



THE FOOD PROCESSING OPERATIONS GUIDE

Safe changeovers. Right labels. Every lot traceable.

From approved supplier to checked pack and fast, honest recall

A capability and evaluation guide for food manufacturers and co-packers who want hazard controls, allergen changeovers, rework, pack checks and lot records to live in one connected record instead of binders and spreadsheets.



PREVENTIVE CONTROLS

ALLERGENS

LOT TO CUSTOMER

INSIDE THE GUIDE

Kettle to customer, check by check.

A food lot passes through purchasing, goods-in, cold and ambient storage, weighing, cooking or mixing, cooling, packing, labelling and dispatch. This guide follows it and shows what each handover must leave behind.

01 / FRAME

pp. 03–05

The rules and the plan

U.S. FDA and USDA, EU, Canada SFCR, Codex and customer schemes; the food safety plan; a production day.

02 / FLOW

pp. 06–14

Supplier to filled tray

Supplier approval, goods-in, storage and shelf life, recipes and allergens, process checks, rework, changeover, lab, pack checks.

03 / DECIDE

pp. 15–18

Correct, verify, improve

Corrections and corrective actions, record review and verification, complaints and CAPA, people.

04 / SUSTAIN

pp. 19–25

Assets, trace, recall

Calibration and maintenance, OEE and loss, traceability records, recall, a timed mock recall, portals, data and AI.

05 / APPLY

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Evidence map and tools

Evidence map, four worksheets, a phased roadmap and a fair four-week evaluation.

06 / SOURCES

pp. 33–35

What this guide rests on

Twenty-two linked primary sources with status and scope, plus the limits of this guide.

Who it is for. Food safety and quality managers, preventive controls and HACCP team members, production, hygiene, engineering and warehouse leads, technical teams at co-packers and brand owners, and anyone choosing a production and quality system for ready meals, sauces, soups, chilled, frozen or ambient processed foods.

How to read it. Every operational page ends with a teal Where V5 fits panel. Everything above it is practice and regulation, useful whether or not you ever use V5. Regulatory statements cite numbered sources; check the current text for your products, sites and markets.

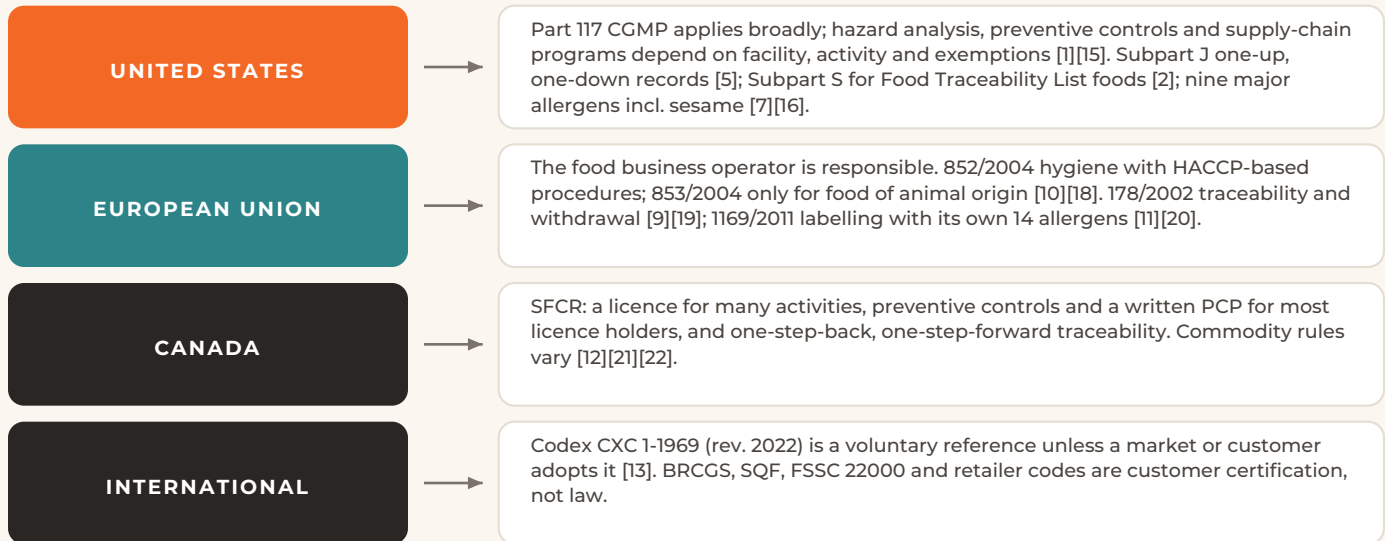
WHERE V5 FITS

V5 records the production, hygiene, laboratory and quality work your food safety plan defines. It does not write your hazard analysis, set critical limits, validate controls, decide whether a food is on a traceability list, or decide to recall. Those stay with your qualified people.

