

ASEPTIC, ESL & IN-PACK STERILISATION — SELECTION GUIDE

How to choose between pasteurisation, extended shelf life, UHT with aseptic filling, hot-fill and in-pack retorting for a liquid or semi-liquid food — the four inputs that decide the route, the pack decontamination each route implies, and the validation numbers that govern it.

VERSION 1.0 · JUL 2026 · 6 ROUTES · 6 PACK FORMATS · GATES: PROCESS SELECTION · TECHNOLOGY FREEZE

HOW TO USE THIS GUIDE

- 1 Answer Section 1 first. **The product decides the route, not the machine on offer** — acidity and particulates rule out whole technology families before any vendor comparison starts.
- 2 Use the tables as a shortlist filter, then confirm with a validated process authority. **Every process condition here must be established for your specific product** — the figures shown are typical industry references, not a specification.
- 3 Freeze the pack format at the same time as the process. The pack decides the decontamination system, the filler class and half the capital cost.
- 4 For low-acid shelf-stable products, the thermal process must be **established and documented by a competent process authority** and filed as required by the applicable regulation.

01 THE FOUR INPUTS THAT DECIDE THE ROUTE

1 — Acidity, and water activity

The single most consequential number is pH. **Above pH 4.6, a shelf-stable product must receive a sterilisation process** designed against *Clostridium botulinum* spores; at or below pH 4.6 — naturally acid or properly acidified — spore outgrowth is prevented by the acid itself and a pasteurisation process can deliver shelf stability. Water activity is the second gate: products at or below a_w 0.85 are similarly not treated as low-acid shelf-stable. Establish both on the finished product, at the least favourable point in the batch, not on the recipe average.

2 — Viscosity and particulates

Viscosity and particle size select the heat exchanger long before efficiency does: plate exchangers for low-viscosity, clean liquids; tubular for higher viscosity, fouling duties and small particulates; scraped-surface for viscous products and large particulates.

Particulates change the safety basis, not just the hardware — the process must be established on the slowest-heating point of the largest particle while the holding tube is sized on the fastest-moving element of the fluid.

3 — Target shelf life and distribution chain

A chilled chain that is genuinely maintained end-to-end makes pasteurised or ESL product viable and avoids the cost and flavour penalty of sterilisation. Where the chain is uncertain, long, or hot, ambient-stable product is an engineering answer to a logistics problem. Decide this before technology selection — it is the difference between a filler costing a fraction of an aseptic line and one costing several times more.

4 — Pack format and what sterilises it

Two philosophies exist. In **aseptic filling**, product and pack are sterilised separately and brought together in a sterile zone — the pack never sees the thermal process. In **in-pack sterilisation**, product is filled and sealed cold or warm, then the sealed pack is sterilised as a unit and must survive it. Hot-fill sits between the two, using the product's own heat to sterilise the pack surface, and is limited to acid products.

02 THERMAL PROCESS ROUTES AT A GLANCE

Typical industry references for liquid foods. Every value must be established for the specific product by a competent process authority.

ROUTE	WHAT IT ACHIEVES	TYPICAL CONDITION	SHELF LIFE / CHAIN
HTST pasteurisation	Destroys vegetative pathogens and most spoilage flora. Product is <i>not</i> shelf-stable — spores survive.	72–75 °C 15–20 s	7–21 DAYS CHILLED
Extended shelf life (ESL)	Higher thermal load plus ultra-clean or hygienic filling in a controlled-environment zone. Still a chilled product.	123–130 °C 2–4 s	21–60 DAYS CHILLED
UHT — indirect (plate / tubular)	Commercial sterility of the product stream, filled into a separately sterilised pack. Highest regeneration efficiency.	135–145 °C 2–6 s	3–9 MONTHS AMBIENT
UHT — direct (injection / infusion)	As above, with near-instant heating and flash cooling — less chemical damage, better flavour on heat-sensitive products. Needs culinary steam.	140–150 °C 2–4 s	3–9 MONTHS AMBIENT
In-pack sterilisation (retort)	Product sterilised inside the sealed pack — no sterile zone to maintain, but the pack must survive the process and the seal is the whole defence.	115–125 °C $F_0 \geq 3$ min	12–24 MONTHS AMBIENT
Hot-fill and hold	Product heat sterilises the pack surface after filling and inversion. Acid or acidified products only ($\text{pH} \leq 4.6$). Simplest and cheapest ambient route.	85–95 °C fill + inverted hold	6–12 MONTHS AMBIENT

REFERENCE BASIS: CODEX CAC/RCP 40-1993 (ASEPTICALLY PROCESSED LOW-ACID FOODS) · CAC/RCP 23-1979 (LOW-ACID & ACIDIFIED CANNED FOODS) · FSSAI PRODUCT STANDARDS

ENGINEER'S NOTE

Direct and indirect UHT are not interchangeable once the product is developed. Direct heating gives a gentler flavour on protein-rich and heat-sensitive products, but it dilutes with condensed steam and needs flash cooling to remove it, so the balance must be designed in. Indirect heating regenerates far more heat and costs less to run, but fouls faster on protein and calcium — and the run length between cleans, not the nameplate capacity, is what determines how much product you actually make in a week.

