, it should not dismiss relevant expert evidence merely because the original analysis was official. The appropriate conclusion depends upon the totality of the evidence.

Protective measures and punitive sanctions

The evidentiary threshold relevant to preventive intervention may differ from that required to establish an administrative offence. A credible analytical finding may justify proportionate protective action while uncertainty remains. However,

a punitive sanction must satisfy the applicable requirements concerning proof of the infringement and responsibility. This distinction prevents two errors: delaying necessary public health protection until every scientific disagreement is resolved, and treating an unresolved suspicion as conclusive proof of punishable conduct.

The probative value of official analytical evidence in Spanish administrative proceedings

Article 77.5 of Law 39/2015

Article 77.5 provides that documents formalised by officials recognised as authorities, recording facts personally established by them and satisfying the relevant legal requirements, have evidentiary value without prejudice to evidence submitted by interested parties. *The provision does not establish that every technical or legal conclusion appearing in an official document is irrebuttably correct.* A distinction must be maintained between facts directly observed by an official, laboratory findings and legal conclusions drawn from those findings. Each category may require different evidentiary assessment.

The presumption of innocence

Article 24.2 of the Spanish Constitution establishes the presumption of innocence. Its guarantees are relevant to administrative sanctioning proceedings, subject to the established constitutional framework governing their application. A sanction cannot properly rest upon an unsupported presumption that the operator committed an infringement. The Administration must possess sufficient legally obtained evidence establishing the relevant elements. Official analytical evidence may satisfy that requirement where reliable and properly interpreted.

However, its official origin does not eliminate the possibility of contradiction.

Procedural defects and annulment

The existence of a sampling defect does not automatically produce nullity of every subsequent administrative decision. Spanish administrative law

distinguishes defects capable of producing nullity, voidability and irregularities without invalidating effect. The legal consequences must be assessed under Articles 47 and 48 of Law 39/2015 and the relevant sectoral provisions. Where a defect materially undermines the evidence or causes legally relevant procedural prejudice, its consequences may be substantial. Where the defect is minor and does not affect the relevant guarantees or result, automatic invalidation may be unwarranted.

The decisive question is the legal and evidentiary significance of the particular defect.

Practical industrial case studies

Case A: A microbiological positive result in a ready-to-eat product. Official laboratory detects a relevant pathogen in a sampled ready-to-eat food. The manufacturer requests a second analysis of a different sample unit. The authority maintains a temporary restriction while investigating the finding. The legal analysis must consider the applicable microbiological criterion, the sampling plan, the relevance of the additional sample, the possibility of heterogeneous contamination and the statutory conditions governing the restriction.

A negative second result does not necessarily negate the first finding. However, the manufacturer retains applicable rights to expert review and evidentiary contradiction.

Case B: A chemical contaminant near the legal maximum. The official analysis identifies a concentration marginally exceeding a maximum level. The operator disputes the result because the laboratory report does not clearly explain the treatment of measurement uncertainty.

The legal assessment should identify the specific contaminant legislation and applicable analytical decision rule. If the governing regime requires consideration of uncertainty in a particular manner, the authority must apply that requirement. The issue is not whether uncertainty exists, but how the law requires it to be treated.

Case C: A proprietary preservation process. The official inspector takes samples from a manufacturer using an innovative preservation system.

The official laboratory reports a microbiological finding that the operator considers inconsistent with its internal validation data. The operator submits process records, independent laboratory results and an expert assessment. The authority must examine the evidence relevant to compliance. However, satisfactory historical validation does not automatically disprove contamination in a particular production lot. Equally, one adverse analytical finding does not necessarily establish that the entire underlying technology is inherently unlawful.

The legal assessment must distinguish product-specific non-compliance from process-wide conclusions.

Case D: A disputed chain of custody. A sample is collected from a food manufacturer and transported to an official laboratory. The operator later discovers inconsistencies between the sample identification recorded during inspection and the laboratory receipt. The authority maintains that the discrepancy is clerical.

The legal question is whether the available evidence reliably establishes that the analysed material corresponds to the sampled product. If the discrepancy can be resolved through independent contemporaneous records, it may not undermine the result. If sample identity cannot be established reliably, the evidentiary foundation of the enforcement decision may be seriously affected.

Analytical framework: The Official Analytical Evidence Integrity Framework

The present research proposes the **Official Analytical Evidence Integrity Framework (OAEIF)** as a structured methodology for evaluating the legality and reliability of analytical evidence used in food safety enforcement.

Dimension	Assessment question
Legal authority	Was sampling conducted by an authorised body under an applicable legal power?
Sampling design	Was the sample collected according to the relevant legal and scientific requirements?
Representativeness	What conclusions can legitimately be drawn about the product or lot?
Identification	Can the analysed material be reliably linked to the sampled goods?

Dimension	Assessment question
Preservation	Were handling, storage and transport conditions appropriate?
Laboratory competence	Was the laboratory appropriately designated and competent for the analysis?
Method suitability	Was the method appropriate for the analyte, matrix and regulatory purpose?
Result interpretation	Were the relevant decision rules and uncertainty requirements correctly applied?
Expert contradiction	Were the operator's applicable rights to expert review respected?
Legal sufficiency	Does the evidence support the specific administrative consequence imposed?

The framework is an original analytical proposal, not an established statutory or judicial test. Its principal contribution is the separation of three questions. **Scientific validity:** Was the analytical result produced through a reliable process? **Evidentiary sufficiency:** What factual conclusions can reasonably be established from that result? **Administrative legality:** Do those conclusions justify the measure or sanction adopted under the applicable law?

These questions are related but not identical. A technically reliable result may be insufficient to establish that an entire establishment is non-compliant. A valid finding of product non-compliance may justify corrective measures without proving that the operator committed a punishable infringement. Conversely, a serious sampling defect may undermine the evidentiary foundation necessary to support an adverse decision.

Chapter conclusions

Official sampling and laboratory analysis are indispensable to effective food safety enforcement. However, their scientific character does not exempt them from legal scrutiny. The current Spanish framework must be understood in light of Royal Decree 562/2025, which replaced the traditional three-analysis approach for official food controls with procedures aligned with Regulation (EU) 2017/625. Article 35 establishes the right to a second expert opinion, while Spanish legislation specifies the procedures through which documentary review and, where applicable, further analysis may be requested. The right to a second

expert opinion is not an unconditional entitlement to repeat every laboratory determination.

Technical feasibility, sample representativeness and the nature of the hazard may justify limitations. Nevertheless, the authority must respect the procedural guarantees applicable to the particular case. Laboratory accreditation and official designation provide important assurances of competence, but they do not make analytical findings irrebuttable. Sampling design, chain of custody, method suitability, measurement uncertainty and the interpretation of results may all affect evidentiary reliability. Finally, the legal sufficiency of an analytical finding must be assessed in relation to the specific administrative consequence imposed.

The central doctrinal conclusion is:

The evidentiary authority of official laboratory findings derives from legally compliant sampling, scientifically reliable analysis and reasoned interpretation—not merely from the institutional status of the laboratory issuing the result.

CHAPTER 10

Administrative Sanctions and the Guarantees of Punitive Proceedings

An infringement finding and a punitive sanction raise related but distinct questions. The latter entails additional guarantees concerning legal classification, attribution, culpability, proof and proportionality.

Introduction: From regulatory supervision to punitive authority

The legal system governing food safety distinguishes several forms of administrative intervention. An inspector may verify hygiene conditions, examine records, collect samples, require corrective action or initiate procedures intended to prevent unsafe food from reaching consumers. Such interventions may be burdensome without necessarily constituting punishment.

A sanction, by contrast, responds to conduct legally classified as an administrative infringement and seeks to impose a punitive consequence. The distinction matters because sanctioning powers engage guarantees that do not necessarily operate identically in ordinary inspection or preventive proceedings.

The Administration may possess sufficient evidence to justify temporarily immobilising a potentially unsafe consignment without yet possessing sufficient evidence to sanction a particular operator. Similarly, a company may be required to correct a deficient hygiene procedure even where the circumstances do not support a punitive finding of culpability.

The legal analysis must therefore distinguish:

- The existence of an objective regulatory deficiency.
- The legality of preventive or corrective intervention.
- The existence of a statutorily defined administrative infringement.
- The attribution of culpable responsibility.
- The procedural and evidentiary sufficiency of the sanctioning decision.

These questions may overlap, but they are not interchangeable. The danger of treating them as equivalent is that a regulatory finding can become an administrative penalty without the independent analysis required by sanctioning law.

The constitutional foundations of administrative sanctioning power

Article 25.1 of the Spanish Constitution (CE)

Article 25.1 CE establishes the constitutional principle that *nobody may be convicted or sanctioned for actions or omissions which, when committed, did not constitute an offence, misdemeanour or administrative infringement under the legislation then in force*. The provision establishes a fundamental limitation upon punitive public authority. An inspector cannot create an infringement merely by declaring that a particular practice is unacceptable. Nor can an administrative authority impose a penalty solely because the operator has failed to follow a recommendation lacking the necessary legal foundation. The conduct must fall within a legally established infringement.

Article 24.2 and the presumption of innocence

The constitutional guarantees associated with Article 24.2 CE, including the **presumption of innocence**, are applicable to administrative sanctioning proceedings in accordance with the established constitutional doctrine. This does not mean that every procedural rule governing criminal trials applies identically to administrative proceedings. It means that punitive administrative decisions must respect the essential guarantees appropriate to their nature. A sanction cannot rest merely upon the assumption that an operator must have committed an infringement because an inspector suspects it. The Administration must establish the facts constituting the infringement through legally sufficient evidence.

Article 9.3 CE and the prohibition of arbitrariness

The constitutional prohibition of arbitrariness also constrains sanctioning decisions. Administrative penalties must be grounded in law, relevant facts and reasoned application of the applicable provisions. The principle does not permit courts to replace every administrative judgment with their own preferred assessment. It does, however, prevent punitive power from being exercised without an adequate legal and factual foundation.

The principle of legality and the statutory classification of infringements

Articles 25 and 27 of Law 40/2015

Article 25 establishes that administrative sanctioning powers must be expressly recognised by legislation and exercised by the competent authority through the legally established procedure. Article 27 develops the *principle of tipicidad*: only infringements established by law may constitute administrative offences, without prejudice to the legally permitted role of implementing regulations. Regulations may introduce specifications or gradations within statutory infringements and sanctions, but they cannot create new infringements or sanctions or alter the nature or limits of those established by law. Article 27.4 also prohibits the analogous application of provisions defining infringements and sanctions.

This prohibition has significant consequences for food inspection. An inspector cannot classify conduct as punishable merely because it resembles conduct expressly prohibited by legislation. The alleged conduct must satisfy the elements of an applicable infringement.

Broad statutory descriptions and their limits

Food safety legislation frequently employs broad formulations. Article 50.1.e of Law 17/2011, for example, addresses infringements of requirements, conditions, obligations or prohibitions established by specific food hygiene or food safety legislation. Such provisions may operate by reference to substantive regulatory requirements. However, their breadth does not eliminate the need to

identify the underlying obligation. A legally adequate sanctioning decision should explain which specific requirement was breached and how the established facts satisfy the statutory description.

A reference merely to poor hygiene practice, inadequate management or non-compliance with recommendations may be insufficient unless connected to an enforceable legal obligation.

The distinction between technical findings and legal classification

Suppose an inspector concludes that a manufacturer's sanitation system is insufficiently robust. That conclusion may justify further investigation. It may also support corrective action if the evidence establishes a breach of applicable hygiene requirements. However, a sanction requires identification of the relevant statutory infringement and evidence supporting its constituent elements. A technical assessment is therefore not equivalent to legal classification.

The Administration must undertake both exercises.

The Spanish sectoral framework: Law 17/2011

Articles 47–53

Chapter IX of Law 17/2011 establishes an important national framework for sanctioning infringements concerning food safety and nutrition. Article 47 sets out general principles, including coordination with criminal proceedings and the prohibition of duplicate punishment for the same facts and protected interests. Article 50 identifies categories of infringements. Article 51 governs classification into minor, serious and very serious infringements. Article 52 establishes penalties and certain consequences concerning closure.

Article 53 regulates additional sanctions. The precise application of these provisions must be considered alongside other applicable legislation, including sector-specific rules and autonomous-community legislation.

Principal categories of food safety infringement

Article 50.1 includes conduct concerning documentary and registration obligations, fraudulent or deficient labelling, obstruction of official controls, inadequate legally required self-control systems, breaches of hygiene and food safety requirements, contaminated or adulterated ingredients, unlawful movements of food or feed, and non-compliance with precautionary measures. The provision is significant because it identifies distinct forms of prohibited conduct. A documentary deficiency should not automatically be treated as equivalent to marketing unsafe food. Nor should every disagreement concerning an inspection requirement be characterised as obstruction.

The precise legal classification must reflect the established conduct.

Classification and financial penalties

Article 51 differentiates minor, serious and very serious infringements according to the statutory criteria and categories.

Article 52 provides the following financial ranges under Law 17/2011:

Classification	Statutory fine
Minor	Up to €5,000
Serious	€5,001–€20,000
Very serious	€20,001–€600,000

These amounts describe the framework of Law 17/2011. However, they must not be presented as a universal tariff applicable to every food-related administrative offence in Spain. A particular infringement may fall under another applicable statutory regime. The competent authority must identify the governing provision before determining the appropriate penalty.

Temporary closure as a sanction

Article 52.2 permits temporary closure of an establishment or installation for a maximum of five years in cases of very serious infringements, under the conditions established by the provision. This is distinct from preventive

suspension or closure intended to address current hygiene or safety deficiencies. Article 52.3 expressly distinguishes certain closures, suspensions and product withdrawals undertaken for health and safety reasons from sanctions. The distinction matters because the legal purpose and applicable guarantees differ. A preventive closure must not be used as a disguised punishment.

Conversely, the mere fact that a protective measure has severe economic consequences does not automatically transform it into a sanction.

Culpability: Why objective non-compliance is not automatically punishable responsibility

Article 28 of Law 40/2015

Article 28.1 establishes that natural and legal persons, and other entities identified by the provision, may be sanctioned for acts constituting administrative infringements where they are responsible through intent or negligence. This formulation excludes a general system of punishment based solely upon the objective occurrence of an infringement. The Administration must establish the legally relevant basis for attributing responsibility. However, the nature of culpability differs according to the person concerned and the particular infringement.

The distinction between intent and negligence

Intentional conduct may involve deliberate disregard of a known legal obligation. *Negligence* may involve failure to exercise the diligence reasonably required in the circumstances. The *absence of intent* does not automatically exclude liability where negligent conduct satisfies the statutory requirements. For example, a food manufacturer may not intend to place unsafe products on the market. Nevertheless, failure to implement legally required controls may constitute negligence where the relevant facts and duties are established.

Conversely, an unforeseeable incident occurring despite appropriate compliance measures may require a different assessment. The Administration must avoid treating every adverse outcome as proof that the operator acted negligently.

Constitutional doctrine

The Spanish Constitutional Court (TC) has recognised the application of culpability principles to administrative sanctions. In STC 76/1990, the Court examined the constitutional framework governing tax sanctions and the relationship between administrative punishment, culpability and evidentiary guarantees. The judgment remains an important reference for understanding why punitive responsibility cannot be reduced to an automatic consequence of an adverse factual result. Nevertheless, its reasoning must be applied with attention to the particular statutory regime and the distinction between natural and legal persons.

Culpability of legal persons

A company may incur administrative responsibility independently of the identification of a single individual who personally performed every element of the infringing conduct. Corporate responsibility may arise from failures in organisation, supervision, control or the performance of duties attributable to the legal person. However, this does not mean that a legal person may be punished without satisfying the applicable statutory requirements of responsibility. The analysis must identify the conduct attributable to the organisation and the relevant basis for culpability. The mere fact that an employee made an error does not, without further legal analysis, resolve every question of corporate responsibility.

Corporate liability and the personal responsibility of directors and technical managers

Corporate responsibility is not automatically personal responsibility

A food business may operate through a legal person possessing its own regulatory obligations. Directors, technical managers and employees may participate in the organisation and performance of those obligations. However, the attribution of an infringement to the company does not automatically establish that every director or technical officer is personally liable. Personal

administrative liability requires a legal basis and facts supporting attribution of responsibility to the individual concerned. The distinction is particularly important where an inspector identifies an alleged deficiency and seeks to attribute it simultaneously to the company and its technical director.

The mere existence of a managerial title is not, by itself, a complete analysis of personal culpability.