FRAME / 01

Start with where you make and sell.

Food processors usually answer to a hygiene and hazard-control regime, a general food law with traceability duties, and labelling rules. The same tray of curry can sit under several at once.



Meat and poultry differ

In the U.S., USDA FSIS establishments follow HACCP under 9 CFR Part 417 [8][17], not Part 117. Mixed sites need to know which product sits under which agency.

One plan does not fit all

No single HACCP plan applies to every processor. Your team owns the hazard analysis, limits and verification for each product and site.

Write the scope down

Record products, sites, markets and which rules apply, and why, in a controlled document. Revisit it when a product, site, customer or market changes.

WHERE V5 FITS

Keep scope, food safety plans and procedures as controlled documents with revisions, owners and review dates. V5 industry packs adjust wording, screens and reports for food work; they do not decide which rules apply to you.

Sources: [1], [2], [5], [7], [8], [9], [10], [11], [12], [13], [15], [16], [17], [18], [19], [20], [21], [22] (linked on pages 33–35)

FRAME / 02

The plan names the controls.

Part 117 asks most facilities for a written food safety plan prepared or overseen by a preventive controls qualified individual (PCQI). HACCP plans elsewhere follow similar logic.

Hazard analysis 117.130: known or reasonably foreseeable biological, chemical and physical hazards, written even when none need a control [1].	Preventive controls 117.135: process, allergen, sanitation and supply-chain controls, and others as needed [1].	Supply-chain program Subpart G (117.405–.475) where a raw material hazard is controlled by your supplier [1].	Recall plan 117.139: a written recall plan for food with a hazard requiring a preventive control [1].	Management 117.140–.170: monitoring, corrective actions, verification, validation and reanalysis [1].
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117.126: THE PLAN IS PREPARED OR OVERSEEN BY ONE OR MORE PCQIs; 117.310: OWNER SIGNS AND DATES IT [1]

PCQI	Prepares or oversees the plan, validation, record review and reanalysis (117.180) [1].	Name them; keep the qualification on file.
Qualified individuals	117.4: everyone who manufactures, processes, packs or holds food is qualified for their duties, with food hygiene and safety training [1].	Training records belong to the person and the task.
Owner or operator	Signs and dates the plan on completion and every modification (117.310) [1].	A plan change is a controlled revision.

WHERE V5 FITS

Food safety plans, hazard analyses, SOPs and validation studies can be kept as controlled documents with revision, approval and review dates, and each control can be linked to the kiosk checks that monitor it. V5 records the plan; your PCQI writes and validates it.

FRAME / 03

One production day.

A worked example chilled ready meal: batch RM-0612, tomato and chickpea curry, recipe revision 4, made on a line that ran a dairy-containing korma the shift before. Follow it through every handover.

05:40	Allergen changeover after the korma: clean, inspect, swab, verify
06:20	Pre-start checks: metal detector test pieces, checkweigher, label on line
06:35	Weigh-up to recipe rev 4; chickpea lot IN-3307 and spice lots scanned
07:50	Cook; core temperature recorded against the critical limit
08:30	Rework from RM-0609 (12 kg) added and scanned
09:15	Blast chill; one cooling check late, correction recorded
10:00	Fill, seal, metal detect, weigh, label; pack check every 30 minutes
14:10	PCQI-led review of the day's monitoring and corrective action records

One record grows

Changeover, weigh-up, cook, chill and pack checks add to one batch record, so review starts from the full day, not a stack of sheets.

Rework is a lot

The 12 kg from RM-0609 brings its own ingredient lots, and allergens, into RM-0612. It is recorded like any other input.

Late is visible

A late cooling check is not hidden in a margin. The correction and who made it are part of the record the reviewer sees.

