

Ingredient Safety Is Supply-Chain Safety

What the 2026 Infant-Formula Incidents Reveal About Supplier Verification, Traceability and the Limits of Finished-Product Testing

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Executive Abstract

Two different 2026 infant-formula safety crises have exposed the same structural weakness: a finished product can inherit hazards created far upstream, while conventional specifications, certificates and end-product testing may fail to reveal them in time. A global cereulide incident was traced to contaminated arachidonic-acid (ARA) oil and triggered recalls across 99 countries and territories. In the United States, two infant-botulism outbreaks involving different formula brands were linked by whole-genome sequencing and shared milk-powder supply-chain elements; FDA subsequently urged manufacturers to strengthen ingredient-source vigilance. These events should not be conflated microbiologically: cereulide is a preformed, heat-stable toxin, whereas infant botulism involves ingestion of *Clostridium botulinum* spores and intestinal toxin production. Their common lesson is governance. This article argues that high-risk food manufacturing needs to move beyond supplier approval toward evidence-based supplier hazard assurance: ingredient-specific hazard models, traceforward completeness, orthogonal testing, process intelligence, genomic and chemical surveillance, and digitally auditable chain-of-custody. The implications extend well beyond infant formula to nutraceuticals, fermentation-derived ingredients, powders, oils and globally sourced functional ingredients.

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1. Two Incidents, One Structural Warning

The most important food-safety signal of 2026 may not be a new pathogen, toxin or analytical method. It may be a governance failure hiding in plain sight since manufacturers can control their own factories rigorously and still inherit a serious hazard from an ingredient supplier or an upstream processor.

Two infant-formula events make the point unusually clearly.

First, a multi-country incident involving cereulide contamination in infant formula and other nutritional products was traced to arachidonic-acid (ARA) oil used as an ingredient. The World Health Organization reported that affected products had been distributed to 99 countries and territories across six WHO regions, with 144 suspected and confirmed cases reported across ten countries by 25 February 2026. EFSA and ECDC assessed the event in Europe, and EFSA established an acute reference dose for cereulide in infants of 0.014 micrograms per kilogram body weight.

Second, the United States investigated two separate infant-botulism outbreaks associated with powdered infant formula. FDA reported that whole-genome sequencing linked a clinical isolate from the 2026 Nara Organics outbreak to a clinical isolate and product/ingredient isolates from the earlier ByHeart outbreak. The two formula supply chains shared organic milk and spray-drying suppliers. FDA also disclosed that, during the earlier traceforward investigation, an upstream supplier had provided an incomplete customer list that omitted supply relevant to the later Nara investigation.

These events are biologically different and must not be merged into a single hazard narrative. But they converge on the same systems question:

How much evidence should a food manufacturer require before it can legitimately treat a supplier-controlled ingredient as safe?

That question is not confined to infant formula. It applies to powdered ingredients, botanical extracts, fermentation products, oils, proteins, enzymes, minerals, additives, nutraceutical actives and any internationally traded ingredient whose safety depends partly on processes outside the buyer's direct control.

2. The Microbiology Matters: Cereulide Is Not Botulism

A technically serious analysis must first separate the hazards.

Cereulide is an emetic toxin produced by certain *Bacillus cereus* strains. It is exceptionally important from a process-control perspective because it is heat stable. WHO reported that the toxin can withstand cooking temperatures and remain stable up to 121 degrees C; therefore, a downstream heat treatment that kills vegetative bacteria cannot be assumed to eliminate preformed cereulide. In the 2025-2026 incident, the suspected hazard originated during production of ARA oil rather than from viable *B. cereus* growing in the finished infant formula.

Infant botulism follows a different mechanism. Infants ingest spores of *C. botulinum*, the organism can colonise the immature intestinal tract, and neurotoxin is then produced in vivo. This makes spore control particularly important. Powdered infant formula is not a sterile product, and environmental spore-formers create a qualitatively different risk from a heat-labile vegetative contaminant.

The distinction has direct consequences for supplier assurance.