Delegation of responsibilities

Industrial organisations frequently allocate responsibilities among quality assurance, production, maintenance, regulatory affairs and senior management. Such allocation may be relevant to the determination of who possessed operational control over a particular matter. However, internal delegation does not automatically eliminate statutory obligations attributable to the company or to individuals who retain relevant duties. The analysis must examine the actual distribution of functions, decision-making authority, resources and knowledge. A technical manager who lacks authority to approve expenditure may occupy a different position from a director who knowingly refuses necessary corrective investment.

Conversely, a formally designated technical officer who knowingly disregards a critical control obligation cannot necessarily avoid responsibility merely by invoking organisational complexity.

Article 28.3 and shared obligations

Article 28.3 of Law 40/2015 addresses situations involving obligations whose fulfilment corresponds jointly to several persons. Where the statutory conditions are satisfied, the persons concerned may respond jointly for the infringements committed and sanctions imposed. For monetary sanctions, the provision contemplates individualisation where possible according to the degree of participation. However, the existence of this rule does not justify automatically treating every participant in a food manufacturing operation as jointly responsible. The underlying obligation and the conditions for shared responsibility must first be established.

The evidentiary importance of corporate governance

Corporate governance documentation may be relevant to sanctioning proceedings. Examples include organisational charts, written delegations, technical procedures, training records, internal reports and documented decisions concerning corrective measures. Such evidence may help establish whether a particular deficiency resulted from an organisational failure, individual negligence, deliberate conduct or circumstances not reasonably attributable to the alleged offender. The documents do not automatically determine the legal outcome. Their significance depends upon the statutory duties and the facts of the case.

The evidentiary burden and the presumption of innocence

Inspection findings are not conclusive proof of every element

Official inspection reports may possess *significant evidentiary value*. However, their legal significance must be assessed under the applicable procedural framework. In such sense, Article 77.5 of Law 39/2015 recognises evidentiary value for documents formalised by officials having the status of authorities, recording facts personally established and satisfying the relevant legal requirements, without prejudice to evidence submitted by interested parties. This does not establish an irrebuttable presumption that every scientific inference or legal classification contained in an inspection report is correct. The distinction between observed facts, technical conclusions and legal responsibility remains essential.

The burden of establishing the infringement

In punitive administrative proceedings, the Administration must establish the factual basis supporting the infringement and the attribution of responsibility. An operator may possess substantive duties to maintain records, validate processes and demonstrate regulatory compliance. Nevertheless, those duties do not eliminate the constitutional presumption of innocence. A failure to provide legally required documentation may itself constitute an infringement where the relevant statutory elements are satisfied. But the Administration must still

identify the obligation, establish the failure and apply the appropriate sanctioning provision.

The danger of evidentiary circularity

An evidentiary problem arises where the authority treats its own initial conclusion as proof of the facts underlying that conclusion.

For example:

An inspector states that a preservation process is unlawful. The inspection report records that statement. The sanctioning authority then treats the existence of the report as conclusive evidence that the process was unlawful. This reasoning is circular unless the report contains or identifies sufficient factual and legal foundations for the conclusion. The official status of the report does not replace the need to establish the applicable legal requirement.

A sanctioning decision must distinguish evidence of what occurred from the legal assessment of whether the conduct constituted an infringement.

Procedural guarantees under Law 39/2015

Initiation and separation of functions

Article 63.1 establishes that sanctioning proceedings must be initiated *ex officio* by the competent authority and requires separation between the investigative and sanctioning phases, entrusted to different bodies. Article 63.2 prohibits the imposition of a sanction without the corresponding procedure. These provisions are essential safeguards against the immediate conversion of inspection findings into punitive decisions. An inspector may identify suspected non-compliance. However, the imposition of a sanction requires the applicable sanctioning procedure.

The *initiation agreement*

Article 64 establishes requirements for the *initiation agreement*, including identification of the persons allegedly responsible, the facts motivating the proceedings, their possible legal classification and the sanctions that may correspond. The purpose is to ensure that the alleged offender understands the

accusation sufficiently to exercise the right of defence. An excessively vague allegation may undermine meaningful contradiction. The operator must be able to identify which conduct is alleged to constitute an infringement.

The right to submit evidence

Article 53.2 recognises specific rights of persons allegedly responsible in sanctioning proceedings, including the presumption of non-existence of administrative responsibility until demonstrated otherwise. Articles 76–78 regulate allegations, evidence and evidentiary practice. The authority must consider relevant evidence according to the applicable procedural rules. This does not require admission of every proposed expert examination regardless of relevance. However, a refusal to admit material evidence must comply with the statutory requirements.

The proposed decision

Article 89 requires the proposed sanctioning decision to identify the facts considered proven, their legal classification, the alleged offender, the proposed sanction and the assessment of evidence. The provision also establishes circumstances in which the instructor must terminate proceedings without formulating a sanctioning proposal. These include cases where the facts are not established, the proven facts manifestly do not constitute an infringement or responsibility cannot be attributed to an identifiable person. This provision is particularly significant because it demonstrates that the initiation of proceedings does not create a presumption that a sanction must follow.

The final decision

Article 90 requires the sanctioning decision to evaluate the evidence and determine the facts, responsible persons, infringements and sanctions, or declare the absence of infringement or responsibility. The decision cannot introduce facts different from those established during the proceedings, although the legal assessment may differ within the statutory limits. Where the deciding authority considers that the infringement or sanction is more serious than indicated in the proposed decision, Article 90.2 requires notification and an opportunity to

submit allegations within fifteen days. These guarantees prevent punitive outcomes from being imposed through unannounced escalation of the accusation.

Proportionality and the individualisation of sanctions

Article 29 of Law 40/2015

Article 29 requires administrative sanctions to comply with the *principle of proportionality*. It identifies criteria relevant to the graduation of sanctions, including culpability or intentionality, continuity or persistence of the infringing conduct, the nature of the damage caused and recidivism under the statutory conditions. The sanction must be appropriate to the seriousness of the infringement. A punitive decision should therefore not be based solely upon the maximum penalty theoretically available.

Risk, actual damage and statutory classification

Food safety infringements may involve different degrees of risk and harm. A documentary deficiency that does not compromise product traceability may be materially different from deliberate falsification of traceability records. Similarly, a failure to maintain an appropriate control system may be more serious where it creates a substantial risk to public health. However, the authority must apply the specific classification criteria established by the governing legislation. The existence of a hypothetical possibility of harm does not automatically justify classification as a very serious infringement.

Where the relevant statutory category requires serious risk, deliberate conduct or other specified elements, those elements must be established.

Economic advantage

Article 29.2 of Law 40/2015 provides that committing an infringement must not be more advantageous than complying with the infringed rules. This principle supports sanctions capable of avoiding economic incentives for non-compliance. However, it does not authorise the Administration to disregard

statutory penalty ranges or impose arbitrary financial amounts. The authority must operate within the legally established framework.

The problem of *disproportionate sanctions against small manufacturers*

A penalty may have materially different economic effects upon businesses of different sizes. Nevertheless, the principle of proportionality does not establish a universal rule requiring sanctions to be calculated as a fixed percentage of turnover. The applicable statutory framework determines the relevant criteria. Where the legislation permits consideration of economic circumstances, those circumstances may be relevant. The authority must not invent additional penalty rules unsupported by law.

***Non bis in idem*: The prohibition of double punishment**

Article 31 of Law 40/2015

Article 31 establishes the prohibition of sanctioning conduct that has already been criminally or administratively punished where the same subject, facts and grounds are present. This is the familiar requirement of *triple identity*. The principle prevents the State from imposing duplicate punishment for the same conduct under the relevant conditions. However, it does not establish that every administrative consequence following an infringement constitutes a second sanction.

Corrective measures and sanctions

A company may be ordered to withdraw unsafe products and separately sanctioned for the conduct giving rise to the infringement. The withdrawal may have a preventive or restorative purpose. The fine has a punitive purpose. The coexistence of these measures does not automatically violate non bis in idem. The legal analysis must examine their nature, purpose and statutory foundation.

A formally preventive measure may nevertheless require scrutiny if its actual function and effects reveal a punitive character.

Multiple infringements arising from one industrial incident

A single incident may involve several distinct legal obligations. For example, a manufacturer may fail to maintain traceability records, distribute a non-compliant product and omit a legally required notification. The possibility of separate sanctions depends upon the statutory provisions, the factual circumstances and the prohibition of double punishment. Article 29.5 of Law 40/2015 also addresses situations in which one infringement necessarily entails the commission of another, providing for imposition of the sanction corresponding to the more serious infringement. The authority must therefore avoid mechanically multiplying sanctions without examining the legal relationship between the alleged infringements.

Administrative and criminal proceedings

Article 47.2 of Law 17/2011 expressly addresses the interaction between criminal proceedings and administrative sanctioning concerning the same facts. Where the statutory conditions are met, criminal proceedings *suspend* the administrative sanctioning process. The provision also addresses the continuation of administrative proceedings where criminal liability is not established and the binding significance of facts declared proven in a final judicial decision. Importantly, protective administrative measures may remain in place under the conditions established by law. This reflects the distinction between *punitive duplication* and the *continuing need* to protect public health.

Prescription, expiry and the temporal limits of punitive power

Article 30 of Law 40/2015

Article 30 governs prescription of administrative infringements and sanctions. The applicable period is determined primarily by the legislation establishing the infringement. Where that legislation does not prescribe a period, Article 30 provides general default periods. The calculation of prescription may be affected by the nature of the infringement and the legally relevant commencement or interruption of the period. The distinction between instantaneous, continuing and permanent infringements may therefore be important.

Prescription and procedural expiry are different institutions

Prescription concerns the passage of time affecting the Administration's ability to pursue an infringement or enforce a sanction. **Procedural expiry** concerns the consequences of failure to complete particular proceedings within the applicable time limits. The expiry of proceedings does not necessarily establish that the underlying infringement has prescribed. Conversely, the Administration cannot avoid prescription merely by repeatedly initiating proceedings without satisfying the applicable statutory requirements.

Continuing infringements

Some food safety infringements may persist over time. For example, an establishment may continue operating without a legally required approval. The legal analysis must determine whether the conduct constitutes a continuing infringement under the applicable legislation. It must not assume that every unresolved regulatory deficiency is automatically a continuing infringement for prescription purposes. The classification has consequences for the calculation of time limits and must be legally justified.

Voluntary payment, acknowledgment of responsibility and reduced sanctions

Article 85 of Law 39/2015 establishes mechanisms for terminating sanctioning proceedings through acknowledgment of responsibility or voluntary payment under the statutory conditions. Where the conditions of Article 85.3 apply, the authority must provide reductions of at least 20% for the relevant circumstances, which may be cumulative, subject to the provision's requirements. The reductions must be specified in the notification initiating proceedings, and their effectiveness is subject to the statutory conditions concerning withdrawal or waiver of administrative actions or appeals against the sanction. These mechanisms can reduce the economic consequences of proceedings. However, they require careful legal evaluation.

Payment is not always an admission of every factual allegation

The legal effects of *acknowledgment* and *voluntary payment* must be distinguished. An operator may consider voluntary payment for commercial reasons, particularly where the cost of litigation exceeds the amount at issue. Nevertheless, the decision may affect the procedural position and available administrative challenges. The company should understand the applicable statutory consequences before acting.

The risk of premature acceptance

An operator should not assume that payment is always the most appropriate response to an inspection-related sanction. Where the underlying legal classification is defective or the evidence is insufficient, accepting a reduction may sacrifice the opportunity to challenge a materially unlawful decision. Conversely, contesting a well-founded minor sanction may impose disproportionate costs. The appropriate choice depends upon the facts, legal merits and consequences of the particular case.

Practical case studies: Four legally distinct sanctioning problems

Case A. An alleged hygiene infringement based on an inspector's preferred procedure: A food manufacturer uses a validated sanitation process that differs from the inspector's preferred method. The inspector considers the process unacceptable and proposes a sanction. The legal analysis must identify the binding hygiene requirement allegedly breached. If the applicable legislation permits alternative compliant methods, departure from the inspector's preference does not independently establish an infringement.

However, if the alternative process fails to satisfy a legally required hygiene outcome, sanctioning liability may arise where the relevant statutory elements and culpability are established. The decisive distinction is between technical disagreement and legally established non-compliance.

Case B. A microbiological finding followed by immediate product withdrawal: An official laboratory detects a pathogen in a ready-to-eat food. The authority orders withdrawal and initiates sanctioning proceedings.

The withdrawal may be justified as a protective measure. However, the sanctioning decision must independently establish the infringement and responsibility under the applicable legal framework. The existence of a protective justification does not automatically establish culpability.

Case C. A technical manager sanctioned solely because of professional position: An industrial facility is found to have deficient traceability records.

The Administration proposes sanctions against the company and its technical manager. The manager argues that responsibility for record maintenance had been assigned to another department. The legal assessment must identify the relevant personal duty, actual functions, knowledge, authority and conduct. A managerial title alone does not resolve culpability. Conversely, an internal delegation cannot automatically exclude responsibility where the individual retained a legally relevant duty and failed to exercise appropriate diligence.

Case D. Multiple sanctions following one inspection: An inspection identifies deficient records, inadequate monitoring and a potentially unsafe product. The Administration proposes separate penalties for several infringements. The legal analysis must determine whether the allegations concern genuinely distinct duties and facts or whether one infringement necessarily entails another. It must also examine whether the same subject, facts and legal grounds have already been sanctioned.

The existence of several inspection findings does not automatically justify the cumulative imposition of every potentially applicable penalty.

Analytical framework: The Administrative Sanctioning Legality and Attribution Framework

The present research proposes the **Administrative Sanctioning Legality and Attribution Framework (ASLAF)** as a structured method for evaluating punitive food safety enforcement.

Dimension	Assessment question
Competence	Does the authority possess the relevant sanctioning power?
Legal basis	Is the infringement established by applicable legislation?
Typicity	Do the proven facts satisfy the elements of the infringement?
Evidence	Is the factual basis legally sufficient?

Dimension	Assessment question
Attribution	Is the conduct attributable to the person sanctioned?
Culpability	Is intent or negligence established as legally required?
Procedure	Have the applicable sanctioning guarantees been respected?
Proportionality	Is the penalty justified under the statutory criteria?
Duplication	Does the sanction infringe non bis in idem or rules concerning overlapping infringements?
Time limits	Have prescription and procedural expiry been correctly assessed?
Judicial review	Is the decision adequately reasoned and open to effective challenge?

The framework is an original research proposal, not an established statutory or judicial test. Its principal contribution is to prevent the automatic progression from an inspection finding to a punitive conclusion. The model requires separate examination of objective non-compliance, statutory classification, attribution of responsibility and culpability. It also distinguishes protective intervention from punishment. This is particularly important where the same factual incident gives rise to several administrative consequences.

A proposed evidentiary sequence

A legally robust sanctioning decision should be capable of demonstrating the following sequence:

Established facts → applicable obligation → statutory infringement → responsible person → culpability → proportionate sanction.

Each stage requires a legally sufficient connection to the next. A failure at one stage may undermine the resulting punitive decision. For example, proof that a product was non-compliant does not necessarily identify the person personally responsible.

Likewise, identification of a responsible operator does not automatically determine the appropriate degree of sanction.

Chapter conclusions

Administrative sanctioning is a distinct exercise of public authority governed by constitutional and statutory guarantees. Food safety inspection findings may

justify investigation, corrective action or preventive measures. However, punitive sanctions require additional legal analysis. The principle of legality prevents authorities from creating infringements through informal inspection criteria. The principle of tipicidad requires the alleged conduct to satisfy the elements of a statutory infringement.

The principle of culpability prevents punishment from becoming a purely automatic consequence of objective non-compliance. The presumption of innocence requires legally sufficient evidence of the infringement and responsibility. Proportionality constrains the classification and amount of sanctions. The prohibition of non bis in idem prevents duplicate punishment where the relevant identities are present. Finally, procedural guarantees ensure that the alleged offender can understand, contest and seek review of the accusation.

The central doctrinal conclusion is:

The power to inspect does not include an unrestricted power to punish. A lawful administrative sanction requires independent proof of a legally defined infringement, culpable attribution of responsibility and compliance with the constitutional and procedural limits of punitive authority.

CHAPTER 11

Administrative Appeals, Judicial Protection and Compensation

Judicial review must offer a remedy capable of addressing both unlawful decisions and the consequences of their immediate execution. This chapter separates administrative challenges, provisional relief and liability for compensable damage.

