DARWIN EVOLUTION

REGULATORY REFERENCE

HACCP System

Hazard Analysis and Critical Control Points · Codex Alimentarius
CXC 1-1969 Rev. 2020

GLOBAL · CODEX ALIMENTARIUS COMMISSION · FAO / WHO · VOLUNTARY INTERNATIONAL STANDARD, THE FOUNDATION FOR FOOD-SAFETY MANAGEMENT

May 13, 2026

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JURISDICTION	TYPE	CATEGORY
Codex Alimentarius Commission · FAO / WHO · voluntary international standard, the foundation for food-safety management	Scheme	Food safety
DARWIN PRODUCTS	**LAST OFFICIAL UPDATE**	**DOCUMENT VERSION**
Captia · Tracium	September 25, 2020	v1.0.0 · 13/05/2026

1. What is it?

HACCP (*Hazard Analysis and Critical Control Points*) is the **foundational international methodology** for preventive food safety management. It was developed in the 1960s by Pillsbury in collaboration with NASA to ensure the safety of food for astronauts. The **Codex Alimentarius Commission** (FAO/WHO) codified it as **CAC/RCP 1-1969** (now **CXC 1-1969**), with the current revision of **2020**.

Unlike IFS, BRC, FSSC 22000 or ISO 22000, **HACCP is not in itself a certification scheme**: it is an **analysis-and-control methodology** that is incorporated into food-safety schemes and regulations. However, several countries demand a **documented HACCP plan** as a direct legal requirement (United States for seafood, juices and low-acid canned foods via FDA; meat and poultry via USDA; many countries require it in national regulation).

2. Who does it apply to?

Covered actors (transversal across the food chain):

- Primary producers (agriculture, livestock, fishing, aquaculture).

- Food manufacturers and processors.
- Packers, warehouses and distribution centers.
- Cold-chain transporters.
- Retailers and food service operators.
- Producers of food-contact inputs.

Covered products: any food or product entering the food chain. HACCP is **inherently flexible**: each operation adapts the plan to its process, products and specific hazards.

Markets (HACCP is mandatory in many):

- **United States**: mandatory by FDA for seafood, juices and low-acid canned foods; USDA for meat and poultry.
- **European Union**: Regulation (EC) 852/2004 requires HACCP-based systems for all food business operators.
- **Mexico**: NOM-251-SSA1-2009 incorporates HACCP.
- **Brazil**: ANVISA Resolution RDC 275/2002 + APPCC (HACCP).
- **Argentina**: SENASA and ANMAT apply HACCP in many sectors.
- **International Codex**: normative reference adopted by more than 180 countries.

Universality: HACCP is the **common base** of every GFSI scheme (IFS, BRC, FSSC 22000, SQF, Global G.A.P.) and of most national food-safety regulations. Correctly implementing HACCP is a prerequisite for any of the above.

3. Key requirements

HACCP is structured in **7 principles** applied through **12 steps**. The first 5 are preparatory; the last 7 are the principles themselves.

The 7 HACCP principles

#	Principle	Focus
1	Hazard analysis	Identify biological, chemical and physical hazards at every process step.
2	Determine Critical Control Points (CCPs)	Steps where control is **essential** to eliminate or reduce the hazard to acceptable levels.
3	Establish critical limits	Measurable values (temperature, pH, time, concentration) that separate acceptable from unacceptable at each CCP.
4	CCP monitoring system	How and how often each CCP is measured, who records it.
5	Corrective actions	What to do when a CCP goes out of control. Includes product disposition.
6	Verification	How the system is confirmed to work (internal audits, calibrations, record review, limit validation).
7	Documentation and records	Required information and system record-keeping.

The 12 steps (5 preparatory + 7 principles)

#	Step	Type
1	Assemble the HACCP team	Preparatory
2	Describe the product	Preparatory
3	Identify intended use	Preparatory
4	Construct process flow diagram	Preparatory
5	On-site confirmation of flow diagram	Preparatory
6	Conduct hazard analysis	Principle 1
7	Determine CCPs	Principle 2
8	Establish critical limits	Principle 3
9	Establish monitoring system	Principle 4
10	Establish corrective actions	Principle 5
11	Establish verification procedures	Principle 6
12	Establish documentation and records	Principle 7

System character

Aspect	Detail
Type	Methodology, not certification. A "HACCP certificate" as such does not formally exist from Codex; what is offered commercially as such is usually a **third-party verification** of the HACCP plan, not equivalent to IFS/BRC/FSSC.
Validation	The HACCP plan is **validated** (demonstrated to work in theory with scientific basis) and **verified** (demonstrated to work in practice with operational data).
Update	Mandatory review upon change of product, process, equipment, ingredients, distribution, or after incident findings.
Role in GFSI	Methodological core of IFS, BRC, FSSC 22000, ISO 22000, SQF and Global G.A.P.

4. How does Darwin cover it?

Captia structures the HACCP plan and captures monitoring events; **Tracium** signs key milestones (approvals, validations, verifications) for immutable evidence. Although HACCP is methodology and not certification, Darwin delivers direct value in **principles 4-7** (monitoring, corrective actions, verification, documentation), which are the most operational.