WHERE V5 FITS

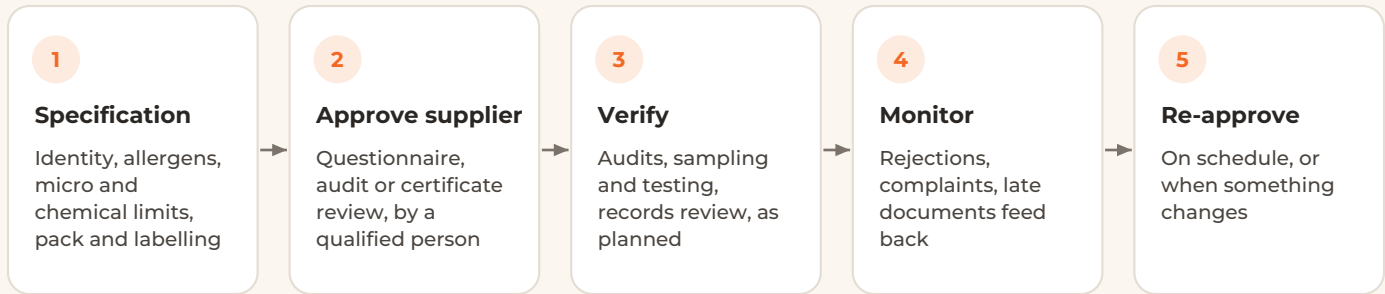
Work orders sit on the production schedule with recipe, line and allergen profile. Kiosk steps capture who did what, with which lots, equipment and values, and the batch record assembles as the batch runs.

Sources: [1] (linked on pages 33–35)

FLOW / 01

Approve the supplier before the lorry.

Raw materials bring hazards with them: pathogens in spices, undeclared allergens, foreign bodies, fraud. Your hazard analysis decides which are controlled at your site and which by your supplier.



When the supplier controls it

If your hazard analysis relies on a supplier to control a hazard, Part 117 Subpart G expects a supply-chain program: approved suppliers, verification activities chosen for the hazard, and records [1].

Approve before receipt

117.420 requires the receiving facility to approve suppliers, and to document that approval, before receiving raw materials and other ingredients from them [1].

Allergens in the spec

Ask suppliers for allergen content and cross-contact risks, and for notice when a recipe or site changes. A spec without allergens is not finished.

WHERE V5 FITS

Approved supplier lists, qualification, scorecards and specifications sit with purchasing and receiving, so an unapproved source is visible at goods-in. Audits route findings to SCAR or CAPA, and suppliers can upload certificates and change notices through the supplier portal where configured.

Sources: [1] (linked on pages 33–35)

Goods-in creates the first link.

What is recorded at the dock is the start of every trace you will ever run: who sent it, what lot, how much, in what condition, at what temperature.



One step back

Part 1 Subpart J requires records of the immediate previous source of food you receive [5]; EU Art. 18 and Canada's SFCR have similar one-step duties [9][12].

FTL foods need more

For foods on the Food Traceability List, Subpart S adds key data elements at receiving, including the traceability lot code and its source [2].

Check, then accept

Temperature, seal, pest and damage checks, documents against the order and the approved supplier list.

WORKED EXAMPLE: ONE RECEIPT

Item	Cooked chickpeas, 500 kg, 20 tubs
Supplier / supplier lot	Approved supplier S-114 / CP-8821
Internal lot	IN-3307, linked to CP-8821
Arrival temperature	3.1 °C; your limit is set in the spec
Allergens declared	None; matches specification rev 2

WHERE V5 FITS

Receiving records supplier, supplier lot, internal lot, quantity, expiry, condition and temperature against the purchase order, and lots can start on hold where configured. Certificate values can be read from a PDF or photo for a person to confirm; AI extraction never accepts a lot.

FLOW / 03

Status, temperature and shelf life.

A chilled ingredient used a day past its date, or a held lot picked by mistake, can undo every control upstream. Status has to be visible where people pick.

On hold

Awaiting checks or results

Released

Can be picked, FEFO

Restricted

Only for named products, e.g. allergen-segregated

Rejected / expired

Cannot be picked



Segregate allergens

117.135(c)(2) allergen controls include protecting food from allergen cross-contact during storage and handling [1]. Dedicated or below-shelf storage is a control to record.

Temperature is a record

Where storage temperature is part of your plan, keep the actual values and who reviewed excursions, not just a set point.

Dates you can defend

Use-by and best-before dates on your own products need evidence. Track ingredient expiry, opened-life and rework life in the record.

WHERE V5 FITS

Lots carry status, location, expiry and opened dates, with FEFO/FIFO picking and storage zones. Scanning a held, rejected or expired lot at the kiosk stops the step according to your workspace rules. Store temperatures can stream in with alerts through supported, configured sensors.

Sources: [1] (linked on pages 33–35)

FLOW / 04

The recipe carries the allergens.

The allergen statement on a label is only as good as the recipe, the sub-recipes and the supplier specs behind it. Build it once, from data, and keep it under revision.