Introduction: The difference between having rights and being able to enforce them

In the preceding chapters we have examined the legal limits of official food controls. Those limits include competence, legality, proportionality, scientific justification, procedural fairness, evidentiary reliability and the prohibition of arbitrary administrative action. However, a further question remains. What happens when an operator considers that those limits have been exceeded? The answer is not simply that the operator may appeal.

Different administrative actions require different procedural responses. An inspection report may constitute evidence rather than an independently enforceable decision. A corrective requirement may impose a concrete legal obligation. A provisional measure may restrict operations before the underlying proceedings have concluded. A sanctioning decision may be subject to administrative review and subsequent judicial challenge.

A material intervention carried out without the necessary legal foundation may raise questions concerning *vía de hecho*. A failure to perform a legally required act may constitute actionable administrative inactivity. These situations cannot be treated as procedurally interchangeable. The legal classification of the administrative conduct determines the available remedies, the relevant deadlines and the possibility of obtaining interim protection. The central practical difficulty is that commercial harm may occur much faster than judicial review can be completed.

A perishable consignment may lose its value within days. A production line may remain inactive while a technical dispute continues. A customer may terminate a supply agreement before the competent court rules upon the legality of the measure. The effectiveness of legal protection therefore depends not only upon the possibility of eventual annulment, but also upon the availability of timely remedies.

The first question: What exactly is being challenged?

Inspection reports

An inspection report ordinarily records observations, findings and relevant circumstances identified during an official control. Its evidentiary function must be distinguished from the legal effects of a subsequent administrative decision. An inspection report does not automatically constitute an independently appealable act merely because the operator disagrees with its contents. However, the legal classification depends upon its actual content and effects, not solely upon its title. If a document formally presented as an inspection report imposes immediately enforceable obligations or produces direct legal consequences, its appealability may require separate examination.

The operator should therefore identify whether the document merely records facts or also contains an operative administrative decision.

Preparatory acts

Article 112.1 of Law 39/2015 permits administrative appeals against resolutions and certain procedural acts. Procedural acts are independently challengeable where they directly or indirectly decide the merits, prevent continuation of the procedure, cause defencelessness or produce irreparable harm to rights or legitimate interests. Other procedural objections may ordinarily be raised for consideration in the final decision. This distinction prevents every intermediate administrative step from becoming a separate appeal. However, it also protects operators against procedural acts whose consequences are sufficiently serious to justify independent review.

Corrective requirements

A corrective requirement may impose a concrete obligation upon the operator. For example, an authority may require a manufacturer to modify a hygiene procedure, cease using a particular ingredient or undertake specified corrective action. Where the requirement constitutes an administrative act producing legal effects, its challengeability depends upon the applicable procedural framework. The operator should identify the issuing authority, legal basis, operative content, notification date and available remedies. A document's designation as a recommendation does not necessarily determine its legal nature.

If the Administration effectively imposes a compulsory obligation, its legal consequences must be examined accordingly.

Provisional measures

Provisional measures may be adopted before the final resolution of proceedings where the applicable statutory conditions are satisfied. Examples include temporary immobilisation of products or suspension of activities. Such measures may be independently challengeable where they produce legally relevant effects. However, their appealability and the appropriate route depend upon the particular measure and governing legislation. The operator must distinguish the legality of the provisional measure from the eventual merits of the underlying proceedings.

A provisional restriction may be lawful even where no sanction is ultimately imposed. Conversely, a measure may be disproportionate despite the existence of a legitimate investigation.

Administrative appeals under Law 39/2015

The appeal for hierarchical review: *Recurso de alzada (RecAl)*

Articles 121 and 122 regulate the *recurso de alzada*. This appeal generally applies to administrative acts that do not terminate the administrative route. It is ordinarily brought before the hierarchical superior of the body that issued the act, although it may be lodged with either the issuing body or the competent reviewing body. For express acts, the ordinary period for filing is one month.

Where the act is not express, the interested party and other potential interested persons may lodge the appeal at any time from the day following that on which the effects of administrative silence arise, subject to the applicable legal framework.

The maximum period for issuing and notifying the appeal decision is three months. The general effect of failure to resolve is dismissal by silence, with the statutory exception concerning certain appeals against presumed dismissals. The precise consequences must be determined under Article 122.2.

The optional reconsideration appeal: *Recurso potestativo de reposición (RecRepo)*

Articles 123 and 124 regulate the *recurso potestativo de reposición*. This appeal may be brought against acts terminating the administrative route, before the same body that issued the act. It is optional. The interested party may instead proceed directly to contentious-administrative judicial review where the statutory conditions are satisfied. For express acts, the ordinary filing period is one month.

The maximum period for resolving and notifying the appeal is one month. Where the act is not express, the relevant rules permit filing after the effects of silence arise. Once a reconsideration appeal has been lodged, contentious-administrative proceedings against the act cannot ordinarily be initiated until the appeal has been expressly resolved or dismissed by silence. This procedural relationship is important because an unnecessary reconsideration appeal may affect the timing of judicial protection.

Extraordinary review

Articles 125 and 126 regulate the *extraordinary appeal* for review against final administrative acts in specified circumstances. These include certain errors of fact evident from the documents in the file and other exceptional grounds. The remedy is not a general substitute for an ordinary appeal that was not lodged within the applicable period. Its availability depends upon the statutory grounds and deadlines.

The danger of assuming that an appeal suspends enforcement

Article 117.1 establishes the general rule that lodging *an administrative appeal does not suspend execution* of the challenged act unless a provision establishes otherwise. This is a critical practical point. A manufacturer cannot assume that filing an appeal automatically authorises continued production in defiance of an enforceable suspension order. Nor can an operator automatically market immobilised products merely because it contests the underlying decision. Where suspension is necessary, it must be requested through the applicable mechanism.

Article 117.2 permits suspension after a reasoned balancing of the harm to the public interest or third parties and the harm to the appellant, where the statutory conditions are met. Article 117.3 also establishes an important procedural consequence to know: *if one month passes after the suspension request enters the electronic register of the competent Administration or body without an express decision being issued and notified, execution of the challenged act is understood to be suspended*. The operation of this rule must be examined in relation to the particular proceedings and any applicable special legislation. It should not be treated as a universal authorisation to disregard food safety restrictions.

The contentious-administrative jurisdiction

Article 106.1 of the Constitution (CE)

Article 106.1 establishes judicial control over regulatory powers, the legality of administrative action and its submission to the purposes justifying it. This constitutional provision is central to the control of food inspection authorities. Administrative expertise does not eliminate judicial review. Nor does the existence of public health objectives render administrative decisions immune from scrutiny. The courts may examine whether the authority possessed competence, applied the correct law, respected procedural guarantees and acted within the limits of its powers.

Article 25 of Law 29/1998

Article 25 identifies the administrative activity subject to contentious-administrative review. This includes express and presumed administrative acts terminating the administrative route, whether final or qualifying procedural acts. The jurisdiction also extends, under the statutory conditions, to administrative inactivity and material action constituting *vía de hecho*. These categories are important because they permit judicial scrutiny of different forms of administrative conduct. A food business may need to challenge an express closure order.

Another may need to contest a presumed rejection. A third may face material interference with its activity without the necessary administrative decision. The appropriate procedural route depends upon the nature of the conduct.

The time limits for judicial proceedings

Article 46 of Law 29/1998 establishes general filing periods. For *express acts*, the ordinary period is *two months* from the day following notification or publication, as applicable. The provision also contains rules concerning *presumed acts*, *administrative inactivity* and *vía de hecho*. The statutory text concerning presumed acts must be interpreted in light of constitutional and judicial doctrine on administrative silence and effective judicial protection. It would therefore be unsafe to calculate every judicial deadline mechanically without identifying the specific situation and applicable case law.

The distinction is particularly important where the Administration has failed to issue the express decision required by law.

Judicial remedies

Articles 31 and 32 regulate the claims that may be brought before the contentious-administrative courts. Depending upon the case, the claimant may seek *annulment* of the challenged act, *recognition* of an individualised legal situation, *restoration* of rights, *compensation* or an order requiring *performance of a legally enforceable obligation*. These remedies are not interchangeable. A claim seeking only annulment may not address every consequence of the

administrative conduct. Conversely, a request for compensation requires satisfaction of the applicable substantive and procedural conditions.

The formulation of the judicial claim is therefore a significant part of effective legal protection.

Interim judicial protection: Preventing irreversible harm

The function of *interim relief*

Judicial review may take substantial time. In food safety disputes, the consequences of administrative intervention may become irreversible before the court issues its final judgment. *Interim relief* exists to preserve the effectiveness of judicial protection. Articles 129–136 of Law 29/1998 establish the general framework governing precautionary measures in contentious-administrative proceedings. Article 129 permits interested parties to request measures capable of ensuring the effectiveness of the judgment.

Article 130 provides that a measure may be adopted where execution of the act or application of the challenged provision could deprive the appeal of its legitimate purpose. The court must also assess whether the measure could cause serious disturbance to the general interest or third-party interests.

Economic damage is relevant but not automatically decisive

An operator may demonstrate that a closure order will cause substantial financial loss. That circumstance may be relevant to the assessment of *interim relief*. However, economic harm alone does not automatically justify suspension. The court must consider the competing interests. Where the administrative measure addresses a credible and serious food safety risk, protection of public health may weigh strongly against suspension.

Conversely, where the legal and factual basis of the measure is seriously contested and the consequences are irreversible, interim protection may warrant careful consideration. The assessment is necessarily case-specific.

Article 135: Particularly *urgent measures*

Article 135 provides a procedure for circumstances of particular urgency. Under the statutory conditions, the court may decide upon an **urgent interim measure without first hearing the opposing party** (*inaudita parte*), followed by the subsequent procedural steps required by law. This mechanism may be especially relevant where the passage of even a short period would render judicial protection ineffective. Examples may include imminent destruction of goods, immediate suspension of essential industrial operations or other measures capable of causing irreversible consequences. However, the existence of commercial urgency does not automatically satisfy the legal threshold.

The court must determine whether the circumstances justify the exceptional procedure.

Article 136: *Inactivity and vía de hecho*

Article 136 establishes a specific framework for interim protection in proceedings concerning administrative inactivity and *vía de hecho*. Its structure differs from the general regime under Article 130. The provision reflects the distinctive legal problems associated with failures to perform enforceable obligations and material administrative conduct lacking the necessary legal foundation. This distinction is important because the operator's remedial strategy must correspond to the form of administrative conduct challenged.

***Vía de hecho*: Material administrative action without sufficient legal foundation**

The concept

The expression ***vía de hecho*** refers to a *legally significant category of material administrative action undertaken without the necessary legal foundation or outside the legally permitted scope of execution*. It must not be confused with every unlawful administrative act. An authority may issue a formally identifiable decision that is legally defective. That situation ordinarily raises questions concerning the validity of the act. *Vía de hecho*, by contrast, concerns material

action that lacks the necessary legal support or exceeds the legally authorised framework in a manner qualifying under the applicable doctrine.

Article 30 of Law 29/1998

Article 30 establishes a specific procedure for challenging *vía de hecho*. The interested party may request that the Administration cease the material action. Where the statutory conditions are met, contentious-administrative proceedings may be initiated within the relevant periods. The provision also permits direct judicial action without a prior cessation request, subject to the applicable time limit. This remedy may be relevant where material interference with industrial operations occurs without an appropriate enforceable administrative basis.

The distinction between *unlawful execution* and *unlawful decision-making*

Suppose inspectors physically prevent access to a production facility. The legal analysis must determine whether an enforceable administrative decision authorised that intervention. If such a decision exists, the dispute may concern its legality or the proportionality of its execution. If the Administration acts materially without the legally required decision or exceeds the scope of the authority conferred, the possibility of *vía de hecho* may arise. The distinction depends upon the actual circumstances and applicable legislation.

Not every urgent protective intervention requires the same prior procedural formalities. Where legislation authorises immediate action under specified conditions, the absence of ordinary prior steps does not automatically establish *vía de hecho*.

Compensation for unlawful administrative action

The statutory framework

Article 106.2 of the Spanish Constitution establishes the constitutional foundation for public liability arising from the functioning of public services. Articles 32–34 of Law 40/2015 regulate the general substantive conditions. Law 39/2015 establishes procedural rules for liability claims. The existence of an

unlawful administrative act may be relevant to a compensation claim. However, Article 32.1 of Law 40/2015 expressly provides that annulment of administrative acts or provisions does not, by itself, presuppose entitlement to compensation.

This qualification is essential. A successful judicial challenge does not automatically establish every element of public liability.

The requirements of compensable damage

The claimant must establish legally compensable injury under the applicable framework. Article 32.2 requires damage to be effective, economically assessable and individualised in relation to a person or group of persons. Other relevant questions include causation, the legal duty to bear the injury and any statutory exclusions. The operator must therefore distinguish the unlawfulness of the administrative decision from the existence and quantification of compensable damage.

Lost profits

A manufacturer may claim that an unlawful closure caused loss of expected sales. However, anticipated revenue is not equivalent to lost profit. A proper economic analysis must consider avoided production costs, variable expenses, the likelihood of completing sales and other relevant factors. Documented purchase orders, established customer relationships, historical margins and production capacity may provide useful evidence. Speculative commercial projections may be insufficient.

Damage to reputation

Food safety enforcement may affect a company's commercial reputation. Customers may interpret official restrictions as evidence that the manufacturer is unsafe or unreliable. However, reputational damage must be established through legally relevant evidence. The mere existence of an adverse inspection or public controversy does not automatically establish a compensable injury. Relevant evidence may include lost contracts, documented customer communications, market effects and a demonstrated causal connection with the administrative conduct.

The importance of *causation*

Suppose a manufacturer is subjected to an unlawful suspension order. During the suspension, the company loses a major customer. The operator must establish whether the loss was caused by the suspension or by other commercial circumstances. The fact that two events occurred close together does not conclusively establish causation. A rigorous damages claim should distinguish losses directly attributable to the administrative measure from losses caused by independent market conditions.

The special problem of *irreversible commercial consequences*

Food safety enforcement presents an important temporal asymmetry. Administrative restrictions may take effect immediately. Judicial review may occur much later. This asymmetry can make eventual annulment insufficient to restore the operator's position.

Perishable goods

A consignment may deteriorate before the court can examine the legality of immobilisation. Even if the operator subsequently obtains annulment, the goods may no longer be commercially usable. Interim relief and compensation may therefore become central to effective protection. However, the court must still consider public health. Where the goods present a credible risk, immediate release may be inappropriate despite the economic consequences.

Industrial shutdowns

A prolonged suspension may interrupt production, damage equipment utilisation, disrupt employment and cause contractual penalties. These consequences may extend beyond the immediate period of inactivity. Nevertheless, a claim for compensation must identify and substantiate each category of loss. The operator should not assume that all subsequent financial difficulties are legally attributable to the original administrative measure.

Loss of market access

An administrative decision may prevent a product from being marketed. Where the product has a short commercial lifecycle, delayed judicial relief may have limited practical value. The availability of interim measures is therefore particularly important. However, the operator must establish why the requested relief is compatible with the applicable public health obligations.

Practical litigation scenarios

Case A. An inspection report containing adverse technical findings: An inspector records that a manufacturer has failed to validate a preservation process. The report does not impose an immediate obligation. The operator disputes the finding. The appropriate initial response may involve submitting technical observations and evidence within the relevant administrative procedure.

An immediate independent appeal may not be available if the report is merely preparatory. However, the finding may later be challenged as part of an appeal against an enforceable decision relying upon it.

Case B. A corrective order requiring expensive modifications: An authority orders a manufacturer to replace a processing system within a specified period. The operator maintains that the requirement lacks a statutory basis.

The company should identify whether the order terminates the administrative route, whether administrative appeal is available and whether suspension should be requested. The operator should not assume that disagreement suspends enforceability.

Case C. An urgent immobilisation of perishable goods: A consignment is immobilised following a suspected contamination event. The operator submits laboratory evidence challenging the suspicion.

The authority maintains the restriction. The legal analysis may involve the legality of the original measure, the continuing factual basis for immobilisation, available administrative remedies and the possibility of urgent judicial protection. The court must consider both commercial harm and the public health interests involved.

Case D. An unlawful closure subsequently annulled: A food manufacturing facility is closed under an administrative decision.

The competent court later annuls the decision. The operator seeks compensation. The annulment establishes the relevant judicial conclusion concerning the challenged act. However, compensation requires separate examination of legally compensable damage, causation and the other statutory conditions. The operator must substantiate the financial consequences attributable to the closure.

