When Food Safety Culture Becomes an Inspection Finding

Evidence, discretion and the limits of regulatory enforcement in European food factories

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Abstract

Food safety culture has moved from management vocabulary into enforceable European hygiene law. Chapter XIa of Annex II to Regulation (EC) No 852/2004 obliges food business operators to establish, maintain and demonstrate an appropriate culture, including management commitment, communication of deviations, training, adequate resources and system integrity during change. Yet inspection of organisational behaviour presents a difficult evidentiary problem: a documented procedure may coexist with unsafe practice, while an unfavourable employee survey may not prove a specific breach. This article examines how inspectors and operators can distinguish observable non-compliance from inference, construct reliable evidence chains, assess proportionality and manage disagreement without compromising public health. It connects regulatory duties to factory realities: shift handovers, production pressure, maintenance deferrals, environmental monitoring, allergen changeovers and corrective-action closure. A comparative assessment covers the EU, Spain, Great Britain and the United States. The proposed research agenda tests whether triangulated operational evidence can improve inspection consistency and predict preventable control failures. The objective is neither regulatory minimalism nor managerial rhetoric, but defensible, risk-based decisions.

Keywords: *food safety culture; official controls; inspection evidence; HACCP; proportionality; organisational behaviour; food manufacturing; regulatory enforcement.*

1. The regulatory problem: a duty to demonstrate a culture

Commission Regulation (EU) 2021/382 amended Annex II to Regulation (EC) No 852/2004 by inserting Chapter XIa, Food Safety Culture. The operative provision requires operators to establish, maintain and provide evidence of an appropriate culture. The obligation is not merely a recommendation, nor does it prescribe a particular survey, proprietary certification or numerical score. The provision identifies five dimensions: management and employee commitment, leadership, hazard awareness, open communication including deviations, and sufficient resources. It then specifies management duties concerning responsibilities, change management, timely controls, documentation, training, legal compliance and improvement. Implementation must reflect the nature and size of the business. [1,2]

The European Commission's 2022 notice on food safety management systems explains that culture is fundamental to the functioning of hygiene controls. It does not replace hazard analysis, prerequisite programmes or operational verification. Rather, it asks whether organisational arrangements allow those systems to work under production conditions. A factory may possess a technically correct HACCP plan yet repeatedly override its critical decisions when dispatch deadlines are threatened. Conversely, a factory with few formal management surveys may demonstrate effective communication, escalation and correction through contemporaneous operational records. [3]

This creates a regulatory tension. The obligation is enforceable, but its language is partly qualitative. An inspector must make a professional assessment, yet public-law decisions affecting an operator should remain anchored in ascertainable facts, applicable legal requirements, reasoned conclusions and proportionate measures. The problem is not whether discretion exists; it is how discretion is constrained by evidence.

2. Culture is not a synonym for paperwork

2.1 The distinction between design, implementation and effectiveness

A management system can be examined at three levels. Design asks whether roles, procedures and resources have been defined. Implementation asks whether personnel follow them in real operations. Effectiveness asks whether the controls prevent, detect and correct relevant failures. These levels should not be collapsed. A signed training sheet establishes that a training event was recorded; it does not prove that the operator can recognise a damaged allergen seal at 03:00. A supervisor's confident interview may reflect rehearsed language rather than routine practice. Equally, a single imperfect answer from an employee does not necessarily demonstrate systemic failure.

The strongest evidence comes from triangulation: independent records, direct observation and interviews evaluated against the same defined risk. For example, an allegation that management discourages reporting deviations should be tested against escalation records, timestamps, corrective-action histories, operator testimony and the consequences of prior reporting. Absence of recorded deviations is ambiguous: it can reflect excellent process control, poor detection or deliberate suppression.

2.2 Why production pressure is a safety variable

Many organisational failures are not caused by ignorance. A shift supervisor may understand the correct cleaning release criterion yet be incentivised to restart a line before verification is complete. Maintenance may know that a damaged gasket creates a hygienic design problem but defer replacement because the line is needed for a major order. Procurement may approve an alternative ingredient without allowing time for allergen and specification review. These are governance decisions that change exposure pathways, not merely defects of attitude.

A culture assessment should therefore examine how competing priorities are resolved. Is a production manager empowered to override a quality hold? Are exceptions documented and reviewed? Who can stop the line, and has that authority been exercised without retaliation? Are resources available to complete corrective actions? A poster proclaiming that safety comes first has little evidentiary value if operating rules consistently reward the opposite behaviour.