	Milk	Egg	Fish	Crust.	Tree nut	Peanut	Wheat	Soy	Sesame	Mustard	Celery
Cooked chickpeas IN-3307	•	•	•	•	•	•	•	•	•	•	•
Tomato base TB-12	•	•	•	•	•	•	•	•	•	•	•
Spice blend SP-40	•	•	•	•	•	•	•	•	•	•	•
Vegetable oil	•	•	•	•	•	•	•	•	•	•	•
Rework RM-0609	•	•	•	•	•	•	•	•	•	•	•
RM-0612 finished	•	•	•	•	•	•	•	•	•	•	•

Worked example. Columns show a subset of regulated allergens across the U.S. and EU lists; check the full list for each market.

U.S. major food allergens

Section 201(qq) of the FD&C Act defines nine major food allergens, including sesame [7]. Part 117 allergen controls cover cross-contact and labelling [1].

EU: fourteen, emphasised

Regulation 1169/2011 lists substances causing allergies or intolerances in Annex II and requires them to be emphasised in the ingredient list [11]. Celery and mustard are on it.

Rework inherits

Rework from RM-0609 brings its allergen profile into RM-0612. If the profiles differ, the rework rule should say so before anyone scoops it.

WHERE V5 FITS

Recipes and sub-recipes are kept under revision with approval, ingredient allergens and nutrition data, and the label preview shows the allergen declaration built from them. Allergen data is only as good as your specs; a person approves the label.

Sources: [1], [7], [11], [16], [20] (linked on pages 33–35)

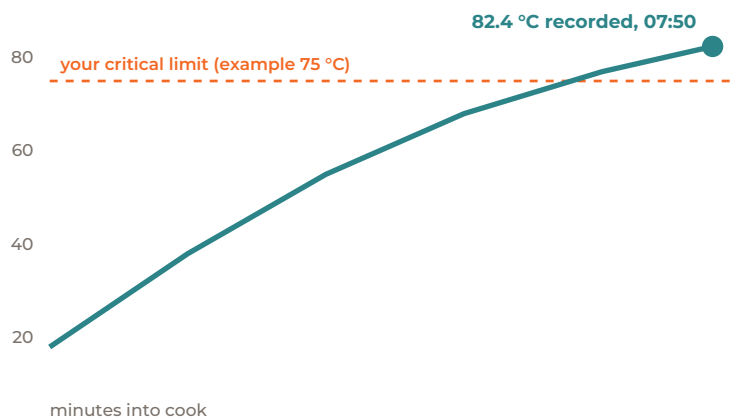
FLOW / 05

Cook, chill, record the actual value.

Process controls such as a cook to a core temperature or a cooling profile only protect consumers if they are monitored, recorded as values and acted on when they fail.



RM-0612 • CORE TEMPERATURE, KETTLE 2 (WORKED EXAMPLE)



Monitor with frequency

117.145: written monitoring procedures with frequency, and records [1].

Actual values

117.305(b): records contain the actual values and observations obtained during monitoring [1].

Limits are yours

The 75 °C line is an example. Your PCQI or HACCP team sets and validates limits for your process.

WHERE V5 FITS

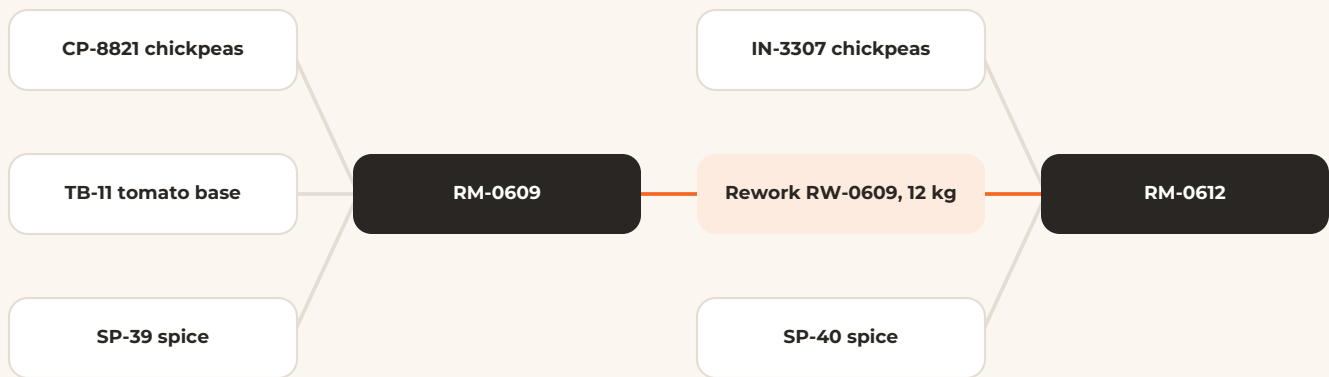
Critical checks are kiosk steps with targets and limits from the recipe; a value outside limits can stop the step and open a correction or deviation. Supported, configured probes and sensors can send readings directly; otherwise operators enter the value and their identity is recorded.