Analytical framework: The Effective Food Enforcement Remedies Framework

The present research proposes the **Effective Food Enforcement Remedies Framework (EFERF)** as a structured method for determining the appropriate legal response to disputed official control activity.

Dimension	Assessment question
Nature of conduct	Is the dispute about a report, administrative act, inactivity or material action?
Legal effects	Does the conduct impose obligations or cause independently relevant harm?
Administrative route	Is hierarchical appeal, reconsideration or another remedy available?
Enforceability	Does the measure remain enforceable during the challenge?
Interim protection	Is suspension or another precautionary measure legally justified?
Evidence	What factual, scientific and economic evidence supports the challenge?
Judicial jurisdiction	Which court and procedural route are competent?
Remedy sought	Is annulment, recognition of rights, performance or cessation appropriate?
Compensation	Are the statutory conditions for public liability satisfied?
Temporal effectiveness	Can the remedy prevent or address irreversible consequences?

This framework is an original research proposal, not an established statutory or judicial test. Its principal contribution is to integrate substantive legality with remedial effectiveness. An operator may possess strong arguments concerning the unlawfulness of an inspection requirement but still fail to obtain effective

protection if it uses an inappropriate procedural route or misses a statutory deadline. Conversely, the availability of a procedural remedy does not guarantee success on the merits. The model therefore requires simultaneous assessment of legal validity, procedural strategy, evidentiary support and the practical consequences of delay.

Chapter conclusions

The legal limits of official food controls are meaningful only if they can be enforced through effective remedies. Spanish administrative law distinguishes inspection reports, preparatory acts, enforceable decisions, administrative inactivity and *vía de hecho*. Each category may require a different procedural response. Administrative appeals permit review within the Administration, but their filing does not ordinarily suspend execution automatically. Contentious-administrative proceedings provide judicial control of administrative legality.

Interim judicial measures may preserve the effectiveness of eventual judgment, particularly where food products are perishable or industrial restrictions threaten irreversible consequences. However, interim protection must account for the public interest in food safety. Compensation may be available where the statutory requirements for public liability are satisfied. Nevertheless, annulment of an administrative act does not automatically establish entitlement to damages. The operator must demonstrate legally compensable injury and the required causal relationship.

The central doctrinal conclusion is:

Effective judicial protection requires timely judicial scrutiny, interim relief against unjustified irreversible harm and compensation where statutory liability has been established.

CHAPTER 12

Institutional Accountability and the Responsibility of Public Officials

Not every erroneous inspection constitutes misconduct. Institutional accountability requires a disciplined distinction among invalid administrative acts, disciplinary breaches, personal liability and exceptionally criminal conduct.

Introduction: Administrative authority and the problem of accountability

Official food inspectors exercise powers that may substantially affect the operation of industrial establishments. Their functions require technical competence, professional independence and the ability to intervene promptly where public health is at risk. However, the same powers may generate serious consequences when exercised incorrectly or unlawfully. An inspection may result in an unjustified production stoppage. A laboratory finding may be misinterpreted.

An inspector may require corrective measures unsupported by the applicable legislation. A competent authority may fail to review a restrictive decision despite the emergence of contrary evidence. In more serious circumstances, allegations may arise concerning deliberate retaliation, falsification of official records, coercion or misuse of administrative powers. These situations cannot be treated as legally equivalent. A mistaken technical interpretation does not automatically constitute misconduct.

An unlawful administrative decision does not necessarily establish negligence. Negligence does not automatically amount to criminal conduct. And an allegation of deliberate abuse requires evidence capable of supporting the relevant legal characterisation. The appropriate analysis must therefore distinguish the different levels of responsibility recognised by Spanish law. This distinction protects food business operators against unlawful administration while also protecting public officials against unsupported personal accusations.

The objective is not to weaken legitimate inspection powers. It is to ensure that those powers remain subject to law, professional responsibility and effective institutional control.

The constitutional duty of objective and lawful administration

Article 103.1 of the Spanish Constitution

Article 103.1 provides that public administration serves the general interest objectively and acts in accordance with principles including effectiveness, hierarchy, decentralisation, deconcentration and coordination, with full submission to the law and the legal system. The provision establishes a constitutional standard for administrative conduct. Food inspection authorities must pursue the protection of public health within the powers legally conferred upon them. They may not legitimately substitute personal preferences, private interests or retaliatory motives for the statutory purposes governing official controls.

The requirement of objectivity does not mean that inspectors must remain neutral between compliance and non-compliance. They are required to identify and address infringements within their competence. However, their assessments must be grounded in relevant facts and applicable law.

Article 9.3: The prohibition of arbitrariness

Article 9.3 guarantees, among other principles, **legal certainty** and the **prohibition of arbitrariness by public authorities**, (*In spanish: Interdicción de la arbitrariedad de los Poderes Públicos*). Administrative arbitrariness is not synonymous with every error or disagreement. A decision may be incorrect without being arbitrary in the constitutionally relevant sense. The legal analysis must examine whether the decision possesses an adequate legal and factual foundation and whether the authority has acted within the purposes and limits established by law. An inspector's technical opinion is not automatically arbitrary because another expert disagrees.

Conversely, a decision cannot be insulated from scrutiny merely because it is described as technical.

Article 106.1: Judicial control

Article 106.1 establishes judicial control over regulatory powers, the legality of administrative action and its submission to the purposes justifying it. This provision is particularly relevant where allegations concern misuse of inspection powers. The courts may examine not only formal compliance with procedural requirements but also whether the Administration exercised its powers for the purposes authorised by law. The constitutional framework therefore rejects the proposition that administrative expertise creates an area of unrestricted authority.

Four distinct levels of responsibility

A rigorous accountability analysis must distinguish at least four legal dimensions.

Dimension	Principal legal question	Possible consequence
Administrative legality	Was the decision or action lawful?	Annulment, cessation or correction
Public liability	Did the functioning of public services cause legally compensable damage?	Compensation by the Administration
Disciplinary responsibility	Did an official commit a disciplinary infringement?	Disciplinary sanction
Criminal responsibility	Did the conduct satisfy the elements of a criminal offence?	Criminal conviction and statutory penalties

These dimensions may coexist. However, none follows automatically from another. An administrative decision may be annulled without establishing personal misconduct. The Administration may incur liability without proof that a particular official committed a criminal offence. A public employee may commit a disciplinary infringement without the conduct satisfying the stricter requirements of criminal law.

Criminal responsibility, where applicable, requires proof of the constituent elements of the relevant offence. The distinction is essential to avoid

transforming ordinary administrative litigation into unsupported allegations of criminal misconduct.

Disciplinary responsibility of public officials

The Basic Statute of Public Employees (TREBEP)

Royal Legislative Decree 5/2015 approves the consolidated **Basic Statute of Public Employees** (Texto Refundido de la Ley del Estatuto Básico del Empleado Público, TREBEP). Articles 52–54 establish principles of professional conduct, while Articles 93–98 regulate disciplinary responsibility. These provisions apply within their statutory scope, subject to the relevant public employment legislation and the particular legal status of the personnel concerned. Their application to an individual inspector therefore requires identification of the official's employment regime and competent disciplinary authority.

Professional duties and ethical standards

Article 52 establishes duties concerning the performance of public functions in accordance with the Constitution and the legal system, and with principles including objectivity, integrity, neutrality, responsibility, impartiality and confidentiality. Article 53 develops ethical principles, including the pursuit of general interests, avoidance of conflicts of interest and abstention from conduct compromising impartiality. Article 54 addresses principles of conduct relevant to professional diligence and relations with citizens. These duties provide an important institutional framework for food inspection.

However, the existence of an ethical duty does not automatically determine the classification of a disciplinary infringement. Disciplinary liability requires the applicable legal classification and procedural guarantees.

Articles 93–95: Disciplinary responsibility and infringements

Article 93 establishes the general framework of disciplinary responsibility. Article 94 requires disciplinary powers to respect legality, typicity, proportionality, culpability and the presumption of innocence. Article 95

distinguishes very serious, serious and minor disciplinary infringements. Among the categories of very serious misconduct are certain discriminatory conduct, abandonment of service and the adoption of manifestly unlawful agreements causing serious harm, subject to the precise statutory elements. Other infringements are governed by the relevant legislation and, where applicable, collective agreements.

The distinction is important. An inspector's incorrect technical conclusion does not automatically constitute a very serious disciplinary offence. However, deliberate conduct satisfying the statutory elements of a disciplinary infringement may justify investigation and, where proven, sanction.

Disciplinary sanctions and procedural guarantees

Article 96 provides for disciplinary sanctions, including suspension, transfer, demotion-related consequences and, in the most serious cases, separation from service or disciplinary dismissal under the applicable conditions. Article 98 governs disciplinary proceedings and provisional measures. The official concerned is entitled to the applicable procedural guarantees. A disciplinary complaint submitted by a food business does not itself establish misconduct. The competent authority must determine whether the allegations justify proceedings and whether the evidence establishes an infringement.

The position of the complainant

An operator may report suspected misconduct to the competent administrative authority. However, submitting a complaint does not necessarily confer the procedural status of an interested party in subsequent disciplinary proceedings. The complainant's rights depend upon the applicable legislation and whether a legally recognised right or legitimate interest is affected. The objective of disciplinary proceedings is the enforcement of public employment duties, not the automatic satisfaction of a private claim for compensation. Where the operator seeks annulment of an inspection decision or recovery of damages, other legal mechanisms may be required.

Deviation of power: When lawful powers are exercised for unlawful purposes (*Desviación de poder*)

The concept of *desviación de poder*

Article 70.2 of Law 29/1998 defines *desviación de poder* as *the exercise of administrative powers for purposes different from those established by the legal system*. The concept addresses a particular form of administrative unlawfulness. An authority may possess formal competence. It may follow apparently correct procedural steps. Nevertheless, the exercise of the power may be unlawful if directed towards a purpose foreign to the one legally authorised.

This possibility is especially relevant where an operator alleges retaliatory inspection activity.

Retaliation disguised as regulatory enforcement

Consider an operator that successfully challenges an administrative sanction. Following the judicial decision, the establishment becomes subject to repeated inspections. The operator alleges retaliation. The sequence may justify examining the selection criteria and institutional decision-making. However, chronology alone does not establish deviation of power.

The authority may possess legitimate reasons for additional controls, including new evidence, changes in risk or previously identified deficiencies. A credible allegation of retaliatory purpose requires objective evidence supporting the inference that the powers were exercised for an improper purpose.

The evidentiary problem

Improper administrative purposes are rarely recorded expressly. Evidence may therefore be circumstantial. Relevant circumstances may include unusual departures from established inspection criteria, contradictory explanations, communications indicating hostility, disproportionate concentration of resources upon a particular operator or differential treatment lacking an adequate factual justification. Each circumstance must be evaluated in context. A high frequency of inspections is not inherently unlawful.

Nor does a personal disagreement between an inspector and an operator necessarily establish improper purpose. The legal question is whether the available evidence supports the conclusion that the authority exercised its powers for an unauthorised purpose.

The relationship between *deviation of power* and *disciplinary misconduct*

Deviation of power concerns the legality of administrative action. *Disciplinary misconduct* concerns the responsibility of the public employee. The same factual circumstances may be relevant to both. However, annulment of an act for deviation of power does not automatically establish every element of a disciplinary infringement. The relevant statutory conditions must be examined independently.

Public liability and the personal responsibility of officials

The general rule: Claims against the Administration

Article 36.1 of Law 40/2015 establishes that individuals seeking compensation for damage caused by authorities or personnel serving the Administration must claim directly against the corresponding public administration. This rule is important because it distinguishes the operator's claim for compensation from the Administration's possible subsequent action against the official. The operator does not ordinarily need to establish that a particular inspector committed a criminal offence in order to pursue public liability. The claim is assessed under the statutory framework governing damage attributable to the functioning of public services.

Article 36.2: Recovery from officials

Article 36.2 provides that, where the Administration has compensated injured persons, it must seek recovery from authorities or personnel whose intentional conduct, gross fault or gross negligence caused the relevant damage, following the prescribed administrative procedure. The provision requires consideration of factors including the damage caused, degree of culpability, professional

responsibility and relationship between the conduct and the resulting injury. This mechanism is not equivalent to automatic personal liability whenever the Administration pays compensation. The statutory threshold is significantly more demanding. Ordinary error or minor negligence does not necessarily satisfy the conditions for recovery.

Damage to public property or rights

Article 36.3 also addresses recovery where authorities or personnel have caused damage to the Administration's own property or rights through intentional conduct, gross fault or gross negligence. The provision establishes a distinct situation from compensation paid to third parties.

Procedural safeguards

Article 36.4 establishes procedural requirements for recovery proceedings. These include opportunities for allegations, evidence, hearing and a reasoned resolution. The official concerned must be afforded the applicable rights of defence. The Administration cannot simply deduct an amount from an inspector's remuneration because a food business has obtained compensation. The statutory procedure and substantive requirements must be respected.

Criminal *prevarication*: The exceptional threshold of Article 404

The statutory offence

Article 404 of the Spanish Criminal Code **addresses the conduct of an authority or public official who knowingly issues an arbitrary resolution in an administrative matter while aware of its injustice**. The offence is commonly described as **administrative prevarication**. It is not equivalent to every unlawful administrative decision. The provision requires the elements established by criminal law, including the requisite subjective awareness.

The distinction between unlawfulness and criminal arbitrariness

A food inspector may incorrectly interpret a technical regulation. A competent authority may adopt a disproportionate measure. A court may subsequently annul the decision. None of these circumstances automatically establishes criminal prevarication. The criminal offence requires a qualitatively different assessment.

The alleged resolution must satisfy the relevant criminal-law understanding of arbitrariness, and the required knowledge must be established. Criminal responsibility cannot be inferred merely from the existence of administrative error.

The significance of deliberate disregard of binding law

More serious questions may arise where an authority knowingly adopts a resolution contrary to a clear legal prohibition or deliberately uses its powers for an impermissible purpose. However, even in such circumstances, the elements of Article 404 must be established through legally sufficient evidence. A complaint alleging prevarication should identify the specific resolution, the person responsible for issuing it, the applicable legal framework and the evidence supporting the alleged knowledge of its injustice. General allegations of hostility or unfairness are not substitutes for those elements.

Why the distinction matters

The threshold protects both the integrity of criminal law and the independence of administrative decision-making. If every administrative error were criminalised, officials could become reluctant to adopt necessary protective measures. Conversely, the exceptional nature of the offence must not be interpreted as immunity for deliberately arbitrary administrative resolutions. The law seeks to distinguish lawful discretion, administrative error and intentional criminal misconduct.

Falsification of inspection reports and official documents

Article 390 of the Criminal Code (CP)

Article 390 establishes offences concerning falsification of public, official and commercial documents by authorities or public officials acting in the exercise of their functions. The provision identifies different forms of falsification, including alteration of essential elements and certain forms of false documentation. The precise criminal classification depends upon the conduct and the statutory elements. An inaccurate inspection report is not automatically a forged official document.

Factual error versus deliberate falsification

Suppose an inspector records that a manufacturing line was operating at a particular temperature. The operator produces evidence showing a different reading. The discrepancy may arise from measurement error, misunderstanding, defective equipment or deliberate misrepresentation. These possibilities must be distinguished. An incorrect factual statement does not necessarily establish intentional falsification.

Conversely, evidence that an official knowingly fabricated an inspection observation may raise substantially more serious legal questions.

Technical disagreement is not documentary falsification

A further distinction concerns scientific or technical conclusions. An inspector may interpret laboratory results incorrectly. The operator may disagree with the interpretation. Such disagreement does not automatically establish falsification. Criminal documentary offences require analysis of the specific conduct described by the relevant provision.

The legal significance of false factual assertions may differ from that of disputed technical opinions.

The importance of contemporaneous evidence

Where falsification is alleged, contemporaneous evidence may be particularly important. Relevant material may include photographs, original laboratory records, inspection notes, digital timestamps, equipment logs, witness statements and communications. However, the authenticity and reliability of each item must be established. A technically persuasive contradiction may support administrative challenge without necessarily proving the subjective elements of a criminal offence.

Coercion, threats and the misuse of enforcement powers

Lawful enforcement pressure

Official food controls necessarily involve the exercise of authority. Inspectors may require access to relevant premises, demand legally required information and warn operators of the consequences of non-compliance. Such conduct is not inherently coercive in the criminal sense. An official who accurately explains that refusal to cooperate may constitute an infringement is ordinarily communicating a legal consequence. The use of lawful enforcement powers must be distinguished from threats or coercion prohibited by criminal law.