For a preformed heat-stable toxin, a negative viable-cell test at the receiving factory can be irrelevant if toxin has already been produced upstream. For a spore-forming organism, a supplier's environmental ecology,

raw-material exposure, drying operation and hygienic zoning may matter more than a conventional total-count specification.

The first principle of advanced supplier verification is therefore simple:

Supplier controls must be hazard-specific, not certificate-specific.

3. Why Finished-Product Testing Cannot Carry the System

Finished-product testing is valuable, but it has mathematical and biological limits.

Contamination can be heterogeneous. A pathogen or toxin may be concentrated in a small fraction of a large lot. Sampling plans examine only a minute proportion of the material. A negative result therefore demonstrates that the analyte was not detected in the tested portions under the method's conditions; it does not prove universal absence from the entire lot.

This problem becomes more acute when the hazard is rare but severe, when the susceptible population is highly vulnerable, or when the contaminant is distributed in clusters.

The infant-formula events also illustrate another limitation as the relevant analyte may not be part of routine testing at all. WHO explicitly noted that cereulide was not a routinely tested contaminant and that limited surveillance capacity complicated case detection. A supplier specification that tests conventional microbiological indicators but omits the actual hazard can create a false sense of control.

The correct role of finished-product testing is therefore confirmatory and verification-oriented. It should sit inside a broader preventive system that understands where the hazard can arise, how it can survive, and what upstream evidence reduces uncertainty.

A robust system asks three questions before deciding what to test:

1. What hazards are biologically plausible for this ingredient and process?
2. Where in the supply chain can those hazards be introduced, amplified or transformed?
3. Which combination of process controls, supplier evidence and analytical methods provides the strongest assurance?

Testing without this model is surveillance by habit.

4. FDA's 2026 Message: Ingredient Selection Is a Food-Safety Control

On 13 July 2026, FDA sent a letter to the infant-formula industry and its supply-chain partners calling for increased vigilance in ingredient selection and sourcing. The agency explicitly connected recent public-health events to risks introduced through supply chains. That intervention is important because it reframes procurement.

Ingredient purchasing is not merely a commercial function supported by quality checks. In high-risk foods, ingredient-source selection is itself a preventive food-safety decision. FDA's post-outbreak materials go further. The agency linked the two US infant-botulism outbreaks through whole-genome sequencing and supply-chain commonalities, while continuing to investigate the precise contamination route. The investigation showed why conventional first-tier supplier oversight can be insufficient: the formula brand may purchase from one entity while the critical hazard is introduced at a processor, dryer, sub-supplier or raw-material source further upstream.

This is the difference between supplier approval and supply-chain assurance. Supplier approval asks whether the direct vendor is acceptable. Supply-chain assurance asks whether the entire hazard-relevant chain is known, controlled, traceable and capable of generating evidence when something goes wrong.

5. Europe Already Has the Legal Skeleton - but Not Necessarily the Operational Depth

EU food law already contains strong general obligations.

Regulation (EC) No 178/2002 establishes food-business-operator responsibility and traceability. Article 18 requires traceability of food, feed, food-producing animals and substances intended or expected to be incorporated into food or feed through all stages of production, processing and distribution. Article 19 requires operators to initiate withdrawal procedures when they consider or have reason to believe that food is not compliant with food-safety requirements.

Regulation (EC) No 853/2004 requires food-business operators to ensure hygiene requirements throughout stages under their control and to implement HACCP-based procedures. Annex II also states that operators must not accept raw materials or ingredients known, or reasonably expected, to be contaminated to an extent that would render the final product unfit even after normal processing.

Infant and follow-on formula are additionally governed by the compositional and information requirements of Commission Delegated Regulation (EU) 2016/127. Microbiological criteria under Regulation (EC) No 2073/2005 include, for relevant dried infant formula, absence of *Salmonella* in 30 samples of 25 g and absence of *Cronobacter* spp. in 30 samples of 10 g for specified products.

These rules are substantial. Yet the 2026 cereulide event demonstrates a structural truth: a legally compliant microbiological programme can still be challenged by an atypical toxin arising from an upstream ingredient process that was not historically central to routine specifications.