Sources: [1] (linked on pages 33–35)

FLOW / 06

Rework without losing the thread.

Rework saves food and money, and it is one of the commonest ways traceability and allergen control break. Treat every kilo of rework as a lot with a history.



Tracing back from RM-0612 now reaches CP-8821, TB-11 and SP-39 through the rework, as well as the day's own inputs.

Define what may be reworked

Which products, into which products, how much, how old, and with which allergen profiles. Write the rule into the recipe or procedure.

Label and hold it

Rework sits in storage with its own lot, date and status like any ingredient, so it can be found, picked FEFO and blocked.

Scan it in

When rework is added, record the rework lot and quantity, so the original lots follow the new batch automatically.

WHERE V5 FITS

Rework can be recorded as its own lot with expiry and status, consumed by scanning into a new batch, and followed in lot genealogy forward and back. Rework rules and limits are set by your team; V5 checks the lot you scan against them where configured.

FLOW / 07

Change over like it matters.

Going from a dairy korma to a milk-free curry is the moment allergen cross-contact is most likely. The changeover is a control with steps, evidence and a sign-off.



01

Plan the sequence

Schedule lower-risk to higher-risk allergen profiles where you can.

02

Clean to SOP

Strip-down points, method, chemicals and time from the cleaning procedure.

03

Inspect

Visual check of named surfaces, hard-to-clean points included.

04

Verify

Swab or test if your plan uses it; record the result, not just 'done'.

05

Release the line

A named person signs off before the next product starts.

What the rule says. 117.135(c)(2) allergen controls include procedures for protecting food from allergen cross-contact, including during handling and use, and for labelling; 117.135(c)(3) sanitation controls cover cleanliness of food-contact surfaces and preventing cross-contact [1]. Swab methods and limits are your validation decisions.

WHERE V5 FITS

Changeovers can be checklists on the kiosk with photos, swab results and supervisor sign-off, and the next work order can be blocked until the changeover is verified where configured. Cleaning schedules and records sit with the equipment and the line.

Sources: [1] (linked on pages 33–35)

FLOW / 08

Test what the plan says to test.

Finished product micro, shelf-life studies, allergen verification and environmental monitoring each answer a different question. The record should say which.

Product testing

117.165(a)(2): product testing for a pathogen or indicator organism or other hazard, as appropriate, as a verification activity [1].

Environmental monitoring

117.165(a)(3): where contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a control [1].

Written procedures

117.165(b): procedures for sampling, tests, laboratory and corrective action when a result is positive or out of spec [1].



EXAMPLE ENVIRONMENTAL MONITORING ZONES

Zone 1

Food-contact surfaces

Zone 2

Next to contact surfaces

Zone 3

Further away in the room

Zone 4

Outside the processing room

Zones are a common industry convention, not a regulatory definition. Sites, frequencies and organisms come from your own hazard analysis and validation.

WHERE V5 FITS

Lab & QC and LIMS cover sample plans, methods, results against specification and positive or out-of-limit escalation, linked to the lot, line or site. Results can be held pending before a lot is released. Analysts and reviewers sign; V5 does not approve results.

Sources: [1] (linked on pages 33–35)

FLOW / 09

Check the pack before it ships.

Wrong label, missing date code, a foreign body, an underweight tray. Most food recalls start in the last ten metres of the line, so pack checks deserve a design of their own.



- Label matches the product**
Right SKU, recipe revision, allergen emphasis, language.
- Date and lot code**
Readable, correct, matching the batch record.
- Metal detection / X-ray**
Test pieces at start, intervals and after changes.
- Weight**
Checkweigher or sample weights, to your market's rules.
- Seal and pack integrity**
Seal checks and gas or vacuum where used.