Article 172 of the Criminal Code

Article 172 regulates criminal coercion under its statutory conditions. The offence cannot be established merely because an operator feels pressured by an inspection. The conduct must satisfy the relevant criminal elements. For example, an inspector's insistence upon compliance with a valid legal order does not automatically constitute criminal coercion. Conversely, conduct involving the unlawful use of force or other legally relevant coercive means may require criminal assessment.

Improper threats concerning sanctions or closure

A difficult situation may arise where an official threatens closure unless an operator accepts a demand lacking legal foundation. The legal characterisation depends upon the circumstances. The statement may constitute an unlawful

administrative threat, evidence of improper purpose or potentially criminal conduct if the relevant statutory elements are satisfied. It would be incorrect to assume that every threatened sanction constitutes a criminal threat. The authority's legal powers, the content of the communication, the means employed and the official's purpose must be examined.

Disclosure of confidential industrial information

The regulatory confidentiality framework

Official food controls may require access to commercially sensitive information. This may include formulations, manufacturing procedures, supplier identities, technical validation data and proprietary process parameters. Regulation (EU) 2017/625 establishes confidentiality obligations, particularly under Article 8. These obligations must be considered alongside applicable transparency legislation, data protection rules and other legally recognised disclosure requirements. Confidentiality is not absolute.

However, access obtained through official control powers does not create unrestricted permission to disclose industrial information.

Article 417 of the Criminal Code

Article 417 addresses disclosure by authorities or public officials of secrets or information obtained through their office or position that should not be disclosed. Its application depends upon the statutory elements. Not every inappropriate communication automatically constitutes the offence. The information concerned, the official's duties, the circumstances of disclosure and the relevant subjective elements must be examined.

The relationship with *trade secret* protection

Directive (EU) 2016/943 and Spanish Law 1/2019 establish frameworks concerning trade secrets. However, the legal consequences of disclosure by a public official may involve different and potentially overlapping regimes. These may include administrative confidentiality obligations, disciplinary

responsibility, public liability and, in sufficiently serious circumstances, criminal law. The operator must distinguish the legal basis of each claim.

Industrial confidentiality and public health

The protection of trade secrets cannot be used to obstruct lawful official controls. Where the authority possesses a legitimate power to obtain information necessary for verification, the operator must comply with the applicable legal obligations. The corresponding safeguard concerns the lawful handling and protection of information once obtained. The balance is therefore between effective regulatory access and legally protected confidentiality, not between unrestricted disclosure and complete secrecy.

Disobedience to judicial decisions and superior orders

Article 410 of the Criminal Code

Article 410 addresses certain refusals by authorities or public officials to comply with judicial decisions, decisions or orders of superior authorities issued within their competence and satisfying the required legal formalities. The offence requires the statutory conditions to be met. A delay or disagreement concerning implementation does not automatically establish criminal disobedience. The nature of the order, the official's obligations, the conduct constituting refusal and the applicable subjective requirements must be examined.

The distinction between administrative non-compliance and criminal disobedience

Suppose a court annuls a closure order and requires the Administration to take a particular action. The authority fails to implement the judgment promptly. This may raise questions concerning judicial execution and administrative responsibility. However, criminal liability requires separate analysis under Article 410 or any other applicable provision. The existence of an unexecuted judgment does not automatically establish every element of criminal disobedience.

Judicial *execution* as the primary institutional mechanism

Law 29/1998 establishes mechanisms governing execution of contentious-administrative judgments. These mechanisms are generally central to obtaining compliance with judicial decisions. Where the Administration fails to execute a judgment, the affected party may seek the appropriate judicial enforcement measures. Criminal proceedings are not a universal substitute for the execution mechanisms established by procedural law. Nevertheless, sufficiently serious and deliberate refusal to comply with binding judicial decisions may raise separate criminal questions.

Institutional audits and systemic accountability

Article 6 of Regulation (EU) 2017/625

Article 6 requires competent authorities to conduct internal audits or have audits conducted on themselves and to take appropriate measures in light of their results. The provision also addresses independent scrutiny and transparency of the audit process. This requirement is important because accountability should not depend exclusively upon individual complaints. A regulatory system should possess mechanisms capable of identifying recurring deficiencies in inspection practice.

The distinction between individual misconduct and institutional failure

Repeated inconsistent inspections may result from inadequate training, unclear internal guidance, poor coordination or deficient quality management. These problems do not necessarily establish intentional misconduct by individual inspectors. However, they may reveal institutional weaknesses requiring corrective action. The appropriate response may involve revised procedures, technical training, internal audits or improved supervisory arrangements.

Measuring the quality of official controls

An effective accountability system should assess more than the number of inspections performed or sanctions imposed. Relevant indicators may include consistency of legal classification, adequacy of sampling procedures, timeliness of decisions, rates of annulment, documented reasons for corrective measures and the treatment of operator complaints. However, quantitative indicators require careful interpretation. A high rate of annulment may reveal legal deficiencies, but it may also be influenced by the nature of cases selected for litigation. Similarly, a low sanction rate does not necessarily indicate ineffective enforcement.

The objective should be legally sound and scientifically credible official controls, not the maximisation of punitive outcomes.

Analytical framework: The Official Accountability and Misconduct Assessment Framework

The present research proposes the **Official Accountability and Misconduct Assessment Framework (OAMAF)** to distinguish unlawful administrative conduct from personal disciplinary, patrimonial and criminal responsibility.

Dimension	Assessment question
Administrative act	What decision, omission or material conduct is challenged?
Legal authority	What statutory power was exercised or omitted?
Objective legality	Was the conduct compatible with the applicable law?
Professional duty	Which official duties governed the conduct?
Attribution	Which authority or individual performed the relevant act?
Mental element	What evidence supports negligence, gross negligence or intentional conduct?
Harm	What consequences are established and causally connected?
Disciplinary classification	Does the conduct satisfy a specific disciplinary infringement?
Criminal classification	Are the elements of a particular offence supported by evidence?
Institutional responsibility	Did organisational deficiencies contribute to the conduct?
Appropriate remedy	Is annulment, compensation, disciplinary review or criminal investigation legally justified?

The framework is an original analytical proposal, not an established statutory or judicial test. Its principal contribution is to prevent the automatic escalation of administrative disagreement into allegations of personal criminal misconduct. It also prevents the opposite error: assuming that administrative annulment is always the only possible consequence of unlawful official conduct. The correct response depends upon the legal nature of the conduct and the evidence available.

A graduated accountability model

The framework distinguishes five situations.

Level I - Lawful professional disagreement Different technical interpretations are advanced within the legally permitted margin of assessment. No misconduct follows merely from disagreement.

Level II - Administrative error or invalidity An act may require correction or annulment without necessarily establishing personal culpability.

Level III - Negligent or deficient performance The conduct may require supervisory or disciplinary assessment, depending upon the applicable statutory duties and degree of fault.

Level IV - Serious disciplinary or patrimonial responsibility Conduct satisfying the relevant statutory thresholds may justify disciplinary sanctions or recovery proceedings under Article 36 of Law 40/2015.

Level V - Potential criminal misconduct

Where evidence supports the constituent elements of a specific criminal offence, the conduct may warrant criminal investigation and adjudication. These levels are analytical categories, not a statutory hierarchy of offences. A particular case may engage more than one form of responsibility.

Practical case studies

Case A. An incorrect technical interpretation: An inspector concludes that a manufacturer's preservation system fails to comply with food hygiene legislation. The operator produces technical evidence demonstrating compliance. The competent authority subsequently withdraws the corrective requirement. The

withdrawal may establish that the original measure should not have been maintained.

However, it does not automatically establish disciplinary misconduct or criminal prevarication. Further analysis would be required to determine whether the inspector acted negligently or deliberately.

Case B. Repeated inspections following a successful appeal: A manufacturer successfully challenges a sanction. The establishment subsequently receives unusually frequent inspections.

The operator alleges retaliation. The appropriate legal analysis should examine inspection selection criteria, the relevant risk profile, comparable establishments, internal communications and the stated reasons for the inspections. The chronology may be relevant but is not conclusive. The legal question is whether the available evidence supports an improper purpose or another legally relevant infringement.

Case C. Alleged falsification of an inspection observation: An inspection report states that a production line was operating when the operator maintains that it was stopped. Contemporaneous equipment records and video evidence appear inconsistent with the report. The discrepancy may justify evidentiary challenge and further investigation. However, criminal falsification requires proof of the relevant statutory elements. The operator should distinguish evidence establishing factual inaccuracy from evidence establishing deliberate falsification.

Case D. Disclosure of confidential manufacturing information: An inspector obtains proprietary process documentation during an official control. The operator later discovers that the information has been disclosed to an unrelated commercial entity. The legal analysis must determine what information was disclosed, whether it was protected, who disclosed it, whether disclosure was authorised and what damage resulted. Depending upon the circumstances, confidentiality, disciplinary, patrimonial or criminal consequences may arise.

Case E. Failure to comply with a judicial decision: A court issues a binding decision concerning an administrative restriction. The competent authority fails to implement the required measures. The affected operator seeks enforcement. The primary legal response may involve judicial execution proceedings.

Where evidence supports deliberate refusal satisfying the statutory requirements, separate criminal questions may arise. However, non-execution alone does not automatically establish criminal liability.

Chapter conclusions

The accountability of food inspection authorities is an essential component of lawful public administration. Spanish law provides several distinct mechanisms for addressing unlawful official conduct. Administrative review permits correction or annulment of defective decisions. Public liability may provide compensation for legally compensable damage attributable to the functioning of public services. Disciplinary law governs misconduct by public employees.

Article 36 of Law 40/2015 establishes mechanisms for recovery from officials whose intentional conduct, gross fault or gross negligence has caused relevant damage. Criminal law addresses exceptional forms of misconduct satisfying specific statutory offences. These mechanisms must not be conflated. An unlawful administrative act does not automatically establish personal culpability. A negligent decision does not automatically constitute criminal prevarication.

A factual discrepancy does not necessarily prove documentary falsification. And an allegation of retaliation requires evidence supporting the claimed improper purpose. Nevertheless, the existence of these distinctions must not be interpreted as immunity from accountability.

The central doctrinal conclusion is:

Official food control powers must be exercised with technical independence and sufficient authority to protect public health, but that independence does not exempt public officials or institutions from the legal consequences of negligence, abuse of power, deliberate misconduct or other conduct satisfying the applicable statutory requirements.

CHAPTER 13

Comparative Administrative Law and Institutional Reform

Comparative analysis helps identify practices worth examining, but procedural solutions cannot be transferred mechanically across jurisdictions. This chapter develops a restrained reform agenda grounded in the Spanish and European legal frameworks.

The comparative problem: Similar objectives, different legal systems

Food safety authorities in Europe, the United Kingdom and the United States pursue broadly comparable objectives. They seek to prevent unsafe food from reaching consumers, detect regulatory non-compliance, investigate incidents and impose legally authorised corrective or punitive measures. However, the legal structures through which these objectives are pursued differ substantially. European Union food law establishes directly applicable requirements and a common framework for official controls, while implementation and enforcement remain distributed among competent authorities.

The United Kingdom operates through domestic legislation, retained or assimilated food law as amended, statutory codes and distinct regulatory arrangements across its constituent nations. The United States relies upon federal and state legislation, administrative agencies and judicial review mechanisms reflecting its constitutional and statutory traditions.

Consequently, a comparative study must distinguish three levels:

- **Substantive obligations:** What must food businesses do?
- **Enforcement powers:** What may the competent authority require or prohibit?
- **Procedural accountability:** How may the operator challenge the authority's action?

A similarity at one level does not establish equivalence at the others. For example, two jurisdictions may require risk-based food inspections while providing different procedures for contesting sampling results or enforcement notices. The comparative objective is therefore not to identify a universally superior model. It is to determine which institutional mechanisms improve legality, technical reliability and accountability within their respective legal frameworks.

The European Union model: Harmonisation without complete administrative uniformity

Regulation (EU) 2017/625 as the institutional foundation

Regulation (EU) 2017/625 establishes the principal horizontal framework governing official controls across the agri-food chain. It addresses competent authorities, risk-based controls, transparency, official laboratories, sampling, administrative cooperation and enforcement. Article 9 establishes the general risk-based approach to official controls. Article 6 requires competent authorities to conduct or arrange audits of their own activities. Article 7 recognises rights of appeal concerning decisions taken by competent authorities under the Regulation.

Articles 34–39 establish requirements concerning sampling and official laboratories. Articles 137–138 address enforcement action where non-compliance is suspected or established. These provisions create a common legal architecture, but they do not establish a single European inspection service exercising every control throughout the Union.

National administrative autonomy

Member States designate competent authorities and organise the performance of official controls within the requirements established by Union law. This permits institutional diversity. In Spain, autonomous communities exercise substantial responsibilities for food controls within their competences. Other Member States may adopt different organisational structures. However, national

administrative autonomy remains constrained by Union law, including the principles of effectiveness and equivalence where applicable.

The existence of institutional diversity does not authorise Member States to undermine the substantive or procedural guarantees established by Union legislation.

Administrative cooperation and cross-border consistency

Food supply chains frequently cross national borders. A product manufactured in one Member State may be distributed throughout the internal market. Inconsistent enforcement interpretations can therefore produce consequences beyond the territory of the authority adopting them. Regulation (EU) 2017/625 establishes mechanisms for administrative assistance and cooperation. These mechanisms are intended to facilitate effective official controls and the exchange of relevant information.

Nevertheless, cooperation does not automatically eliminate differences in technical assessment. Authorities may still disagree concerning the significance of particular evidence. The legal challenge is to ensure that those disagreements are addressed through the appropriate institutional mechanisms rather than through unsupported unilateral requirements.

The importance of documented reasoning

The Union model relies upon traceable administrative decision-making. Inspection records, sampling documentation, laboratory reports and reasoned enforcement decisions contribute to the reviewability of official controls. However, documentation is not an end in itself. A technically extensive file may still fail to establish the legal basis for a restrictive measure. The relevant question is whether the evidence and reasoning support the particular administrative consequence imposed.

The United Kingdom: Statutory enforcement notices and structured regulatory discretion

Institutional arrangements

The United Kingdom's food safety enforcement system involves several institutions, including the Food Standards Agency, Food Standards Scotland and local enforcement authorities. The precise allocation of responsibilities differs among England, Wales, Scotland and Northern Ireland. The Food Standards Agency is not the sole body conducting every food inspection throughout the United Kingdom. Local authorities perform substantial enforcement functions, while central agencies provide regulatory oversight, policy coordination and technical support within their respective remits.

Following the United Kingdom's withdrawal from the European Union, the applicable food law framework must be examined separately for Great Britain and Northern Ireland. It would be inaccurate to treat the United Kingdom as a single undifferentiated regulatory jurisdiction.

The Food Safety Act 1990

The Food Safety Act 1990 remains an important statutory foundation for food safety enforcement. Section 10 provides for improvement notices where an authorised officer has reasonable grounds for believing that a food business is failing to comply with relevant regulations. The notice must identify the grounds for the officer's belief, specify the matters constituting non-compliance and identify the measures considered necessary to secure compliance. The provision is particularly interesting from a comparative perspective because it expressly contemplates compliance through the specified measures or measures at least equivalent to them.

The statutory mechanism therefore recognises a distinction between the required regulatory outcome and the particular technical method proposed by the inspector.

An important lesson for *innovative food technologies*

Consider a manufacturer operating an **unconventional but validated sanitation process**. An enforcement officer identifies a deficiency and proposes a corrective method. The British statutory formulation illustrates an approach in which the operator may satisfy the requirement through an equivalent measure, provided the applicable conditions are met. This is not a universal right to substitute any method preferred by the manufacturer. Nor does it override legislation requiring a specific procedure.

Its significance lies in the explicit recognition that **regulatory compliance may sometimes be achieved through technically equivalent solutions**. For Spanish reform, the relevant principle would be to distinguish legally mandatory methods from outcome-based obligations permitting validated alternatives.

Appeals against improvement notices

Sections 37–39 of the Food Safety Act 1990 establish judicial appeal arrangements for specified enforcement decisions, including improvement notices. The appeal framework allows judicial scrutiny of the notice and, under Section 39, permits the court to cancel, affirm or modify it. Section 39 also addresses the treatment of compliance periods while an appeal is pending. These mechanisms illustrate a relatively direct statutory connection between an enforceable corrective notice and a defined judicial remedy.