The regulatory architecture therefore needs to be translated into dynamic hazard intelligence. HACCP cannot remain a static list of familiar hazards if the ingredient portfolio and manufacturing technologies evolve.

6. The ARA-Oil Lesson: Functional Ingredients Can Carry Process-Specific Hazards

ARA oil is nutritionally valuable. Arachidonic acid is a long-chain polyunsaturated fatty acid used in infant nutrition. Its presence in formula does not itself create the *cereulide* problem. The incident instead demonstrates why ingredient identity is insufficient for safety assessment.

Two suppliers can sell materials under the same generic ingredient name while using different organisms, fermentation conditions, downstream processes, purification steps, carriers, antioxidant systems, storage conditions and release criteria. The hazard profile can therefore differ even when the compositional specification appears similar. This is particularly important for fermentation-derived ingredients.

A microbial process can introduce hazards through production-organism characteristics, contaminating organisms, secondary metabolites, process deviations, cleaning failures, oxygen or temperature excursions, water quality, downstream concentration or storage. The correct safety object is therefore not simply 'ARA oil'. It is: **ARA oil + production organism + process architecture + impurity profile + storage history + analytical controls + change history.**

The same logic applies to enzymes, vitamins, amino acids, fermentation-derived preservatives, microbial proteins and nutraceutical actives.

7. The Analytical Response Is Already Emerging

The scientific response to the cereulide incident has been rapid.

A 2026 study developed and validated a UPLC-MS/MS method specifically for quantitative determination of cereulide in ARA oil and microencapsulated ARA powder. The reported method achieved an LOD of 0.03 micrograms/kg and an LOQ of 0.1 micrograms/kg, with high recoveries in both matrices.

This is more than an analytical footnote. It illustrates how an outbreak can create a new quality-control requirement almost overnight. Before the incident, cereulide may not have been part of routine ARA specifications. After the incident, sensitive matrix-specific methods become strategically relevant. But industry should resist the temptation to solve every new hazard by simply adding another end-product test.

Analytical capability should be used to strengthen causal understanding:

- Which process conditions permit toxigenic *B. cereus* growth?
- At what stage can cereulide form?
- Is the toxin partitioned or concentrated during downstream processing?
- Which raw-material or environmental signals predict elevated risk?
- Can process monitoring prevent toxin formation before analytical release testing is needed?

The best analytical method is most powerful when connected to process intelligence.

8. Traceability Is Not a Spreadsheet Problem

The US botulism investigations revealed a particularly uncomfortable fact revealing that a traceforward exercise can fail if the supplier's customer information is incomplete. This exposes a common misconception. Traceability is often treated as an IT or recordkeeping capability. In reality, it is an evidence-integrity capability.

A database is only as reliable as the business events recorded in it. A high-integrity traceability system needs at least four properties, to know:

Completeness: every relevant movement, transformation and customer relationship is captured.

Granularity: records identify lots, batches, process dates and transformation relationships at a resolution useful for risk management.

Timeliness: information can be retrieved rapidly enough to support containment.

Verifiability: records can be reconciled against independent evidence such as invoices, transport records, production logs, certificates, ERP transactions or laboratory data.

This is where digitalisation can add genuine value. Distributed ledgers are not automatically necessary, and blockchain should not be treated as a synonym for traceability. More important are interoperable identifiers, event-based data structures, master-data governance and reconciliation rules capable of identifying missing links. The critical innovation is not immutable data. It is detectable incompleteness.

9. Supplier Approval Should Become Supplier Hazard Assurance

Conventional supplier approval frequently relies on questionnaires, certifications, specifications, certificates of analysis, audits and complaint history. These are useful, but they can become ritualised.

A stronger model is **supplier hazard assurance**.

Under this model, the buyer constructs an ingredient-specific assurance case containing five layers.

Layer 1 - Hazard model. What microbiological, chemical, allergenic, physical and authenticity hazards are plausible for this material and its production process?

Layer 2 - Process evidence. Which supplier controls prevent or reduce those hazards, and how are critical parameters monitored?