03 PACK FORMAT & HOW THE PACK IS DECONTAMINATED

The pack decides the decontamination system, the filler class and a large share of the capital cost — freeze it with the process, not after.

PACK FORMAT	HOW THE PACK IS DECONTAMINATED	WHAT FAILS IN PRACTICE
Paperboard aseptic carton	Web or formed pack treated with hydrogen peroxide, then removed by hot sterile air before filling in a sterile zone.	Longitudinal seal and crease integrity; peroxide residue limits; strip application at the seam.
PET bottle — wet system	Sprayed or rinsed with a peroxide or peracetic-acid solution, rinsed with sterile water, dried with sterile air.	Sterility of the final rinse water; neck-finish coverage; closure sterilisation treated as an afterthought.
PET — dry / preform system	Preform or bottle treated with vaporised peroxide or an electron beam; no rinse water in the sterile zone.	Dose mapping and dosimetry; shielding and access control; validation of shadowed geometry.
Cup / tray form-fill-seal	Base web and lidding film decontaminated in line (peroxide plus heat, or radiant), filled under sterile-air overpressure.	Product splash on the seal area; loss of zone overpressure during faults and restarts.
Aseptic pouch / bag-in-box	Pre-sterilised bags (often irradiated) filled through a sterilised port, or in-line web decontamination.	Port sterilisation and handling discipline; bag damage in transit and storage.
Can / glass / retort pouch	Not decontaminated separately — the sealed pack is sterilised as a unit in the retort.	Seam or seal integrity; recontamination through a wet seam during cooling — cooling water must be treated.

04 THE STERILE BOUNDARY

An aseptic line is not a steriliser with a filler attached; it is a **closed sterile envelope** that begins at the holding tube and ends at the sealed pack. Everything that crosses that envelope — a valve stem, a seal, a sample point, a tank vent, the air in the filling chamber — is a route in. The envelope is established by pre-sterilisation of the whole product path before production, held by sterile-air overpressure and steam or condensate barriers during production, and lost the moment any one of them lapses.

Design consequences worth fixing early: aseptic valve blocks with steam barriers rather than single seals; sterile-air filtration that is integrity-testable in place; an aseptic surge tank sized so a short downstream stop does not force the steriliser into recirculation; and a CIP-then-SIP sequence that cannot be run out of order. **Cleaning and sterilisation are different operations** — a plant that is sterile but not clean will foul, and a plant that is clean but not sterile will spoil.

05 THE NUMBERS THAT GOVERN THE PROCESS

Definitions are industry convention; the target values must be established for your product and filed as your process authority directs.

MEASURE	WHAT IT MEANS	CONVENTIONAL BASIS
F₀	Sterilising effect expressed as equivalent minutes at 121.1 °C. The standard measure for in-pack sterilisation of low-acid foods.	$z = 10\text{ }^{\circ}\text{C}$ $F_0 \geq 3\text{ MIN}$ (BOTULINUM COOK)
B*	Sterilisation effect for UHT, referenced to 135 °C. A commercial UHT process conventionally targets B* of at least 1.	$B^* = 1 \equiv 10.1\text{ s}$ AT 135 °C $z = 10.5\text{ }^{\circ}\text{C}$
C*	Chemical damage — browning, vitamin and flavour loss — on the same reference. Quality is won by keeping C* low while B* is met.	$C^* = 1 \equiv 30.5\text{ s}$ AT 135 °C $z = 31.4\text{ }^{\circ}\text{C}$
Holding-tube basis	Residence time must be taken on the fastest-moving element, not the average. In fully developed laminar flow the maximum velocity is twice the mean — halving the effective hold.	$v(\text{MAX}) = 2 \times v(\text{MEAN})$ LAMINAR CASE
Pre-sterilisation	The whole product path and the filler sterile zone are brought to condition and held before production starts; the cycle is recorded as a critical control.	PER EQUIPMENT VALIDATION
Release testing	Incubation of finished packs before release, at mesophilic and thermophilic conditions, with pack-integrity and seal checks on a defined frequency.	PER PRODUCT SPECIFICATION

ENGINEER'S NOTE

Aseptic failures rarely start in the steriliser. The steriliser is instrumented, alarmed and interlocked; the sterile boundary usually is not. In practice the recurring causes are a valve without a working steam barrier, a sterile-air filter that was never integrity-tested in place, a seal replaced without re-sterilising, and a restart after a short stop that skipped the sterilisation sequence. Instrument the boundary and write the restart rules before the line is commissioned — retro-fitting discipline after a spoilage incident is far more expensive.

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