The significance of statutory codes of practice

Food law codes of practice and associated guidance provide important operational frameworks for enforcement authorities. However, their precise legal status depends upon the enabling legislation and the particular instrument. A statutory code may have a different legal effect from ordinary advisory guidance. The distinction is relevant to Spain, where administrative manuals, interpretative criteria and technical recommendations are sometimes treated as though they were legally interchangeable. A sound system should identify clearly whether an instrument is binding law, a statutory code, an internal instruction or non-binding technical guidance.

The United States: FDA inspections, observations and escalating enforcement

Institutional architecture

The United States food safety system distributes responsibilities among federal and state authorities. The U.S. Food and Drug Administration regulates a broad range of foods and food establishments under the Federal Food, Drug, and Cosmetic Act and other applicable legislation. The United States Department of Agriculture (USDA), exercises important responsibilities concerning meat, poultry and certain egg products. State authorities also perform significant inspection and enforcement functions. The American model therefore cannot be reduced to FDA activity alone.

Risk-based inspection

The FDA describes its food inspection programme as risk-based, distinguishing surveillance inspections, compliance follow-up inspections and inspections initiated for specific causes. Relevant considerations include identified food safety risks and the history or circumstances of the facility. The approach reflects an institutional preference for allocating inspection resources according to risk rather than applying identical inspection frequencies to all operators. However, risk-based selection does not eliminate the need for statutory authority or procedural safeguards.

FDA Form 483

An important feature of the American inspection system is FDA Form 483, used to communicate inspectional observations concerning conditions that may constitute violations of applicable requirements. The FDA's published materials associate observations with relevant legal or regulatory citations and specific conditions identified during inspection. This structure is significant because it promotes an identifiable connection between observed facts and the regulatory provisions considered relevant. However, a Form 483 should not be equated automatically with a final agency determination of violation or with an

enforceable sanction. Its legal function differs from subsequent enforcement action.

Warning letters

FDA warning letters may identify significant regulatory concerns and request corrective action. They can have substantial commercial and reputational consequences. However, their legal status must be distinguished from formal judicial orders, administrative detention orders or other enforceable actions. The FDA publishes information concerning warning letters and their subsequent resolution, including close-out letters in appropriate circumstances. The system demonstrates the potential value of documenting not only alleged non-compliance but also the regulator's recognition that identified deficiencies have been adequately addressed.

The danger of importing American enforcement terminology into European law

Terms such as **warning letter**, **administrative detention**, **injunction** and **consent decree** have specific meanings within United States law. They should not be used as direct substitutes for Spanish concepts such as *requerimiento*, *medida provisional*, *inmovilización cautelar* or *resolución sancionadora*. The comparison must focus upon institutional function and legal safeguards rather than superficial similarities of terminology.

Comparative judicial review: Three different legal traditions

The European, British and American systems share a commitment to legal constraints upon administrative power. Nevertheless, their judicial review mechanisms differ.

Spain and the European administrative-law tradition

Spanish contentious-administrative jurisdiction permits review of administrative acts, certain procedural acts, inactivity and *vía de hecho*. The courts may examine legality, competence, procedure, evidentiary foundations, proportionality and the purposes for which administrative powers were

exercised. The availability of interim judicial measures is particularly important where food safety enforcement produces immediate economic consequences. The relevant framework is established principally by Law 29/1998.

The United Kingdom

British food legislation provides specific appeal mechanisms for particular enforcement notices and orders. Judicial review may also be available under the applicable public-law framework. However, the existence of a statutory appeal can affect the appropriateness or availability of judicial review. The applicable remedy therefore depends upon the nature of the challenged action. A manufacturer should not assume that every dispute with a British food authority proceeds through the same judicial route.

The United States

United States administrative law includes judicial review under the Administrative Procedure Act, subject to statutory conditions, exclusions and the requirement that the challenged conduct be reviewable agency action. Under 5 U.S.C. § 706, reviewing courts apply standards that include the prohibition of arbitrary or capricious agency action, subject to the applicable statutory framework. However, not every FDA inspection observation or preliminary communication is immediately reviewable as final agency action. The distinction between preliminary regulatory communication and legally operative agency action is therefore important.

The common doctrinal problem

Across these systems, a recurring difficulty is the **distinction between regulatory communication and enforceable administrative action**. An inspector may express a concern. An authority may issue a formal notice. A laboratory may identify a potential hazard. A regulator may impose a restriction.

Each step may carry different legal consequences. The comparative lesson is that procedural rights should be connected to the actual legal and practical effects of the regulatory intervention, without treating every preliminary observation as a final administrative decision.

Risk-based inspection and the limits of selective enforcement

Risk differentiation is legitimate

A food manufacturer handling high-risk ready-to-eat products may reasonably be subject to a different inspection profile from an establishment performing lower-risk operations. Risk-based enforcement is therefore not inherently discriminatory. Indeed, Regulation (EU) 2017/625 requires competent authorities to take account of relevant risks and other statutory considerations.

Selective enforcement becomes problematic when risk cannot explain selection

Suppose two comparable manufacturers operate under similar conditions. One receives repeated inspections while the other receives substantially fewer. The difference may reflect legitimate risk factors. However, where the authority cannot identify relevant differences or explain departures from its ordinary selection criteria, questions concerning consistency and objectivity may arise. The legal significance depends upon the facts and the applicable constitutional and administrative principles.

The importance of documented selection criteria

A mature inspection system should be capable of explaining why a particular establishment was selected for control. This does not require disclosure of every confidential intelligence source or the advance announcement of inspections. It does require an institutional framework capable of demonstrating that inspection resources are allocated for legitimate regulatory reasons. Such documentation can protect both operators and inspectors. It assists operators in identifying potentially arbitrary patterns while providing authorities with evidence that their decisions were objectively justified.

Regulatory discretion and scientific disagreement

Technical discretion is not unlimited discretion

Food safety enforcement frequently requires expert judgment. Inspectors may need to evaluate unfamiliar processes, emerging hazards or incomplete scientific evidence. A regulator cannot always wait for complete certainty before acting. However, technical discretion must remain connected to the applicable legal powers and scientific evidence.

The precautionary principle

Article 7 of Regulation (EC) No 178/2002 recognises the precautionary principle under specified circumstances. Where an assessment of available information identifies the possibility of harmful effects on health but scientific uncertainty persists, provisional risk-management measures may be adopted under the conditions established by the provision. Such measures must be proportionate and reviewed within a reasonable period, depending upon the nature of the risk and the scientific information required. The principle does not authorise unrestricted intervention based upon unsupported speculation.

Nor does it require the authority to establish actual harm before acting where the statutory conditions for precautionary intervention are satisfied.

Innovative industrial processes

The comparative issue becomes particularly important *where manufacturers introduce innovative technologies*. An inspector may encounter a process not described in familiar technical guidance. **The absence of an established guidance document does not necessarily establish illegality.** The authority must determine whether the process satisfies the applicable regulatory requirements. Conversely, novelty does not exempt the operator from demonstrating compliance with legally required safety outcomes.

Where the technology falls within a specific authorisation regime, compliance with that regime remains necessary.

A proposed technical disagreement procedure

A useful reform would be to introduce a structured procedure for significant disputes concerning innovative processes. Such a procedure could permit the operator to submit technical validation data, identify the relevant legal requirements and obtain a reasoned assessment from appropriately qualified specialists. Where appropriate, the authority could consult independent expertise. However, the procedure should not delay urgent protective action where a legally sufficient public health risk requires immediate intervention. The objective would be to improve the quality of regulatory decisions, not to create a general exemption from enforcement.

A significant contemporary development: The United Kingdom's 2025 enforcement modernisation

In October 2025, the Food Standards Agency announced updated Food Law Codes of Practice and Practice Guidance for England, Wales and Northern Ireland. The stated objectives included greater flexibility in risk-based controls, improved consistency and more effective allocation of enforcement resources. This development is particularly relevant to the present research because it demonstrates that official food control systems are not institutionally static. Regulators themselves recognise the need to revise inspection models as industrial processes, market structures and risk information evolve.

The associated English practice guidance also addresses the distinction between legal requirements and advice, the documentation of departures from enforcement policies and the monitoring of official control quality.

Why this matters for Spain

A common regulatory weakness arises when inspection criteria evolve informally without corresponding updates to published guidance or internal training. **Different inspectors may then apply different interpretations to equivalent industrial processes.** An updated and accessible inspection framework can reduce that risk. However, a code of practice cannot legitimately replace the substantive requirements of binding legislation. The institutional value of guidance lies in promoting lawful and consistent enforcement.

The importance of differentiating advice from legal obligations

One particularly useful feature of the British approach is the emphasis placed upon distinguishing enforceable requirements from advice. For Spanish reform, this distinction could be incorporated into standard inspection documentation.

Every significant inspection demand could identify whether it constitutes:

- A binding statutory requirement.
- A formal corrective measure adopted under a specified legal power.
- A non-binding technical recommendation.
- A request for information within the authority's inspection powers.

Such classification would reduce disputes arising from the ambiguous presentation of recommendations as compulsory orders.

The United States Administrative Procedure Act and the review of regulatory reasoning

Section 706 of Title 5 of the United States Code provides standards governing judicial review of agency action. These include review of action that is arbitrary, capricious, an abuse of discretion or otherwise contrary to law. The provision also addresses action exceeding statutory authority, procedural violations and other legally specified defects. Section 706 further recognises judicial authority, under the applicable conditions, to compel agency action unlawfully withheld or unreasonably delayed.

The relevance of reasoned decision-making

The comparative importance of Section 706 lies partly in the requirement that agency action remain legally and rationally defensible. Regulatory expertise does not create unrestricted discretion. An agency must act within its statutory authority and satisfy the applicable standards of review. However, the precise intensity of judicial scrutiny depends upon the nature of the decision and the governing legal framework.

A necessary qualification concerning judicial deference

United States doctrine concerning judicial review of agency statutory interpretation has evolved significantly. Following the Supreme Court's 2024 decision in *Loper Bright Enterprises v. Raimondo*, courts exercising review under the Administrative Procedure Act must exercise independent judgment in determining the meaning of statutes rather than applying the former Chevron framework of deference merely because a statute is ambiguous. This development should not be confused with the separate treatment of agency fact-finding or technical expertise under applicable review standards.

The distinction reinforces a broader comparative principle:

Technical expertise may be relevant to the assessment of evidence, but it does not confer final authority upon an administrative agency to determine the meaning of legislation beyond judicial review.

The limits of transplantation

Spanish courts operate within a different constitutional and procedural framework. The American doctrine cannot be imported directly into Spanish administrative litigation. Nevertheless, the underlying question is comparable in terms of how should courts distinguish legitimate technical assessment from administrative interpretations that exceed statutory authority? The appropriate Spanish answer must be derived from the Constitution, applicable legislation and Spanish and European jurisprudence.

Comparative synthesis: Institutional strengths and limitations

Dimension	European Union / Spain	United Kingdom	United States
Principal framework	EU official controls and national administrative law	Domestic food legislation and statutory codes	Federal and state food law
Risk-based inspection	Expressly required under EU official controls	Incorporated into enforcement models and guidance	Central to FDA inspection prioritisation
Technical guidance	EU, national and regional materials	Statutory codes and practice guidance	Agency guidance and regulatory materials

Dimension	European Union / Spain	United Kingdom	United States
Corrective action	Measures under EU and national law	Improvement notices and other statutory measures	Agency enforcement tools under applicable statutes
Operator challenge	Administrative and judicial remedies	Statutory appeals and judicial review	Administrative and judicial remedies depending on action
Institutional oversight	Audits, supervision and judicial review	Central guidance, local accountability and courts	Agency oversight, judicial review and other institutional controls
Principal challenge	Territorial consistency and administrative fragmentation	Coordination across jurisdictions and authorities	Federal-state coordination and complexity of enforcement tools

The table describes broad institutional features rather than asserting that the systems are legally equivalent.

No system eliminates regulatory error

Risk-based inspection does not eliminate the possibility of inconsistent selection. Accredited laboratories do not eliminate analytical error. Statutory guidance does not prevent every unlawful instruction. Judicial review does not guarantee timely correction. The relevant measure of institutional quality is therefore not the absence of all error.

It is the capacity to identify, correct and prevent recurrent error while preserving effective public health protection.

The danger of measuring success through sanctions

A high number of sanctions may indicate active enforcement. It may also reflect persistent non-compliance or ineffective preventive strategies. A low number of sanctions may indicate high industry compliance. It may alternatively reveal inadequate enforcement. Neither measure is sufficient in isolation.

Regulatory performance should be evaluated through a broader combination of risk reduction, compliance outcomes, legal quality and institutional accountability.

Reform proposal I: A standardised legal-basis statement for significant inspection demands

A first reform would require significant inspection demands to identify their legal foundation. The document should distinguish the statutory obligation from the technical means proposed to achieve compliance. Where an inspector requires a particular corrective measure, the authority should explain why that measure is necessary or why the operator's proposed alternative is insufficient. This approach would not prevent urgent oral instructions where legally authorised. Nor would it eliminate the operator's duty to cooperate with official controls.

Its purpose would be to ensure that enforceable demands are traceable to an identifiable legal power.

Expected benefits

Such a system could improve administrative consistency, facilitate internal supervision and reduce litigation concerning ambiguous requirements. It could also protect inspectors by demonstrating the legal foundation for their decisions.

Potential limitations

Excessive documentation requirements could delay urgent protective intervention. The reform should therefore distinguish routine technical observations, formal corrective measures and emergency actions. The documentation burden should remain proportionate to the legal and practical consequences of the measure.

Reform proposal II: Independent technical review for complex industrial disputes

Food inspection disputes increasingly involve sophisticated technologies. Examples include novel preservation systems, advanced sanitation processes, non-conventional ingredients and innovative analytical methods. These disputes may exceed the specialised experience of an individual inspector. A structured mechanism for independent technical review could improve decision-making.

Proposed scope

The mechanism could apply where a dispute concerns a significant technical question, the legal framework permits alternative methods and the operator submits credible supporting evidence. The review could examine validation studies, analytical methodology, process controls and the relevant regulatory requirements.

Institutional independence

The reviewing experts should possess appropriate competence and be free from relevant conflicts of interest. Their conclusions should be documented. However, expert review should not automatically transfer statutory decision-making authority away from the competent administration. The final administrative decision would remain subject to the applicable legal framework.

Urgent risk exceptions

The review mechanism should not prevent prompt intervention where a credible and legally sufficient public health risk requires immediate action. In such circumstances, technical review could proceed alongside proportionate protective measures. The objective is not to subordinate food safety to commercial convenience. It is to ensure that scientific uncertainty is addressed through technically competent and legally accountable procedures.

Reform proposal III: A national consistency mechanism for harmonised food requirements

Spain's territorial organisation creates particular challenges concerning the uniform application of harmonised European food legislation. Autonomous communities exercise significant responsibilities for official controls. However, divergent interpretations of directly applicable Union requirements may generate uncertainty for manufacturers operating across several territories. A national consistency mechanism could assist in identifying and addressing recurring interpretative disputes.

Proposed functions

The mechanism could collect anonymised cases involving divergent interpretations, identify recurring technical questions and facilitate coordinated guidance. It could also encourage consultation between competent authorities where a dispute has implications beyond a single territory.

Respect for constitutional competences

Any mechanism would need to respect the distribution of competences established by the Constitution, statutes of autonomy and applicable legislation. It should not be designed as an informal means of transferring powers away from competent autonomous-community authorities. Its function would be coordination and consistency, not unauthorised centralisation.

Publication of interpretative criteria

Where legally appropriate, coordinated criteria could be published. Such publication would improve predictability. However, interpretative guidance must remain distinguishable from binding legislation. An agreed administrative interpretation cannot amend a directly applicable European regulation.

Reform proposal IV: A transparent system for evaluating inspection quality

Regulatory authorities should evaluate not only the quantity of official controls but also their quality. A structured system could examine legal compliance, scientific reliability, proportionality and the treatment of operator rights. Possible indicators include:

Indicator	Purpose
Quality of legal reasoning	Assess whether significant measures identify their statutory foundation
Sampling compliance	Evaluate adherence to applicable sampling procedures
Technical consistency	Identify unexplained differences in equivalent cases
Decision timeliness	Detect unjustified delays affecting operators
Corrective effectiveness	Assess whether interventions resolve identified risks

Indicator	Purpose
Appeal outcomes	Identify recurring legal or evidentiary defects
Confidentiality incidents	Monitor handling of protected industrial information
Internal audit findings	Support continuous institutional improvement

Avoiding misleading performance incentives

Inspection quality indicators must not create incentives to minimise the recording of problems. For example, measuring success solely through low annulment rates could discourage appropriate risk-taking or encourage authorities to avoid difficult cases. Similarly, rewarding the number of sanctions could encourage excessive punitive activity. Indicators should therefore be interpreted collectively and subjected to independent scrutiny.