Layer 3 - Analytical evidence. Which tests verify the hazards that cannot be sufficiently controlled or inferred from process evidence?

Layer 4 - Traceability evidence. Can every relevant upstream and downstream lot relationship be reconstructed quickly and completely?

Layer 5 - Change intelligence. How will the buyer know when the supplier changes raw materials, production organism, process, site, dryer, carrier, specification or subcontractor?

The last layer is routinely underestimated. A supplier that was safe when qualified can become a different risk after an uncommunicated process change. Supplier assurance therefore needs a life-cycle model, not a one-time approval.

10. Certificates Are Evidence - Not Truth

Certificates of analysis, GFSI-recognised certifications and audit reports are important tools, but none should be treated as a substitute for hazard reasoning.

A certificate of analysis answers only the questions that were tested. A certification demonstrates conformity with a management-system or scheme standard within its scope. An audit samples evidence during a defined period. None guarantees that an unanticipated hazard is absent. This is especially important when a hazard is process-specific and low-frequency. The right question is not 'Does the supplier have certification?' It is 'What uncertainty remains after considering certification, audit evidence, process controls, analytical data, incident history and supply-chain transparency?'

That framing converts supplier quality from compliance checking into risk inference.

11. Orthogonal Verification: Do Not Ask One Method to Prove Everything

The strongest assurance systems use independent evidence streams that fail differently.

For example, microbial safety of a powdered ingredient might be assessed through:

- supplier environmental monitoring;
- process lethality or control evidence;
- finished-lot testing;
- periodic independent laboratory verification;
- whole-genome sequencing when isolates are recovered;
- trend analysis of indicator organisms;
- facility and hygienic-design audits;
- supply-chain incident intelligence.

For a heat-stable toxin, the evidence package might instead combine:

- control of organism growth before toxin formation;
- process temperature/time history;
- targeted toxin analysis;
- metabolomic or non-targeted screening;
- supplier deviation data;
- retention-sample investigation.

When two independent methods point to the same conclusion, confidence rises. When they disagree, the disagreement is itself valuable information. This is the principle of **orthogonal verification**.

12. Whole-Genome Sequencing Has Changed What 'Unrelated' Means

The 2026 US investigation demonstrates the power of whole-genome sequencing (WGS) in supply-chain forensics.

Historically, two outbreaks separated by brand, time or geography might have been treated as independent. WGS can reveal that isolates are genetically linked closely enough to support investigation of a common source. That capability changes the economics of weak traceability. If genomic evidence can connect illnesses and products across months, brands and factories, the supply chain must be capable of explaining those connections with equivalent precision.

WGS does not by itself prove the route of contamination. FDA explicitly stated that the common source or route remained under investigation. Genomic similarity must be integrated with epidemiology, ingredient records, process data and environmental evidence. But the strategic message is clear: microbiological forensics is becoming more precise than many commercial traceability systems. That asymmetry is unsustainable.

13. The Vulnerable-Population Principle

Infant formula deserves unusually conservative controls because the consumer population is uniquely vulnerable and, for many infants, formula is the sole or predominant source of nutrition.

This principle has broader regulatory significance. Risk controls should reflect not only the probability of contamination but also the susceptibility of the intended consumer and the consequences of failure. Foods for infants, immunocompromised people, older adults, hospital patients and people dependent on specialised nutrition warrant stronger supplier assurance than an identical ingredient used in a lower-risk population or product.

This suggests that ingredient qualification should include a vulnerability multiplier since the same ingredient can justifiably require different evidence depending on where it is used. That is risk-based regulation in its proper sense: not weaker control, but control proportionate to consequence.

14. Cross-Jurisdictional Consequences

The 2026 incidents also show why global ingredient companies cannot manage safety jurisdiction by jurisdiction in isolation.

In the EU, operator responsibility, HACCP, traceability and microbiological criteria form the legal backbone. The cereulide event required rapid EFSA/ECDC risk assessment and multinational recalls.