3. Seven recurrent factory failure mechanisms

Failure mechanism	Operational warning	Evidence worth examining
Shift-handover loss	Unresolved sanitation or hold status disappears between teams	Handover logs, electronic timestamps, release authorisations
Allergen changeover drift	Line starts before cleaning verification or label clearance	Changeover records, label reconciliation, swabs where appropriate
Environmental-monitoring complacency	Repeated positives classified as isolated events	Trend analyses, zoning, root-cause investigations
Maintenance deferral	Temporary repairs become permanent in product zones	Work orders, risk assessments, preventive-maintenance backlog
Supplier substitution	Alternative raw material enters production before review	Specification changes, approvals, traceability, hazard review
Corrective-action closure by signature	Actions marked complete without effectiveness checks	CAPA evidence, recurrence rates, independent verification
Management-of-change failure	New line speed or recipe changes invalidate assumptions	Change controls, HACCP review, commissioning data

These mechanisms are examples for risk analysis, not a claim that each constitutes an independent statutory offence. Their relevance depends on product, process, likelihood, severity, existing controls and the actual legal obligation. A dry ambient cereal facility and a chilled ready-to-eat meat plant do not have identical microbial exposure pathways. An inspection method that treats them as interchangeable risks confusing standardisation with fairness.

3.1 Environmental monitoring: a culture problem or a sampling problem?

An apparent cluster of environmental positives may indicate persistent contamination, an intensified sampling programme or a changed analytical method. A regulator should investigate whether the operator interpreted the findings competently, protected potentially affected product and implemented effective corrective action. A simplistic count of positive swabs is insufficient without sampling intensity, site selection, organism, method, historical baseline and production context. Similarly, an operator should not use uncertainty about source attribution as an excuse to avoid risk-based containment.

3.2 Allergen management: a high-consequence illustration

Commission Regulation (EU) 2021/382 also amended hygiene provisions concerning equipment used for allergenic materials. This connection is important: the same regulatory instrument addresses both operational control and culture. An allergen incident may originate in poor physical segregation, but its persistence can reveal failures of communication, authority, training or change control. The inspector should establish the material pathway and the management decisions that allowed it, rather than merely labelling the entire company culture “weak”. [1]

4. From observation to a defensible inspection finding

An inspection finding should contain at least six separable elements: the applicable legal provision; the factual observation; the source and reliability of evidence; the inference connecting the observation to the legal duty; the associated food-safety significance; and the measure considered necessary. When these elements are

compressed into a phrase such as “insufficient food safety culture”, both regulatory accountability and operator learning deteriorate.

Element	Weak formulation	Stronger formulation
Fact	Staff do not care about safety	Two sampled line releases lacked the required verification signatures and records showed production began before release
Norm	Poor culture	Chapter XIa duty concerning timely verification, management responsibility and effective controls, alongside relevant hygiene duties
Inference	Management is negligent	The repeated release pattern and escalation records suggest that verification was not reliably implemented
Risk	Serious issue	Specific product/process exposure and potential failure of the preventive barrier are identified
Action	Fix culture immediately	Define corrective action, responsible owner, verification evidence and risk-proportionate deadline

This approach does not prohibit qualitative professional judgment. It makes the judgment inspectable. The operator can accept a factual failure while contesting an unsupported inference; the authority can justify intervention without relying on vague managerial labels. Both sides benefit from a common chain of reasoning.

5. The legal architecture of official controls

5.1 EU law: inspection powers and operator responsibilities

Regulation (EU) 2017/625 establishes the framework for official controls and other official activities. Competent authorities verify compliance using appropriate methods and techniques, including examination of controls, procedures, documentation, interviews, inspection and sampling where relevant. The regulation also addresses transparency, official-control records and actions in cases of established non-compliance. The existence of an official-control power does not make every possible remedial measure automatically appropriate. [4]

The operator remains responsible for compliance with applicable food law under Regulation (EC) No 178/2002 and for hygiene procedures under Regulation (EC) No 852/2004. Article 5 of the latter concerns procedures based on HACCP principles, subject to the applicable flexibility. Chapter XIa adds an organisational requirement, not a replacement for technical preventive controls. A serious immediate risk may justify urgent intervention irrespective of whether a formal culture assessment has been completed. Conversely, a low-severity documentary deficiency should not automatically be described as evidence of imminent harm. [2,5]