RM-0612 PACK CHECKS (WORKED EXAMPLE)

10:00 start	Test pieces Fe 2.0 / non-Fe 2.5 / SS 3.0 rejected	OK
10:30	Label, date code, seal, 5 tray weights	OK
11:00	Label roll changed; first label re-checked	OK
11:30	Metal detector test failed on SS piece	HOLD
11:48	Detector reset; product since 11:00 re-screened	OK

WHERE V5 FITS

Pack checks run as timed kiosk tasks, with checkweigher and detector results through supported connections, and a hold when a check fails. Label printing uses data from the batch record so the date and lot come from the record, not a keyboard.

DECIDE / 01

Correction or corrective action?

Part 117 draws a useful line between fixing a small problem on the spot and a full corrective action. Both get recorded; they ask different questions.

CORRECTION

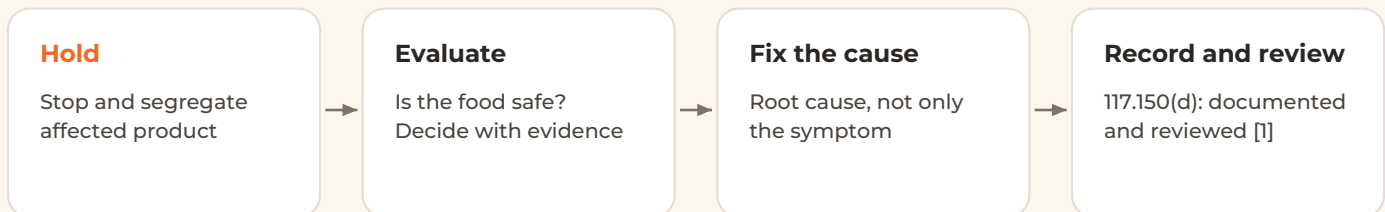
117.3 defines a correction as an action to identify and correct a problem that occurred during production, without other actions associated with a corrective action procedure. 117.150(c) allows corrections for conditions not consistent with allergen or sanitation controls, or a minor, isolated problem that does not directly impact product safety, when taken in a timely manner [1].

Example: a late cooling check on RM-0612 is taken, the value is in limits, and the reason is recorded.

CORRECTIVE ACTION

117.150(a) procedures, when a preventive control is not properly implemented, identify and correct the problem, reduce the chance of recurrence, evaluate affected food for safety, and prevent adulterated food entering commerce [1].

Example: the metal detector fails its stainless test piece at 11:30. Product since the last good check is held and re-screened, the cause is found, and the action is reviewed.



Unanticipated problems. 117.150(b) also covers problems with no specific corrective action procedure, including when a preventive control turns out to be ineffective, and may require reanalysis of the plan [1].

WHERE V5 FITS

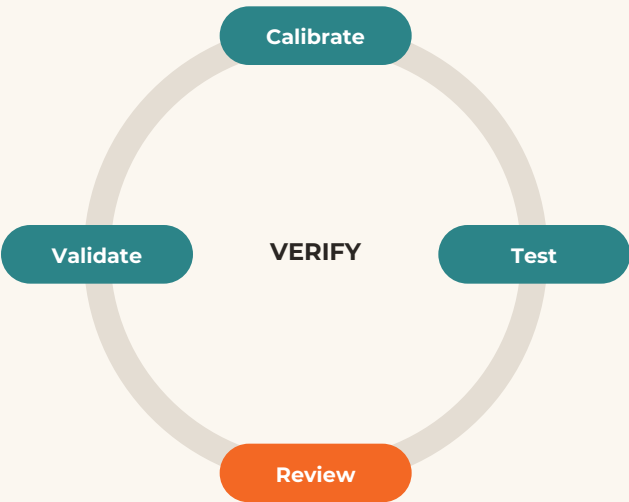
Out-of-limit values can open a correction or deviation from the step, linked to the batch, line, equipment and people, with hold of affected lots. AI can suggest a classification or draft a summary for a person to edit. A person decides product disposition.

Sources: [1] (linked on pages 33–35)

DECIDE / 02

Review the records, within the week.

Verification is how you show the plan works on real days. Part 117 sets a specific clock for reviewing monitoring and corrective action records.



- Calibrate**
Monitoring and verification instruments, 117.165(a)(1) [1].
- Test**
Product testing and environmental monitoring, (a)(2)–(3) [1].
- Review**
Monitoring and corrective action records within 7 working days, (a)(4)(i) [1].
- Validate**
Process controls proven adequate, 117.160 [1].

WHAT A GOOD RECORD CONTAINS • 117.305 [1]

Original, true copy or electronic	117.305(a)
Actual values and observations	117.305(b)
Accurate, indelible, legible	117.305(c)
Created at the time of the activity	117.305(d)
Plant, date, time, person, product and lot	117.305(f)
Kept at least 2 years after prepared	117.315(a)(1)

WHERE V5 FITS

A review queue can show each day's monitoring and correction records with exceptions first, and record who reviewed them and when. Reports show overdue reviews. Signing a review is a person's act; V5 makes the 7-day clock visible but does not review for you.

