DARWIN EVOLUTION

REGULATORY REFERENCE

ISO 22000

Food Safety Management Systems, 2018 edition (current)

GLOBAL · ISO · INTERNATIONAL ORGANIZATION FOR STANDARDIZATION · GENEVA · VOLUNTARY INTERNATIONAL STANDARD

May 13, 2026

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JURISDICTION	TYPE	CATEGORY
ISO · International Organization for Standardization · Geneva · voluntary international standard	Standard	Food safety
DARWIN PRODUCTS	**LAST OFFICIAL UPDATE**	**DOCUMENT VERSION**
Captia · Tracium	June 19, 2018	v1.0.0 · 13/05/2026

1. What is it?

ISO 22000 is the international standard for **Food Safety Management Systems**, published by the **International Organization for Standardization (ISO)** from Geneva. The current version is **ISO 22000:2018**, published on June 19, 2018, replacing ISO 22000:2005. It defines the requirements for an organization to demonstrate its capacity to control food safety hazards and deliver safe products. It is the foundation on which GFSI-recognized schemes such as **FSSC 22000** are built.

Unlike IFS, BRC or FSSC 22000, **ISO 22000 alone is not recognized by GFSI**. ISO 22000 certification is valid and commercially useful, but buyers requiring a GFSI scheme ask for FSSC 22000 (which incorporates ISO 22000 + sector-specific PRPs + additional requirements).

2. Who does it apply to?

Covered actors (broad voluntary scope):

- Primary producers (agriculture, fishing, aquaculture).
- Food manufacturers and processors.
- Transporters and cold-chain logistics operators.
- Packers and warehouses.

- Food retailers and wholesalers.
- Food service (catering, industrial restaurants).
- Input producers (packaging, additives, equipment, cleaning services, pesticides, fertilizers).

Covered products: applies to any kind of food or food-chain related product. The standard describes **what** the organization must do, not **how**; each organization adapts the system to its context.

Markets: globally recognized and adopted standard. Used by companies seeking an international food safety management framework without necessarily targeting GFSI certification. A common **path-to-FSSC** is to certify ISO 22000 first and then upgrade to FSSC 22000 when a major buyer demands GFSI recognition.

Voluntary nature: ISO 22000 is not legally mandatory in any jurisdiction. It is chosen voluntarily to demonstrate systematic control, open markets, integrate with other management systems (ISO 9001 quality, ISO 14001 environment, ISO 45001 occupational health and safety) and simplify customer audits.

3. Key requirements

The standard follows the **High Level Structure (HLS)** shared with ISO 9001 and ISO 14001, which facilitates integration. It has **10 clauses**.

HLS structure

Clause	Focus
1	Scope of the system.
2	Normative references.
3	Terms and definitions.
4	Context of the organization (stakeholder mapping, FSMS scope).
5	Leadership (commitment, policy, roles and responsibilities).
6	Planning (actions to address risks and opportunities, objectives).
7	Support (resources, competence, awareness, communication, documented information).
8	**Operation** (technical core: PRPs, traceability, **HACCP**, emergency, control of nonconforming product).
9	Performance evaluation (monitoring, internal audit, management review).
10	Improvement (nonconformities, corrective actions, continual improvement).

Clause 8 — Operation (technical core)

Sub-clause	Requirement
8.1	Operational planning and control.
8.2	**Prerequisite Programs (PRPs)** — infrastructure, personnel hygiene, cleaning, pest control, cross-contamination, etc. The ISO 22002-x series provides sector-specific detail but is not mandatory unless under schemes like FSSC.
8.3	**Traceability system** — linkage between raw-material lots, work-in-progress and finished product.
8.4	**Emergency preparedness and response** — recall, withdrawal, communication.
8.5	Hazard control — **HACCP** plan (oPRPs and CCPs), hazard analysis, control measures, validation.
8.6	FSMS updating.
8.7	Control of monitoring and measurement.
8.8	Verification of PRPs and hazard control plan.
8.9	Control of product and process nonconformity.

Certification

Aspect	Detail
Nature	Voluntary. An organization can implement ISO 22000 without certification (internal use) or seek certification through an accredited certification body.
Validity	Certificate lasts **3 years**.
Surveillance	Annual audit during the cycle.
Recertification	Full audit at the close of the 3rd year.
GFSI	**Not GFSI-recognized on its own**. For GFSI recognition use FSSC 22000.
Accreditation	Certification bodies must be accredited by national bodies (UKAS in UK, ANAB in USA, IRAM/OAA in Argentina, INMETRO in Brazil, etc.).

Nonconformity classification

Type	Description
Major	Systemic failure affecting the FSMS or an unmet normative requirement. Blocks or suspends certification depending on timing.
Minor	Point-in-time deviation against a requirement that does not compromise the FSMS. Corrective action with deadline.
Observation	Opportunity for improvement. No impact on the certificate.

4. How does Darwin cover it?

Captia captures production events in plant and field; **Tracium** anchors records to the immutable ledger. The combination especially supports **clause 8 (Operation)**, which is the technical core of the FSMS.