In the United States, infant formula is subject to the Federal Food, Drug, and Cosmetic Act and detailed requirements in 21 CFR Parts 106 and 107, including CGMP, quality-control procedures, records, testing and recall provisions. FDA's July 2026 industry letter signals increased attention to upstream ingredient sourcing and supplier vigilance.

Great Britain operates under its retained and amended food-law framework and Food Standards Agency oversight. Because global ingredient lots can enter multiple markets, an upstream incident can trigger different legal mechanisms while sharing the same factual root cause.

For suppliers, the efficient solution is not separate safety systems for every country. It is a high-quality core evidence architecture capable of being mapped to jurisdiction-specific legal requirements. Global compliance should be modular, not fragmented.

15. Research & Innovation Opportunity

Supplier Hazard Digital Twin for High-Risk Food Ingredients

We faced here an unresolved problem

Supplier qualification is usually document-centric. Specifications, audit reports, certificates, complaints, test results and traceability records exist in separate systems. This makes it difficult to detect when the real risk profile of an ingredient changes.

Why it matters

The 2026 infant-formula incidents show that upstream process hazards can propagate across brands and countries, while incomplete traceforward information can delay recognition of shared exposure.

What is already known

HACCP, supplier approval, WGS, targeted mass spectrometry, environmental monitoring, ERP traceability and statistical process control are mature tools. What is missing is an integrated representation of the supplier-controlled hazard state.

Proposed hypothesis

A digital twin of a high-risk ingredient supply chain could combine supplier/process identity, hazard models, lot genealogy, analytical results, deviations, environmental-monitoring trends, audit findings, logistics events and external incident intelligence. A risk engine could then identify changes that warrant enhanced sampling, supplier intervention or temporary hold.

Development pathway

1. Define a canonical ingredient and supplier-process identity model.
2. Map hazard-relevant process nodes, not merely commercial supplier tiers.
3. Ingest lot genealogy and traceforward/traceback events.
4. Integrate laboratory results and environmental-monitoring trends.
5. Add supplier change notifications and audit findings.
6. Establish rules for hazard-specific escalation.
7. Validate retrospectively against known incidents.
8. Conduct prospective pilots with blinded risk scoring.
9. Measure detection lead time, false positives and containment speed.
10. Maintain human expert review for consequential decisions.

Regulatory constraints

A digital model cannot replace statutory operator responsibility, HACCP or required testing. It must also respect commercial confidentiality, data-protection requirements and evidentiary integrity. Algorithmic risk scores should be explainable and auditable.

Potential industrial relevance

The platform could be applied to infant-formula ingredients, fermentation-derived actives, powdered proteins, spices, botanical extracts, fats and oils, enzymes and other ingredients in which upstream processing materially determines safety.

This is a proposed research programme, not an established regulatory requirement.

16. Research & Innovation Opportunity II: Detecting the Unknown Specification Gap

A second white space is more conceptual.

Most quality systems are designed to detect non-conformance against known specifications. The **cereulide** incident demonstrates the danger of the unknown specification gap that reveals that a relevant hazard is absent from the specification because the industry did not previously treat it as a routine control target.

A future system could continuously compare ingredient-process profiles with emerging literature, outbreak databases, regulatory alerts and analytical developments to identify hazards that are biologically plausible but not currently specified.

For example, an AI-assisted surveillance layer could ask:

- Has a toxin or metabolite recently been associated with this production organism?
- Has a similar process generated an unexpected impurity elsewhere?
- Has a regulator changed the health-based guidance value?
- Is a new analytical method now sensitive enough to reveal a previously invisible hazard?
- Has another sector reported a contamination pathway relevant to our process?

The output should not be an autonomous decision. It should be a ranked list for expert review.

The research challenge is to measure whether such a system detects meaningful hazards earlier without overwhelming users with false positives.

17. Implications for INTABIOTECH and other Ingredient Businesses

For an ingredient company, the lesson is direct and it can be practically translated into a simple sentence. Technical dossiers should increasingly describe not only what the product is, but how its safety is preserved through the supply chain. A strong dossier architecture should distinguish:

- identity and composition;
- origin and manufacturing process;
- hazard-relevant process steps;
- microbiological and chemical specifications;
- supplier and sub-supplier controls where relevant;
- analytical methods and limits;
- batch release logic;
- change-control obligations;
- traceability expectations;
- transport and storage controls;
- incident escalation procedures.