DECIDE / 03

Complaints, and the fix that sticks.

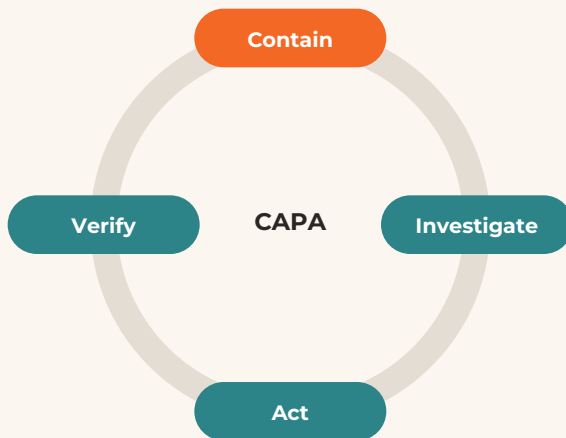
A customer finds a piece of plastic in a tray, or reports a reaction to an undeclared allergen. The complaint links to a lot, the lot to its records, and the records to a cause.

LOG AND LINK

- Product, pack date and lot from the photo or code
- What, where, when, who reported it
- Linked batch record, pack checks, changeovers
- Severity and whether it may affect other lots

DECIDE, WITH PEOPLE

- Is there a food safety risk? Who decides?
- Hold or withdraw other lots? Notify customers?
- Does it trigger reanalysis of the plan?
- Report to the authority where your law requires



Feed CAPA from every source

Complaints, failed checks, positive swabs, supplier issues, audit findings and trends. Link them so a repeat is visible.

EU duty to act

Art. 19 of the General Food Law requires operators to withdraw unsafe food and inform the authorities [9].

Agree effectiveness first

Decide what evidence will show the action worked, and review it on a date.

WHERE V5 FITS

Complaints can be logged, linked to batch and lots, and routed to CAPA with root-cause workflow and effectiveness checks. AI can draft a summary for a person to edit. V5 does not decide food safety risk, recall or authority notification.

Sources: [1], [9] (linked on pages 33–35)

DECIDE / 04

The right person, trained for today.

A changeover signed by someone untrained on the new cleaning SOP is not evidence. Training and permission belong at the step.

Qualified for the job

117.4(b): each individual has the education, training or experience to do their job, and is trained in food hygiene and food safety [1].

Training is recorded

117.4(d): records of hygiene and food safety training are kept [1]. Keep SOP-specific training against the revision.

Hygiene and health

117.10 covers personnel cleanliness, protective clothing and excluding people whose illness could contaminate food [1].

EXAMPLE COMPETENCE AND PERMISSION MATRIX

	Recipe rev 4	Allergen clean SOP	Swab method	Record review
Line operator	Trained	Retraining due	—	Not permitted
Hygiene team	—	Trained	Trained	Not permitted
QA technician	Trained	Trained	Trained	Not permitted
PCQI / QA manager	Trained	Trained	Trained	Trained

Languages and shifts. Many food sites run multilingual night and weekend shifts. Instructions and checks should be clear on a gloved tablet in the language the operator reads, and training needs to reach every shift.

WHERE V5 FITS

Document control keeps SOPs and instructions under revision with read-and-understood training. The skills matrix can block untrained operators at the kiosk where configured, and role permissions decide who can record, verify, review or approve.

SUSTAIN / 01

Calibrated, cleaned, maintained.

A probe thermometer that reads two degrees high, a checkweigher out of calibration or a detector with a tired sensor can turn every record downstream into doubt.



Calibrate what monitors

117.165(a)(1): calibration of process monitoring and verification instruments, or accuracy checks, as appropriate [1]. Records are verification records.

Look back on a failure

An out-of-tolerance probe raises a question about every batch it measured since its last good check. Find them in minutes.

Hygienic maintenance

Engineering work on a line is a contamination risk: tools, swarf, lubricants. Release the line back to production with a check.

WHERE V5 FITS

Each instrument and machine can have an equipment record with calibration schedule, tolerance checks, certificates, planned maintenance and use history. Out-of-calibration devices can be blocked at the kiosk and the batches that used them listed. Predictive failure analytics are not offered today.