5.2 Spain: proportionality, reasons and administrative procedure

In Spain, directly applicable EU hygiene and official-control law operates alongside national rules on administrative procedure and public-sector legal regime, including Laws 39/2015 and 40/2015 where applicable. Administrative decisions must be evaluated under the relevant procedural rules, competence requirements and principles of proportionality; the precise guarantees depend on whether the act is a control measure, corrective requirement, interim measure or sanction. These legal categories should not be conflated. [6,7]

An operator receiving an adverse finding should preserve the inspection record, identify the precise legal basis, distinguish factual observations from evaluative statements and respond within the applicable procedure. Where sampling or laboratory results are central, the operator should examine sampling representativeness, chain of custody, analytical uncertainty and any available procedural mechanisms for challenge or counter-

analysis. A general right to an identical second sample should not be assumed in every context; the specific regime governs.

An allegation of deficient culture is particularly vulnerable to ambiguity if it relies only on an unvalidated questionnaire, an unexplained composite score or a small convenience sample of interviews. That does not render employee interviews irrelevant. It means their probative weight depends on method; context, corroboration and the concrete inference being made. The administrative record should enable an independent reviewer to understand why the conclusion follows.

5.3 Great Britain and Northern Ireland

Great Britain retains its own domestic hygiene and enforcement arrangements; businesses and advisers must consult the relevant retained or assimilated legislation as amended and the competent authority for the territory and activity. Northern Ireland is subject to distinct arrangements, and EU developments should not be assumed to apply identically across the United Kingdom. The European Chapter XIa wording is a useful comparator, but a British enforcement decision must rest on the domestic legal instrument in force, not simply on an EU provision cited by analogy. [8]

5.4 United States

The US FDA's preventive-controls framework under the Food Safety Modernization Act and 21 CFR Part 117 requires covered facilities to establish appropriate hazard analysis, preventive controls, monitoring, corrective actions, verification and records, subject to exemptions and modified requirements. The US framework does not impose the identical EU Chapter XIa formulation as a freestanding universal "food safety culture" duty. However, many of the same underlying behaviours become visible through implementation failures, inadequate records, uncorrected deviations and deficient preventive-control governance. The legal basis of an FDA observation must be the relevant US requirement, not an imported European management concept. [9]

6. What an inspector can reasonably infer, and what remains uncertain

Direct observation of an unverified line release is strong evidence about that release. It may support a broader conclusion if repeated events, management instructions and ineffective corrective actions demonstrate a pattern. But inference to an entire organisation requires additional support. The fact that an employee fears retaliation, for example, may be important evidence of a reporting barrier, yet the assessment should consider interview conditions, anonymity, potential confounders and independent corroboration.

Culture measurement tools can provide useful diagnostic information, particularly when they have documented construct validity, appropriate sampling, transparent scoring and evidence of repeatability. Their role is ordinarily to inform investigation and management improvement. A survey score should not be treated as if it were a harmonised microbiological limit. No single questionnaire, as such, is mandated by Chapter XIa.

A legally and scientifically sound inspection must also recognise contrary evidence. If the operator documents repeated voluntary production stops, rapid escalation of near misses and timely preventive investment, these facts may materially qualify an adverse inference. They do not excuse an actual unsafe release; they affect the interpretation of whether the observed event represents a systemic failure and what remedial action is proportionate.

7. The economics of culture failures: where the hidden costs accumulate

The direct cost of a failure may include wasted raw material, additional cleaning, laboratory analysis, line downtime and disposal. Indirect costs include lost production slots, customer chargebacks, refrigerated

storage, replacement transport, retailer delisting, external expert fees, litigation and reputational effects. The relevant economic question is not the cost of a training programme in isolation but the expected cost of preventable control failure across the product lifecycle.

A simple decision model is useful: expected annual loss equals the sum, over defined failure scenarios, of estimated event probability multiplied by total consequence. The probabilities and costs must be derived from facility data or transparently identified scenarios; they should not be presented as universal industry statistics. Where an intervention reduces the frequency of unreleased deviations but increases early detection and controlled holds, short-term “incidents reported” may rise even as overall risk falls. Management KPIs must distinguish detection from harm.

For example, consider a hypothetical chilled-food facility that experiences four avoidable release-related shutdowns per year at a fully loaded cost of €18,000 each. A verified change-control and escalation programme costing €25,000 annually would break even if it prevented at least 1.39 such events per year, ignoring secondary benefits and uncertainty. This is an illustrative arithmetic scenario, not an empirical estimate. The calculation becomes meaningful only after incorporating event severity, uncertainty, implementation costs and the probability that the intervention works.

