

HACCP Plan Template - Infant Formula

Food Safety & Quality Template · Provided by GIFSQ

There's no room for 'good enough' in infant formula - the consumers are weeks old and the product isn't sterile. This is the most rigorous plan in the set: heat treatment, dry-blend controls, *Cronobacter* environmental monitoring, the lot.

Don't just fill in the blanks - the value is the team discussion the Codex steps force you to have. Replace every [bracketed] entry with your operation's detail and validate each critical limit for your own product and equipment.

1. Document control

Field	Details
Document title	HACCP Plan Template - Infant Formula
Document no.	[QA-HACCP-019]
Version	[1.0]
Effective date	[YYYY-MM-DD]
Prepared by	[Name / Title / Date]
Approved by	[Name / Title / Date]
Review date	[YYYY-MM-DD]

2. Product description

Item	Description
Product name	[e.g., Infant formula powder, 0-6 months]
Description	[Powdered infant formula - not sterile]
Ingredients	[Milk proteins, oils, lactose, vitamins, minerals - list all]

Item	Description
Packaging	[Tin with scoop, nitrogen-flushed - describe]
Shelf life	[e.g., 24 months ambient]
Distribution	[Ambient distribution to retail]

3. Intended use and consumers

- Infants 0-12 months - highly vulnerable. Product is not sterile; preparation instructions on label must be followed.

4. Process flow diagram

Don't draw this from memory in a meeting room. Walk the line, watch what really happens, then number the confirmed flow.

1. Receiving ingredients
2. Storage
3. Wet mixing
4. Heat treatment (pasteurization)
5. Evaporation
6. Spray drying
7. Dry blending (vitamins/minerals)
8. Sifting
9. Filling and sealing
10. Metal detection
11. Ambient storage
12. Dispatch

5. Hazard analysis (Codex Principle 1)

The weakest hazard analyses are copy-paste jobs. Think through your own ingredients, equipment and history - that's what this table is for.

Process step	Hazard (B / C / P)	Significant? Rationale	Control measure
Receiving	B: <i>Cronobacter sakazakii</i> , <i>Salmonella</i> in dry ingredients; C: heavy metals, melamine (adulteration)	Y	Approved suppliers; COA; contaminant testing program
Heat treatment	B: survival of vegetative pathogens	Y - CCP	Validated time-temperature (CCP 1)
Spray drying	B: survival if drying inadequate	Y	Validated outlet temperature and moisture/aw
Dry blending	B: introduction of <i>Cronobacter</i> / <i>Salmonella</i> with dry ingredients	Y	Microbiological specs on every lot; hygienic handling
Filling and sealing	B: post-process contamination; seal defects	Y - CCP or OPRP	Dry hygienic filling; seal integrity
Environmental	B: <i>Cronobacter</i> in dry processing environment	Y	Environmental monitoring program with defined zones and actions
Metal detection	P: metal fragments	Y - CCP	Validated metal detector (CCP 2)

6. CCPs, critical limits and monitoring (Principles 2-4)

Treat these limits as candidates, not gospel. Confirm each works for your product on your line, and set monitoring your team can sustain every shift.

CCP	Significant hazard	Critical limit	Monitoring (what / how / frequency / who)	Corrective action	Verification	Records
CCP 1 - Heat treatment	Survival of vegetative pathogens	Validated schedule: [temp/time per validation ref ____]	Continuous recording each batch; [role]	Hold; re-process or dispose; investigate	Record review; calibration	Heat treatment log
CCP 2 - Metal detection	Metal fragments	Detector rejects test pieces [sizes set by validation]	Challenge test start/end and [hourly]; [role]	Hold since last good check; re-screen	Function checks	Metal detection log

7. Corrective action procedure (Principle 5)

1. Hold and segregate all product made since the last acceptable check; tag it and enter it in the hold log.
2. Restore control (re-cook, adjust temperature, repair equipment) and confirm it before restarting.
3. [QA Manager / designee] assesses the affected product - release, rework or disposal - and records the justification.
4. Find and fix the root cause; record the deviation, investigation and disposition, signed within [1 working day].

8. Verification procedures (Principle 6)

- A trained reviewer checks CCP monitoring and corrective action records at [frequency, e.g., within 7 days].
- Calibrate monitoring instruments per the calibration schedule.
- Periodic product testing (microbiological, chemical or physical) per the verification schedule.
- Internal audit at least [annually]; full HACCP reassessment annually or after any significant change.

9. Record-keeping (Principle 7)

- Hazard analysis worksheet and CCP decision records

- CCP monitoring records, signed and dated
- Deviation and corrective action records
- Verification records, including calibration
- Training records for the HACCP team and CCP monitors

Approval and control

Role	Name	Signature	Date
Prepared by	[Name]	[Signature]	[Date]
Reviewed by (QA)	[Name]	[Signature]	[Date]
Approved by	[Name]	[Signature]	[Date]

Keep completed forms for [Define retention period, e.g., 2 years beyond shelf life] at [defined location] - and make sure someone besides you knows where that is.

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