Analytical framework: The Comparative Regulatory Accountability and Quality Framework

The present research proposes the **Comparative Regulatory Accountability and Quality Framework (CRAQF)** as an analytical instrument for evaluating food safety enforcement systems. The framework is an original research proposal, not an existing statutory or internationally recognised assessment standard. It comprises eight dimensions.

Dimension	Core assessment
1. Legality	Are enforcement actions traceable to valid legal powers?
2. Scientific reliability	Are technical findings supported by appropriate evidence and methods?
3. Risk orientation	Are inspection resources allocated according to relevant risks?
4. Consistency	Are comparable cases treated according to coherent criteria?
5. Proportionality	Are interventions appropriate to the risk and legal objective?
6. Procedural protection	Can operators understand and challenge adverse decisions?
7. Institutional accountability	Are errors, misconduct and systemic deficiencies independently reviewable?
8. Regulatory adaptability	Can the system evaluate innovative technologies without arbitrary barriers?

From enforcement intensity to enforcement quality

The proposed framework rejects the assumption that more intensive enforcement is necessarily better enforcement. The number of inspections or sanctions may be relevant to institutional performance. However, these indicators must be evaluated alongside compliance outcomes, legal quality and the effectiveness of risk reduction. A regulator that conducts fewer but better-targeted inspections may achieve stronger public health protection than one relying upon indiscriminate inspection frequency. Conversely, reducing inspections without adequate risk assessment may weaken consumer protection.

The appropriate objective is not minimal enforcement. It is effective, proportionate and legally accountable enforcement.

A possible empirical research programme

The framework could support comparative empirical research involving Spain, the United Kingdom and selected United States jurisdictions. Potential research questions include whether documented legal-basis requirements reduce successful appeals, whether independent technical review improves the resolution of scientific disputes and whether greater transparency improves consistency. Such hypotheses would require testing. The present article does not claim that these outcomes have already been empirically demonstrated.

Methodological limitations

Comparative institutional performance cannot be assessed solely through published sanction counts. Differences in legal definitions, industrial structures, reporting systems and risk profiles may distort comparisons. A rigorous study would require harmonised variables, transparent data selection and careful treatment of confounding factors. The CRAQF should therefore be understood as a proposed research architecture rather than a validated performance index.

Chapter conclusions

The European Union, the United Kingdom and the United States employ different legal and institutional approaches to official food controls. Despite these differences, several common principles emerge. Inspection powers require

a legal foundation. Risk-based selection can improve the allocation of regulatory resources. Technical findings must remain open to appropriate scrutiny.

Enforceable measures should be distinguishable from advisory guidance. Operators must have access to the procedural remedies established by law. And institutions should possess mechanisms for identifying and correcting regulatory error. The United Kingdom's improvement-notice system provides a useful illustration of the distinction between mandatory compliance outcomes and technically equivalent corrective measures. The United States FDA system demonstrates the importance of structured inspection observations and differentiated enforcement mechanisms.

European Union law provides a common framework for risk-based controls, laboratory competence, cooperation and appeal rights. For Spain, the most promising reform opportunities concern legal clarity, technical consistency, independent review, institutional coordination and systematic evaluation of inspection quality.

The central doctrinal conclusion is:

The legitimacy of food safety enforcement should be measured not by the intensity of administrative intervention, but by its capacity to protect public health through legally authorised, scientifically credible, proportionate and effectively reviewable decisions. Principal legal and institutional references

- Regulation (EU) 2017/625 — Articles 6, 7, 9, 34–39 and 137–138.
- Regulation (EC) No 178/2002 — Article 7, precautionary principle.
- Spanish Constitution — Articles 9.3, 103 and 106.
- Law 29/1998 — Judicial review of administrative action.
- United Kingdom Food Safety Act 1990, Section 10 — Improvement notices.
- United Kingdom Food Safety Act 1990, Section 39 — Appeals against improvement notices.
- Food Standards Agency, 2025 Food Law Code modernisation.
- Food Standards Agency, Food Law Practice Guidance (England), 2025.
- FDA, Inspections to Protect the Food Supply.
- FDA, Inspectional Observations and Citations.

- United States Code, 5 U.S.C. § 706 — Judicial review of agency action.
- *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024) — Judicial interpretation of statutes under the Administrative Procedure Act.

CHAPTER 14

An Integrated Model of Lawful and Accountable Food Control

The final chapter brings the separate doctrinal analyses into a coherent account of legitimate enforcement. It identifies institutional improvements that follow from existing duties and distinguishes those from proposals requiring further evidence or legislative change.

Introduction: From individual illegality to systemic regulatory design

The constitutional limits of official food controls cannot be understood exclusively through the examination of individual administrative acts. An unlawful inspection requirement may arise from a mistaken interpretation of legislation. However, repeated mistakes may reveal deeper institutional problems. These may include insufficient legal training, inconsistent technical criteria, inadequate supervisory procedures, poorly defined decision-making responsibilities or the absence of mechanisms for reviewing complex scientific disputes. Similarly, excessive enforcement may result not from deliberate misconduct but from organisational incentives that reward inspection volume rather than the quality of regulatory outcomes. A comprehensive legal analysis must therefore address two distinct questions.

First, what makes an individual inspection or enforcement decision lawful?

Second, what institutional arrangements make lawful decisions more likely, errors more detectable and corrective action more effective?

The first question concerns administrative legality. The second concerns regulatory governance. A mature food control system requires both. The reform objective is not to reduce the capacity of competent authorities to intervene where public health is threatened. Nor is it to establish a presumption that industrial operators are compliant merely because they possess technical expertise or private certifications.

The objective is to ensure that intervention is grounded in identifiable legal authority, supported by appropriate evidence and subject to proportionate and effective review. This requires a transition from a predominantly event-based conception of inspection to a lifecycle-based conception of regulatory accountability.

The constitutional architecture of legitimate food enforcement

Legality as the foundation

Article 9.3 of the Spanish Constitution, (CE), guarantees legal certainty, the hierarchy and publicity of norms, and the prohibition of arbitrariness. Article 103.1 requires public administration to act objectively and with full submission to law. Article 106.1 establishes judicial control over administrative action and its submission to the purposes justifying it. These provisions form the constitutional foundation of legitimate official controls. However, they do not prescribe every operational procedure that an inspection authority must follow.

Their implementation depends upon European Union legislation, Spanish statutes, applicable autonomous-community rules and judicial interpretation. The proposed reform model must therefore operate within the existing hierarchy of norms.

Public health as a constitutional objective

Article 43 CE recognises the right to health protection and assigns public authorities responsibilities concerning public health. Food safety enforcement contributes directly to this constitutional objective. Nevertheless, the importance of public health does not eliminate the other constitutional guarantees. The Administration must pursue health protection through legally authorised means. The constitutional system does not establish an unrestricted exception to legality whenever an authority invokes food safety.

Freedom of enterprise

Article 38 CE recognises freedom of enterprise within the framework of the market economy. This freedom is subject to lawful regulation, including

requirements necessary to protect public health. However, restrictions upon economic activity must possess an adequate legal foundation and satisfy the applicable requirements of proportionality. A manufacturer has no constitutional entitlement to market unsafe food. Equally, an inspector cannot impose an otherwise unsupported technological or commercial restriction solely because the inspector considers it preferable.

Effective judicial protection (*Tutela Judicial Efectiva*)

Article 24 CE establishes the right to effective judicial protection. In food safety enforcement, this guarantee has particular importance because administrative measures may produce irreversible consequences before final judicial review. The availability of appeals must therefore be considered alongside the effectiveness of interim protection, procedural timeliness and appropriate remedies. A legal system that permits eventual annulment but cannot address avoidable irreversible damage may present a significant problem of remedial effectiveness.

The European regulatory foundation: Regulation (EU) 2017/625

Regulation (EU) 2017/625 provides the principal horizontal framework for official controls throughout the agri-food chain. Its provisions address risk-based inspections, competent authorities, transparency, official laboratories, sampling, administrative cooperation and enforcement. The Regulation establishes important constraints upon national reform. Spain cannot unilaterally replace directly applicable Union requirements with inconsistent domestic procedures. Nor can administrative guidance lawfully amend obligations established by Union legislation.

However, Member States retain responsibilities concerning institutional organisation, procedural implementation and enforcement within the limits established by Union law.

Risk-based official controls

Article 9 requires official controls to be performed regularly, on a risk basis and with appropriate frequency. Relevant factors include identified risks, the operator's compliance record, the reliability of its own controls and other information indicating possible non-compliance. This approach rejects the assumption that every food establishment should receive identical inspection treatment. Risk differentiation is a legitimate component of effective enforcement. However, risk-based selection must remain distinguishable from arbitrary targeting.

Administrative accountability

Article 6 requires competent authorities to conduct internal audits or have audits conducted on themselves, and to take appropriate measures in light of the results. This provision creates an important institutional foundation for quality assurance. It demonstrates that regulatory performance is itself subject to systematic examination.

Rights of appeal

Article 7 recognises a right of appeal concerning decisions taken by competent authorities under the Regulation. The provision also requires written notification of decisions and information concerning the reasons and applicable appeal procedures, subject to the relevant legal framework. This requirement supports the principle that significant enforcement decisions should be legally identifiable and reviewable.

Suspected and established non-compliance

Articles 137 and 138 distinguish action where non-compliance is suspected from action where it is established. The distinction is essential to the proposed model. Preventive intervention may be justified before every factual question has been conclusively resolved. However, the legal basis, evidentiary threshold and proportionality of the measure must correspond to its purpose and consequences. A precautionary restriction must not be treated as conclusive proof of a punishable infringement.

A critical legislative qualification: The 2025–2026 Spanish official-controls framework

A reform programme must begin with an accurate account of existing law. Royal Decree 562/2025 introduced significant provisions complementing Regulation (EU) 2017/625. The consolidated Spanish text consulted for this edition includes the amendment published on 30 September 2026. This development means that several safeguards proposed in abstract terms already possess a statutory foundation. The research must distinguish deficiencies in the law from deficiencies in implementation.

Written records and rapid factual verification

The decree contains requirements concerning the written recording of official controls and, under the relevant conditions, provides an opportunity to request a new official control when the operator disputes what was recorded. This is an important existing safeguard. A proposed reform should therefore focus on whether operators are adequately informed of the procedure, whether requests are processed correctly and whether the mechanism provides effective review in practice.

Second expert opinions

The decree also establishes detailed procedures for the second expert opinion recognised by Article 35 of Regulation (EU) 2017/625. For relevant unfavourable analytical findings, the operator may request documentary review, a second analysis where legally and technically available, or both. The procedure is subject to specific conditions and deadlines. A further point deserves emphasis: Article 31.4 of the consolidated text provides that, where a second analysis, test or diagnosis is performed under that provision, its result prevails over the first. This statutory rule must be distinguished from a general proposition that any privately commissioned contradictory analysis automatically supersedes an official finding.

The two situations are not legally equivalent.

Consequences for the reform programme

The appropriate question is not simply whether Spain should recognise technical contradiction. It already does so within the statutory framework. The research should instead investigate whether the rights are effectively communicated, whether technical feasibility is assessed consistently and whether operators possess practical access to qualified experts and eligible laboratories. The distinction between formal recognition and effective exercise of rights is central to regulatory accountability.

Reform architecture: What can be changed without amending legislation?

Not every institutional improvement requires a new statute. Many deficiencies may be addressed through administrative organisation, staff training, internal auditing and clearer communication. However, administrative reform must remain within the powers of the relevant authority.

Administrative improvements

Potential measures include standardised inspection report templates, legal-basis checklists, documented escalation procedures for technical disputes and improved staff training. Authorities could also establish internal procedures for identifying inconsistent interpretations. These measures may improve decision-making without changing substantive legal obligations.

Measures requiring formal regulatory action

Other reforms may require a regulatory instrument. Examples could include additional procedural specifications, new interadministrative coordination arrangements or legally binding documentation requirements. Their adoption would require examination of competence, legal hierarchy, statutory authorisation and the applicable rulemaking procedure.

Measures requiring legislation

Reforms affecting fundamental procedural rights, sanctioning powers, statutory deadlines or the allocation of competences may require legislative amendment. The appropriate legal instrument depends upon the subject matter. A national statute cannot simply override the constitutionally established distribution of powers. Nor can domestic legislation displace directly applicable Union requirements.

Matters requiring European Union action

Certain reforms would require changes at Union level. Examples could include alterations to harmonised official-control obligations or the substantive conditions established by directly applicable regulations. Spain may advocate such changes through the relevant European institutions. However, it cannot implement them unilaterally where Union law precludes national divergence.

The proposed Constitutionally Accountable Food Control Model

The research proposes the **Constitutionally Accountable Food Control Model (CAFCoM)** as an *integrated architecture for the governance of official food controls*. The model is an original academic proposal. It does not represent an existing Spanish statutory system or a formally adopted European regulatory standard. It organises regulatory intervention into nine stages.

CAFCoM · REGULATORY LIFECYCLE

Conceptual framework. The stages describe an accountability lifecycle, not a mandatory sequence for every inspection. Urgent protective action may lawfully precede ordinary participation or review where the applicable legislation permits it.

Risk-based selection

Inspection selection should reflect relevant risks and the statutory criteria governing official controls. The authority should maintain sufficient records to demonstrate that its approach is objective and defensible. This does not require

disclosure of confidential intelligence or advance notification of unannounced inspections.

Legal authority

Before imposing a compulsory requirement, the authority should identify the legal power under which it acts. This stage distinguishes binding legislation from technical guidance, voluntary standards and individual professional preferences.

Evidence collection

Sampling, document review, observations and technical investigations must comply with the applicable procedural and scientific requirements. Evidence should be sufficiently traceable to permit subsequent assessment.

Scientific assessment

The authority should distinguish established facts, scientific uncertainty, technical interpretation and legal classification. A laboratory finding should not automatically be equated with proof of a sanctionable infringement.

Operator participation

The operator should be afforded the rights established by the relevant procedural framework. These may include access to documentation, allegations, expert review and opportunities to submit evidence. Urgent measures may require adaptations expressly permitted by law.

Reasoned decision

Significant restrictive measures should identify their legal foundation, factual basis and the reasoning supporting the selected intervention.

Proportionate enforcement

The authority should select measures consistent with the applicable statutory powers and proportionality requirements. Article 4 of Law 40/2015 expressly

addresses the selection of less restrictive measures, the justification of intervention and the periodic evaluation of its effects.

Independent review

Administrative and judicial review should permit meaningful examination of the decision's legality and evidentiary basis. The availability of interim protection is particularly important where irreversible consequences are possible.

Institutional learning

Inspection outcomes, successful challenges, laboratory disputes and internal audit findings should inform future training and procedural improvement. The objective is to prevent repeated institutional error.

Integrating the doctrinal frameworks developed throughout the research

the preceding chapters introduced several analytical frameworks addressing different aspects of official controls. These should not remain isolated conceptual models. Their value lies in their integration.

Analytical domain	Function within CAFCoM
Legality and proportionality	Determines whether intervention possesses a valid legal basis and justified scope
Normative status and enforceability	Distinguishes binding obligations from guidance, standards and private commitments
Scientific precaution	Evaluates intervention under uncertainty
Official analytical evidence integrity	Examines sampling, laboratory competence and evidentiary reliability
Administrative sanctioning legality	Separates objective non-compliance from punishable responsibility
Effective enforcement remedies	Identifies appropriate administrative and judicial responses
Official accountability	Distinguishes institutional error, disciplinary misconduct and criminal responsibility
Comparative regulatory quality	Provides criteria for institutional evaluation and reform

The problem of excessive conceptual fragmentation

An analytical framework is useful only if it clarifies legal reasoning. An excessive proliferation of acronyms may obscure rather than improve the analysis. For the definitive academic publication, the individual frameworks should therefore be consolidated into a single coherent architecture. CAFCoM would function as the overarching model. The earlier frameworks would become specialised assessment modules.

Legal validity and scientific validity

The integrated model must preserve a fundamental distinction. A scientifically credible finding does not automatically justify every administrative consequence. Similarly, an administratively correct procedure does not guarantee that the scientific assessment is sound. Both dimensions require independent examination.