8. Designing an inspection-ready evidence system without creating bureaucracy

The most effective system is not the one with the largest number of forms. It is the one that preserves the chain from risk to decision. For each high-consequence operational barrier, the business should identify the accountable owner, the release or stop criterion, how deviations are escalated, what records are generated and how effectiveness is checked. The evidence should be available across shifts, sites and product changes.

A practical monthly review can examine a small number of leading indicators: overdue high-risk corrective actions, unresolved temporary repairs in hygienic zones, release overrides, repeated environmental trends, training competence failures and supplier substitutions made without hazard review. These indicators should be interpreted with production volume, sampling intensity and process changes. Reporting more near misses can signal better detection rather than deterioration.

Management review should include adverse evidence, not only a dashboard of green indicators. A credible system records decisions to stop production, rejected commercial exceptions, investments made to eliminate recurring risks and instances in which planned changes triggered a revised hazard analysis. The aim is to show how safety priorities survive contact with commercial pressure.

9. Research & Innovation Opportunity

9.1 Research question and prior art

Food safety culture assessment, safety climate surveys, organisational learning and regulatory inspection are established fields. It would be incorrect to claim that linking management behaviour to safety performance is new. The narrower proposed question is whether a preregistered, process-specific evidence model can improve agreement between independent inspectors while identifying operational failures that conventional document audits miss. A systematic literature and patent/public-disclosure review would be required before any claim of proprietary novelty.

9.2 Hypothesis and experimental design

Hypothesis (unvalidated): triangulation of objective barrier-performance records, structured observational evidence and carefully sampled employee reports will produce more consistent and predictive regulatory-

relevant assessments than either document-only audits or uncalibrated culture surveys. The proposed improvement is not presumed; it must be demonstrated against independently defined outcomes.

A multicentre study could recruit facilities across dry foods, dairy, chilled ready-to-eat products and ingredient manufacturing. Stage one would specify common legal questions and process-specific hazards. Stage two would collect blinded evidence packages from a fixed historical period, preserving timestamps, corrective-action closure data and operational context. Stage three would ask independent assessors to evaluate the same cases using conventional records, survey-only information and integrated evidence, in randomised order. Stage four would test agreement, calibration and association with subsequent verified control failures.

9.3 Outcomes, ethics and legal safeguards

Primary outcomes should include inter-rater agreement, reproducibility across sectors and accuracy against prespecified independently adjudicated failures. Secondary outcomes might include inspection time, unnecessary corrective-action burden, sensitivity to serious deficiencies and operator understanding of findings. Confounding by inspection intensity, facility size, certification status and product risk must be addressed. Employee confidentiality, consent where appropriate, labour-law constraints and data protection require explicit governance. A negative result would be informative: it might show that complex scoring systems add little beyond careful direct inspection.

The research would not confer legal authority on an algorithm or a private rating scheme. Competent authorities would retain statutory decision-making responsibilities. A validated tool could assist consistency and transparency, but could not replace factual investigation, due process or proportionality.

10. A practical decision pathway for operators and authorities

When a culture-related finding is raised, the operator should first establish whether there is an immediate food-safety risk requiring containment. Second, it should identify the precise legal and technical requirement. Third, it should preserve contemporaneous evidence, including contrary evidence. Fourth, it should separate a discrete event from any alleged systemic pattern. Fifth, it should agree or contest the facts explicitly, rather than arguing about broad labels. Sixth, it should propose risk-proportionate corrective actions with measurable effectiveness criteria. Finally, it should document how lessons are incorporated into management-of-change, resources and supervisory practice.

For the authority, the corresponding discipline is to describe the observation accurately, test alternative explanations, identify the legal duty, articulate the risk significance and explain the intervention selected. For both parties, the best outcome is not a perfectly worded report but a demonstrably safer process and a defensible administrative record.

11. Conclusions

The European food safety culture requirement is legally real and industrially consequential. It should not be reduced to posters, surveys or a new layer of signatures. Its substantive value lies in whether the organisation can recognise hazards, communicate deviations, allocate resources and preserve control when production conditions change.

At the same time, enforceability does not eliminate the need for evidence. A qualitative obligation demands more careful reasoning, not less. Inspectors should distinguish observable failures from organisational inference; operators should answer adverse findings with verifiable process evidence rather than public-relations language. The strongest model combines rigorous risk control with transparent administrative justification. This is where industrial effectiveness and legal certainty can reinforce one another.

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