For INTABIOTECH (and many other businesses) specifically, this reinforces the value of integrating technical, regulatory and quality work rather than treating them as separate departments. It also supports a more demanding supplier policy for ingredients used in vulnerable-population products, high-moisture or high-risk applications, and technologies whose efficacy or safety depends strongly on manufacturing consistency.

The commercial advantage is not bureaucracy. It is faster, more credible answers when a customer asks the most important question: **'How do you know this ingredient is safe beyond the certificate?'**

18. A Practical Supplier-Assurance Framework

Food businesses can translate the lessons of 2026 into a practical framework.

Step 1 - **Classify ingredient criticality**. Consider consumer vulnerability, severity of plausible hazards, processing kill steps, exposure and detectability.

Step 2 - **Map the real process chain.** Identify processors, dryers, blenders, toll manufacturers and other hazard-relevant sub-suppliers, not merely the invoicing entity.

Step 3 - **Build the hazard model.** Include process-specific toxins, spore-formers, allergens, chemical contaminants, adulterants and NIAS where relevant.

Step 4 - **Define evidence requirements.** Decide what must be demonstrated through process controls, testing, audit evidence and historical performance.

Step 5 - **Use independent verification.** Periodically test high-risk materials through independent laboratories or alternative methods.

Step 6 - **Reconcile traceability.** Test traceforward and traceback completeness against commercial records.

Step 7 - **Monitor change.** Require notification of material process, site, raw-material, production-organism and subcontractor changes.

Step 8 - **Monitor external signals.** Review regulatory alerts, outbreaks, literature and analytical developments.

Step 9 - **Simulate incidents.** Conduct mock recalls that begin at an upstream ingredient lot rather than only at the finished-product level.

Step 10 - **Measure assurance performance.** Track time to trace, missing links, supplier response latency, recurring deviations and verification failures.

This approach is more demanding than a supplier questionnaire. It is also more aligned with the way modern food-safety incidents actually propagate.

19. What Industry Should Not Conclude

Several overreactions would be scientifically unsound.

The **cereulide** incident does not mean ARA oil is inherently unsafe.

The **botulism** outbreaks do not establish that every milk-powder supplier presents the same risk.

WGS linkage does not automatically prove the precise contamination route.

More testing is not automatically better if sampling is poorly designed or the wrong analyte is measured.

Blockchain is not automatically superior traceability.

Supplier certification is not useless; it is simply insufficient as a standalone assurance mechanism for every hazard.

And zero risk is not an achievable regulatory standard.

The correct response is proportionality in the line of stating higher-quality evidence where the combination of hazard severity, consumer vulnerability and upstream uncertainty justifies it.

20. Conclusions

The 2026 infant-formula incidents should be remembered for more than their individual microbiology.

They expose a structural reality of modern food manufacturing: safety is increasingly distributed across companies, countries and process steps that the brand owner does not directly control. The **cereulide** event showed how a functional ingredient can carry a preformed, heat-stable toxin into products distributed globally. The US **infant-botulism** investigations showed how genomic evidence and shared upstream

suppliers can connect apparently separate brands and outbreaks, and how incomplete traceforward information can undermine containment.

The regulatory response is already visible. FDA has explicitly called for greater vigilance in ingredient selection and sourcing. EU law already places responsibility for safe ingredients, HACCP and traceability on food-business operators. The next step is operational rather than rhetorical.

Supplier approval should evolve into supplier hazard assurance.

That means understanding the production process, modelling ingredient-specific hazards, using orthogonal evidence, validating traceability completeness, detecting change, and integrating emerging scientific signals before they become specifications written after the next incident.

The deepest lesson is simple: **A food manufacturer does not outsource risk when it outsources production.** So we should have in account that ingredient safety is supply-chain safety.

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