The significance of proportionality

Proportionality connects legal validity and technical assessment. An authority may possess power to intervene and reliable evidence of a hazard. Nevertheless, the selected measure must still satisfy the applicable proportionality requirements. The least restrictive measure principle does not necessarily require selecting the least burdensome measure imaginable. It requires selecting an appropriate measure within the legally relevant assessment of effectiveness, necessity and competing interests.

Industrial innovation and technological neutrality

The regulatory challenge

Food manufacturing increasingly incorporates technologies that do not fit neatly within traditional inspection manuals. These may include advanced preservation systems, innovative packaging, automated monitoring, novel analytical techniques and non-conventional processing methods. The existence of technological novelty may create uncertainty. However, unfamiliarity is not

itself a legal category of non-compliance. The competent authority must identify the applicable requirements and determine whether the process satisfies them.

The limits of technological neutrality

Technological neutrality should not be misunderstood as an unconditional right to use any industrial technology. Some technologies, ingredients or processes fall within specific authorisation regimes. Where legislation requires prior approval, the operator must comply. Similarly, performance-based requirements may necessitate substantial validation evidence. The principle proposed here is narrower.

Where the applicable legal framework permits alternative methods, the Administration should assess their demonstrated compliance rather than impose an unsupported preference for familiar technology.

The operator's evidentiary responsibility

Innovation does not eliminate the operator's responsibility for food safety. Under Article 17 of Regulation (EC) No 178/2002, food business operators have primary responsibilities concerning compliance with relevant food law requirements. The operator must therefore possess the evidence required to establish that its processes meet applicable obligations. A proprietary technology cannot be defended solely by invoking commercial confidentiality. Confidential information may need to be made available to competent authorities under the relevant statutory powers, subject to applicable safeguards.

A proposed innovation review protocol

For complex cases, the competent authority could establish a structured technical review procedure. The operator would identify the regulatory requirements and provide validation evidence. The authority would identify unresolved scientific or legal questions. Where necessary, independent specialists could evaluate the evidence. The procedure should permit proportionate protective intervention where legally justified.

Its purpose would be to improve the quality of technical assessment rather than create an exemption from ordinary food law.

Confidentiality as a structural requirement of trustworthy inspection

Industrial confidentiality is frequently treated as a secondary issue. That approach is inadequate. Food inspection authorities may obtain access to commercially sensitive information that would not ordinarily be disclosed to competitors, customers or the public. Such information may include formulations, manufacturing parameters, proprietary analytical methods and supplier arrangements. Regulation (EU) 2017/625 establishes confidentiality requirements under Article 8.

Spanish trade secret legislation may also be relevant, subject to the applicable legal conditions.

Confidentiality and regulatory cooperation

Operators may be more willing to provide detailed technical evidence where they can rely upon lawful protection of confidential information. This proposition is plausible but requires empirical validation. It should not be presented as an established causal relationship without supporting research.

A proposed confidentiality protocol

A structured protocol could identify confidential materials, restrict unnecessary dissemination, document authorised access and establish procedures for legally required disclosure. Such arrangements should respect transparency obligations and the legal powers of competent authorities. Confidentiality must not become a mechanism for concealing unlawful conduct. The objective is to protect legitimate industrial information while preserving effective official controls.

Administrative remedies and the problem of irreversible harm

The temporal asymmetry

Official controls may produce immediate consequences. Judicial review may occur much later. This creates a particular difficulty for perishable products,

time-sensitive supply contracts and continuous manufacturing operations. A measure may be annulled after the commercial opportunity it affected has disappeared.

The existing legal framework

Law 39/2015 regulates administrative appeals and suspension of challenged acts. Article 117 establishes the general rule that filing an administrative appeal does not automatically suspend enforcement, while providing mechanisms for suspension under specified conditions. Law 29/1998 establishes judicial precautionary measures, including mechanisms for urgent protection. These safeguards are significant. However, their practical effectiveness depends upon the circumstances of the case and the ability to obtain a timely decision.

Proposed institutional improvements

Authorities could develop rapid internal review procedures for particularly burdensome measures. Such procedures might involve prompt reconsideration of restrictions where new technical evidence emerges. They should not replace statutory appeals or judicial remedies. Nor should they prevent necessary protective action. Their purpose would be to correct avoidable errors before irreversible consequences arise.

Compensation as a secondary safeguard

Compensation may address certain legally compensable losses. However, monetary relief cannot always restore customer relationships, lost production opportunities or damaged market positions. This supports the importance of timely review. Nevertheless, the existence of potential economic damage does not automatically justify lifting restrictions necessary to protect public health.

A regulatory quality index: Methodological proposal

The research proposes the development of a **Regulatory Legitimacy and Quality Index (RLQI)** as a potential empirical instrument. The index would not measure success through sanction totals alone. Instead, it would evaluate multiple dimensions of regulatory performance.

Proposed analytical dimensions

Legal basis

Are decisions grounded in identifiable powers?

Scientific quality

Are technical findings reliable?

Proportionality

Are measures justified in scope and intensity?

Consistency

Are comparable cases treated coherently?

Timeliness

Are decisions and reviews completed promptly?

Operator rights

Are procedural guarantees respected?

Accountability

Are errors independently examined?

Risk reduction

Do controls achieve relevant safety outcomes?

Why a composite index may be useful

A composite instrument could support comparison among inspection programmes and identify areas requiring improvement. However, its design would require careful methodological development. Indicators should be measurable, relevant and resistant to manipulation.

The weighting problem

Different dimensions may not be equally important. For example, a serious failure to protect public health cannot necessarily be offset by excellent administrative timeliness. Similarly, a high level of scientific competence does not compensate for deliberate unlawful conduct. A simple arithmetic average could therefore produce misleading results. The proposed index should consider

minimum thresholds or non-compensatory criteria for fundamental legal and safety requirements.

The need for empirical validation

The index is not yet validated. Future research would need to define variables, test reliability, examine inter-rater consistency and evaluate whether the instrument predicts meaningful regulatory outcomes. Without such work, the index should remain a conceptual research proposal rather than an operational performance score.

A phased implementation strategy for Spain

An integrated reform programme should distinguish immediate administrative improvements from measures requiring legislative or institutional change.

Phase	Principal actions	Legal requirements
I. Administrative clarification	Standardised legal-basis statements, staff training and improved documentation	Generally possible within existing competences
II. Technical quality assurance	Specialist review, sampling audits and structured assessment of complex technologies	Administrative organisation; possible regulatory development
III. Institutional coordination	Shared interpretative criteria and inter-administrative consultation	Respect for national and autonomous-community competences
IV. Procedural enhancement	Review of deadlines, access to expertise and remedies for burdensome measures	May require statutory or regulatory amendment
V. Evaluation and research	Pilot testing of CAFCoM and the proposed quality index	Research design, institutional participation and data safeguards

Phase I: Administrative clarification

The initial priority should be to reduce ambiguity concerning inspection requirements. Significant compulsory demands should identify their legal foundation. Inspectors should distinguish recommendations from enforceable

obligations. Authorities should provide appropriate training concerning administrative procedure and proportionality.

Phase II: Technical quality assurance

The second phase should focus upon complex scientific disputes. Authorities could improve access to specialist expertise and standardise the review of unfamiliar technologies. Sampling and analytical procedures should be audited for compliance with applicable legal and scientific requirements.

Phase III: Institutional coordination

The third phase should address interpretative consistency across competent authorities. The objective would be to identify recurring disagreements and facilitate coherent application of harmonised requirements. Any coordination mechanism must respect the constitutional distribution of competences.

Phase IV: Procedural enhancement

A subsequent phase could evaluate whether existing remedies adequately protect operators against disproportionate or erroneous measures. Particular attention should be devoted to perishable goods, urgent restrictions and access to qualified technical review. Legislative change should be proposed only where a demonstrable deficiency cannot adequately be addressed through existing mechanisms.

Phase V: Empirical evaluation

The final phase should test the proposed model. Potential research could compare inspection outcomes before and after implementation of specific procedural improvements. The analysis should examine public health outcomes, legal quality, administrative efficiency and operator compliance. The research design must account for differences in risk, industry structure and enforcement intensity.

Research and innovation opportunity: Building an evidence-based regulatory accountability system

The integrated reform programme creates a research opportunity extending beyond doctrinal legal analysis. It would be possible to develop a multidisciplinary programme combining administrative law, food safety science, regulatory economics and institutional performance measurement.

Proposed research hypothesis

The principal hypothesis could be formulated as follows:

Official food control systems incorporating explicit legal-basis documentation, structured technical review and systematic institutional feedback achieve greater legal consistency without reducing the effectiveness of public health protection.

This is a testable hypothesis, not an established empirical conclusion.

Research design

A suitable programme could involve selected competent authorities and participating food manufacturers. The research could examine administrative decisions, inspection reports, technical disputes and appeal outcomes. Potential endpoints would include the proportion of decisions identifying a precise legal basis, the frequency of substantiated procedural defects, the time required to resolve technical disputes and measures of relevant food safety performance.

Protecting confidential information

The programme would require safeguards concerning personal data, commercially sensitive information and confidential regulatory material. Data access would need to comply with the applicable legal framework. Published results should avoid identifying individual operators or officials unless disclosure is lawful and justified.

Avoiding institutional conflicts of interest

Independent research oversight would be important. A study conducted solely by the authority whose performance is being evaluated could face concerns

regarding independence. Conversely, research controlled exclusively by regulated industry could raise questions concerning commercial influence. A credible design should therefore incorporate transparent governance, declared interests and independent methodological scrutiny.

Final conclusions: From constitutional limits to regulatory legitimacy

The analysis developed throughout Part I demonstrates that the legality of official food controls cannot be reduced to the existence of inspection powers. Those powers operate within a broader constitutional and administrative framework. The competent authority must act within the law, pursue legitimate public purposes, respect procedural guarantees and ensure that intervention is supported by an appropriate factual and scientific foundation. Food business operators remain responsible for compliance with applicable food law. They must cooperate with lawful official controls and implement effective safety management systems.

However, regulatory responsibility does not eliminate their rights. The Administration must distinguish binding obligations from voluntary guidance. It must distinguish scientific uncertainty from established infringement. It must distinguish preventive measures from punitive sanctions. It must distinguish institutional error from personal misconduct.

And it must provide access to the remedies established by law. The proposed CAFCoM framework seeks to integrate these principles into a coherent institutional architecture. Its purpose is not to establish a new legal doctrine by assertion. It is to provide a structured analytical model capable of supporting future doctrinal development, empirical research and regulatory reform.

The principal conclusion is:

The strongest food safety enforcement system is not necessarily the one that intervenes most frequently or imposes the greatest number of sanctions. It is the one capable of demonstrating that its interventions are legally authorised, scientifically justified, proportionate, consistently applied and effectively reviewable—while achieving the public health objectives for which its powers exist.

PRIMARY LEGAL MATERIALS AND CASES

The materials below identify the principal primary sources used across the volume. References to consolidated instruments should be checked against the legally applicable version for the date and sector of the disputed measure.

Constitutional and administrative law

1. Spanish Constitution of 1978, especially Articles 9.3, 18.2, 24, 25, 38, 43, 103 and 106. Official text:
<https://www.boe.es/legislacion/documentos/ConstitucionINGLES.pdf>
2. Law 39/2015 of 1 October, on the Common Administrative Procedure of Public Administrations (BOE-A-2015-10565).
<https://www.boe.es/buscar/act.php?id=BOE-A-2015-10565>
3. Law 40/2015 of 1 October, on the Legal Regime of the Public Sector (BOE-A-2015-10566). <https://www.boe.es/buscar/act.php?id=BOE-A-2015-10566>
4. Law 29/1998 of 13 July, regulating the contentious-administrative jurisdiction (BOE-A-1998-16718). <https://www.boe.es/buscar/act.php?id=BOE-A-1998-16718>
5. Law 1/2019 of 20 February, on Trade Secrets (BOE-A-2019-2364).
<https://www.boe.es/buscar/act.php?id=BOE-A-2019-2364>
6. Royal Legislative Decree 5/2015 of 30 October, approving the consolidated Basic Statute of Public Employees (BOE-A-2015-11719).
<https://www.boe.es/buscar/act.php?id=BOE-A-2015-11719>
7. Organic Law 10/1995 of 23 November (Spanish Criminal Code, BOE-A-1995-25444). <https://www.boe.es/buscar/act.php?id=BOE-A-1995-25444>

European Union food law

1. Regulation (EU) 2017/625 of 15 March 2017 on official controls and other official activities. <https://eur-lex.europa.eu/eli/reg/2017/625/oj>
2. Regulation (EC) No 178/2002 of 28 January 2002 laying down general principles and requirements of food law. <https://eur-lex.europa.eu/eli/reg/2002/178/oj>
3. Regulation (EC) No 853/2004 of 29 April 2004 on the hygiene of foodstuffs. <https://eur-lex.europa.eu/eli/reg/2004/852/oj>

4. Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. <https://eur-lex.europa.eu/eli/reg/2005/2073/oj>
5. Regulation (EC) No 853/2004 of 29 April 2004 laying down specific hygiene rules for food of animal origin. <https://eur-lex.europa.eu/eli/reg/2004/853/oj>
6. Commission Notice 2022/C 355/01 on the implementation of food safety management systems covering good hygiene practices and procedures based on the HACCP principles, including facilitation/flexibility of the implementation in certain food businesses.
7. Directive (EU) 2016/943 of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets). <https://eur-lex.europa.eu/eli/dir/2016/943/oj>

Spanish food-control legislation

1. Law 17/2011 of 5 July on Food Safety and Nutrition (BOE-A-2011-11604). <https://www.boe.es/buscar/act.php?id=BOE-A-2011-11604>
2. Royal Decree 562/2025 of 1 July on official controls and other official activities in the agri-food chain (BOE-A-2025-13409); consolidated text consulted as amended on 30 September 2026. <https://www.boe.es/buscar/act.php?id=BOE-A-2025-13409&p=20260930>
3. Royal Decree 1945/1983 of 22 June (BOE-A-1983-21105), cited only with regard to its historical framework and provisions remaining applicable following subsequent repeals. <https://www.boe.es/buscar/act.php?id=BOE-A-1983-21105>

Judicial decisions examined in the text

1. Spanish Constitutional Court, Judgment 69/1999 of 26 April (corporate premises and constitutional domicile protection).
2. Spanish Constitutional Court, Judgment 54/2015 of 16 March (consent and entry into protected premises).
3. Spanish Constitutional Court, Judgment 76/1990 of 26 April (constitutional guarantees in administrative sanctioning).
4. Court of Justice of the European Union, Grimaldi, Case C-322/88, judgment of 13 December 1989 (interpretive significance of recommendations).
5. European Court of Human Rights, Saunders v. United Kingdom, 17 December 1996, application 19187/91.

6. European Court of Human Rights, *Funke v. France*, 25 February 1993, application 10828/84.
7. European Court of Human Rights, *J.B. v. Switzerland*, 3 May 2001, application 31827/96.
8. Court of Justice of the European Union, *Commission v. Denmark*, Case C-192/01, judgment of 23 September 2003.
9. Court of Justice of the European Union, *Monsanto Agricoltura Italia*, Case C-236/01, judgment of 9 September 2003.
10. General Court of the European Union, *Alpharma Inc. v. Council*, Case T-70/99, judgment of 11 September 2002.

Comparative materials

1. United Kingdom: Food Safety Act 1990 and relevant secondary legislation; enforcement guidance and material of the Food Standards Agency.
2. United States: Federal Food, Drug, and Cosmetic Act and Administrative Procedure Act; Food and Drug Administration inspection and enforcement guidance.

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Official food control is indispensable to public health protection, consumer confidence and market integrity. Its legitimacy, however, depends not only on the public interest it serves, but on the competence, legal basis, factual and scientific justification, proportionality and procedural guarantees governing each intervention.

This volume offers a rigorous legal analysis of the boundaries of official food controls in Spain, examining constitutional principles, general administrative law, and the European Union framework applicable to inspection, enforcement and judicial review. It studies the duties of cooperation owed by food businesses alongside the enforceable rights of operators, the treatment of documentary and analytical evidence, the limits of precautionary and punitive action, and the system of administrative and judicial remedies.

Conceived as a research monograph, the work seeks to distinguish lawful enforcement from excess of authority, and to contribute to a more coherent, accountable and legally disciplined model of food-safety administration.

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