- **Principle 1 (Hazard analysis)**: **Captia** structures the hazard matrix (biological, chemical, physical) per process step, with severity and probability assessment. Versions signed in **Tracium**.
- **Principle 2 (CCP determination)**: **Captia** ties each identified CCP to a specific process step, with documented rationale.
- **Principle 3 (Critical limits)**: **Captia** records the limits per CCP (temperature, pH, time, concentration) with validation evidence (studies, literature, trials).
- **Principle 4 (Monitoring)**: **Captia Field** captures floor readings (thermometers, pH meters, integrated IoT sensors, timers), with timestamp, operator and linkage to the affected lot. **Tracium** signs each reading for audit-ready evidence.
- **Principle 5 (Corrective actions)**: **Captia** workflow to record the deviation, decide product disposition (quarantine, rework, discard), notify quality, and close with evidence.
- **Principle 6 (Verification)**: **Captia** schedules the verification calendar (equipment calibration, record review, internal audits), records results and enables periodic revalidation of the HACCP plan.
- **Principle 7 (Documentation and records)**: **Captia** archives the complete HACCP plan (flow diagram, hazard matrix, CCPs, limits, procedures) with version control and electronic signature; **Tracium** signs milestones for immutable evidence.
- **Traceability associated with monitoring**: when a CCP goes out of control, the lot-keyed query in **Tracium** identifies all affected product in seconds for action.

Areas not yet covered in V1 (transparent):

- **Laboratory analysis** (microbiological, chemical, allergen): Darwin records external-lab results but does not perform the assays.
- **Physical instrument calibration**: **Captia** schedules and records calibration evidence, but calibration is performed by qualified technical staff.
- **HACCP plan construction**: the logic of the plan (what is a CCP, what limits to apply, what hazards to analyze) requires **technical expertise** from the

client team or a certified consultant. Darwin supports the built plan; it does not auto-build it.

5. Sanctions and consequences of non-compliance

HACCP on its own is methodology, but **many regulations demand it as a legal obligation**. Consequences depend on the applicable regulatory framework.

Direct regulatory risk:

- **United States (FDA)**: failing HACCP in seafood, juices and low-acid canned foods generates *Warning Letters*, mandatory recall, possible criminal charges in serious cases.
- **United States (USDA)**: in meat and poultry, inspectors may suspend operations if the HACCP plan is not executed as documented.
- **European Union (852/2004)**: operators without a functional HACCP system can be sanctioned by the competent national authority. Closure risk.
- **LATAM countries**: SENASA (Argentina), ANVISA (Brazil), COFEPRIS (Mexico), SAG (Chile), DIGESA (Peru), among others, can impose fines, product seizure and operational suspension for non-compliance.

Commercial risk:

- **Impossible to certify** under IFS, BRC, FSSC 22000, ISO 22000 without a functional HACCP plan. These schemes verify HACCP as a core item (KO in IFS, fundamental in BRC, Codex requirement in FSSC).
- Loss of **agreements with major buyers** that demand documented and operational HACCP.

Operational risk:

- Without a functional HACCP system, **recalls are slow and costly**: identifying the affected lot, scope of the problem and corrective disposition can take days where the system should respond in hours.

6. Timeline

- **1960s**: Pillsbury Company develops HACCP in collaboration with NASA and U.S. Army Laboratories for space food safety.
- **1971**: first public presentation at the U.S. National Conference on Food Protection.

- **1985**: the U.S. National Academy of Sciences recommends HACCP as the preferred system.
- **1993**: **Codex Alimentarius Commission** adopts the HACCP system in its Code of Practice (CAC/RCP 1-1969).
- **1995 - 1998**: FDA mandates HACCP for seafood (1995) and juices (2001). USDA mandates it for meat and poultry (1996-2000).
- **2004**: European Union publishes Regulation (EC) 852/2004 with transversal HACCP requirement.
- **September 2020**: **Codex publishes the current revision CXC 1-1969 Rev. 2020**, with emphasis on food-safety culture and alignment with other practices.
- **2026 (expected)**: possible interpretive clarifications and additional sector-specific guidelines.

7. Official source and updates

- **Primary source (Codex Alimentarius)**: Codex Alimentarius FAO/WHO
- **HACCP Principles & Application Guidelines (FDA)**: FDA HACCP
- **HACCP System (FAO)**: HACCP System and Guidelines for its Application (FAO)
- **EU Regulation 852/2004 (Hygiene of foodstuffs)**: consult EUR-Lex.
- **Last official update verified**: September 25, 2020 (Codex CXC 1-1969 Rev. 2020).
- **Darwin doc version**: 1.0.0.
- **Darwin doc date**: May 13, 2026.

Legal notice

This document is **informational material** prepared by Darwin Evolution for commercial and educational purposes. **It does not constitute legal advice and is not a substitute for consultation with a regulatory compliance specialist.** Regulations may be updated after the date of this document; always verify the official source.

For operational implementation in your company or for formal audits, consult with a certified compliance advisor in the applicable jurisdiction.

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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