- **8.3 Traceability**: **Captia** generates Traceability Lot Codes for every production event and links raw materials, work-in-progress and finished product; **Tracium** persists and signs each lot on-chain, enabling bidirectional traceability (forward and backward) demonstrable to the auditor in minutes. Meets the identification and linkage requirements of the clause.
- **8.4 Emergency preparedness and response**: a lot-keyed query in **Tracium** returns the full affected-product tree in seconds, enabling withdrawals and customer/authority communication within procedure-defined timeframes.
- **8.5 Hazard control / HACCP**: **Captia** structures the HACCP plan, records CCP and oPRP monitoring with evidence (readings, photos, signatures) and retains the documentary traceability the auditor compares against floor observation. Control-measure validations are signed in **Tracium**.
- **8.2 PRPs**: **Captia** records evidence of operational PRP compliance (cleaning, personnel hygiene, pests, cross-contamination) in audit-ready format, linked by shift and line.
- **8.7 / 8.8 Monitoring, measurement and verification**: **Captia** schedules the verification calendar, records results and alerts on deviations; **Tracium** signs results with timestamps for immutable evidence.
- **8.9 Control of nonconforming product**: **Captia** workflow to identify, segregate, decide disposition (rework, discard, reclassify) and close with evidence.
- **9.2 Internal audit**: **Captia** schedules, records findings, assigns action plans and closes them with evidence.

- **9.3 Management review**: **Captia** consolidates the required inputs (audit results, performance data, nonconformities, opportunities) and records the outputs (decisions, actions).
- **10.1 / 10.2 Nonconformities and corrective actions**: workflow with deadlines, owners, root-cause analysis and closure with traceable evidence.
- **7.5 Documented information**: **Captia** archives FSMS documents with version control, approval and electronic signature; **Tracium** signs key milestones (procedure approval, revision release) for immutable evidence.

Areas not yet covered in V1 (transparent):

- **Physical site aspects** (infrastructure, physical pest control, metal detection, in-plant equipment validation): Darwin records the evidence but does not perform the physical control.
- **Senior management decisions** (food safety policy, resource allocation, strategic review): **Captia** archives documentary evidence; substance is built by the client.
- **Internal and external communication** under clause 7.4: **Captia** records evidence but plan development is the client's responsibility.

5. Sanctions and consequences of non-compliance

ISO 22000 is **voluntary** and does not impose legal sanctions. The consequences are **commercial and reputational**.

Certificate loss:

- A **major nonconformity** not closed within the defined deadline suspends the certificate. The plant falls outside the scheme until remediation + re-audit.
- Certificate **revocation** forces starting the cycle from scratch.
- Without a certificate, buyers that require ISO 22000 (or an ISO 22000-based GFSI scheme like FSSC) suspend purchases.

Commercial risk:

- **ISO-aware buyers** often accept ISO 22000 without requiring FSSC. Maintaining the certificate signals mature management.
- In international tenders and export to markets with less-than-GFSI requirements, ISO 22000 is often sufficient.
- When the buyer requires GFSI, ISO 22000 alone is **not enough**: a migration to FSSC 22000 is required.

Reputational risk:

- Certification bodies publish certificate status (current, suspended, withdrawn). In B2B tenders this register is checked.

6. Timeline

- **2005**: **ISO 22000:2005** first edition published.
- **June 19, 2018**: **ISO 22000:2018 published**. Introduces the High Level Structure (HLS) shared with ISO 9001 and ISO 14001 to integrate management systems.
- **June 2021**: deadline to migrate from ISO 22000:2005 to ISO 22000:2018. Certificates under 2005 became invalid.
- **2026 to 2028 (expected)**: possible intermediate revisions or clarifications; eventual ISO 22000:202X.

7. Official source and updates

- **Primary source**: ISO · 22000:2018
- **ISO informational page**: ISO 22000 Food Safety Management
- **Purchase the standard text**: through the ISO catalog or national representatives (IRAM in Argentina, AENOR in Spain, ABNT in Brazil, AFNOR in France, BSI in UK).
- **Last official update verified**: June 19, 2018 (ISO 22000:2018 publication).
- **Darwin doc version**: 1.0.0.
- **Darwin doc date**: May 13, 2026.

All-in-One Digital Product Platform

Traceability, compliance and operational efficiency for food and agro-industrial supply chains.

From origin to market. From traceability to trust.

Traceability is now market-access infrastructure

Food supply chains must demonstrate origin, process, compliance and evidence. Pressure converges from regulators, global buyers, consumers, brands and higher-value markets.

Regulators	Buyers	Consumers	Markets
FSMA 204 / EUDR	visibility and response	trust with evidence	origin, quality and access

Darwin covers the full traceability cycle

captia — From origin to action

Capture at origin

Offline mobile, forms, photos, documents, geolocation, timestamp and validation.

tracium — supply chain traceability

End-to-end traceability

Events, lots, actors, CTEs/KDEs, documents, certifications and verifiable evidence.

fidenta — digital product passport

Digital identity

QR and views for consumer, buyer, retailer, auditor, certifier and authority.

AI LAYER Intelligence applied over traceable data: inconsistencies, gaps, risks, alerts, queries and audits.

What it solves

- Fragmented data across field, plant, logistics and customers.
- Slow audits and traceability rebuilt after the fact.
- Gap between market requirements and operational reality.
- Low digitalization at producers and rural areas.

What it enables

- **Comply better**: structured, auditable and verifiable data.
- **Operate better**: fewer errors, rework and manual load.
- **Sell better**: demonstrable origin, quality and sustainability.
- **Include better**: producers connected to higher-value chains.

Multi-standard compliance

Capture once, structure correctly and reuse the data for regulatory, commercial and operational purposes.

FSMA 204
CTEs / KDEs

EUDR
DDS and deforestation

Certifications
GlobalGAP, BRC, organic

Private standards
retailers and buyers

One platform, different value cases

- **Producers** — evidence and market access
- **Exporters** — control and compliance
- **Retailers and brands** — risk, recalls and claims
- **Certifiers** — audit-ready evidence
- **Industry bodies** — sectoral standardization
- **Governments** — inclusion and markets

Rollout: Discovery, Pilot and Go-live

Differentiators: traceability at the core · capture at origin · interoperability · verifiable evidence · all-in-one modular · AI on top of real traceability.

01 Discovery → 02 Pilot → 03 Go-live

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