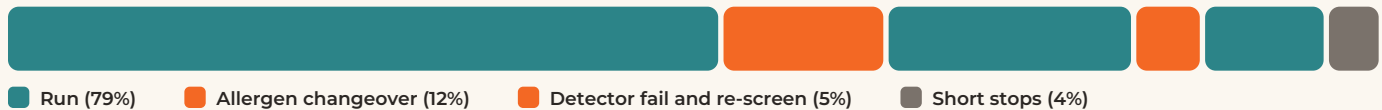
Sources: [1] (linked on pages 33–35)

SUSTAIN / 02

Where the shift really goes.

Food lines lose time to changeovers, cleans, small stops and waiting for a release. Some of that time protects consumers. Measure it so you can tell which.

LINE 3 • ONE 8-HOUR SHIFT (WORKED EXAMPLE)



WORKED OEE ARITHMETIC

Availability

79%

6.3 h run of 8 h planned

Performance

93%

actual vs ideal trays per hour

Quality

98.5%

good trays, first time

OEE

72.4% $0.79 \times 0.93 \times 0.985$

Don't shrink the clean

Allergen changeover time is a control, not waste. Improve it with better sequencing and design, never by skipping verification.

Waiting for release

Hours between pack and release tie up chilled shelf life. Find which test or review step holds lots.

Yield and giveaway

Overfill above declared weight is product given away. Track it alongside rejects and rework.

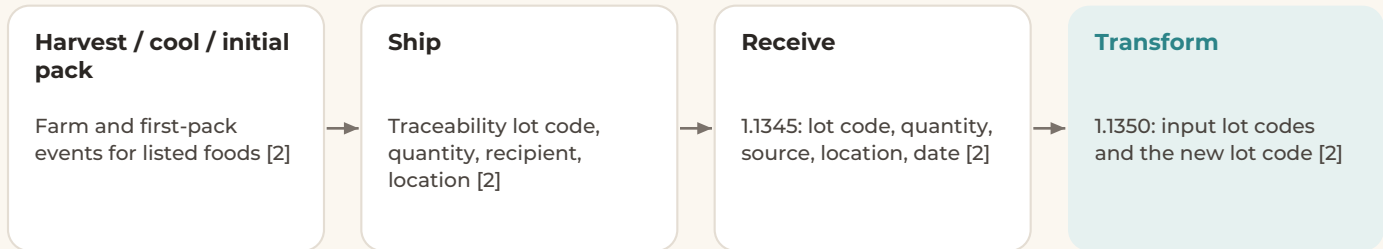
WHERE V5 FITS

Downtime reasons, changeovers, rejects and OEE come from the events your team and supported connected machines record, with reports and dashboards where your plan includes them. AI demand and yield forecasting and process anomaly detection are coming soon, not available today.

SUSTAIN / 03

Traceability records: what the U.S. rule adds.

Subpart S applies to people who manufacture, process, pack or hold foods on FDA's Food Traceability List. It is built on critical tracking events and key data elements.



Is your food listed?

The FTL lists specific foods, such as certain fresh produce, shell eggs, nut butters and some seafood and cheeses, and foods containing them as ingredients in some cases. Check the current list and exemptions [2][3].

A plan and a spreadsheet

1.1315 requires a written traceability plan; 1.1455 requires records within 24 hours of an FDA request and, in some cases, an electronic sortable spreadsheet [2].

Check the compliance date

The rule stands, but the original 20 Jan 2026 date is not current. FDA proposed 20 Jul 2028, and Congress directed FDA not to enforce before then [3][4][14].

SUBPART S IS NOT EVERYTHING

Foods not on the list still fall under Part 1 Subpart J one-step records [5], your recall plan [1], the EU's Art. 18 [9] and Canada's SFCR traceability documents, which must be provided within 24 hours of a request in most cases [12]. Most processors need good lot genealogy whether or not Subpart S applies.

WHERE V5 FITS

Lot codes, quantities, sources, locations and dates are recorded at receipt, transformation and shipment, so trace reports and exports can be produced from the record. V5 does not decide whether your foods are on the FTL or which exemptions apply; that is your regulatory call.

Sources: [2], [3], [4], [5], [9], [12], [14] (linked on pages 33–35)

SUSTAIN / 04

Trace both ways, then act.

A supplier tells you spice lot SP-40 may contain undeclared peanut. The questions are always the same: which batches, which packs, which customers, and what else shared the line.



Recall plan

117.139: written procedures to notify consignees, notify the public when appropriate, check effectiveness and dispose of recalled food [1].

FDA recall policy

21 CFR Part 7 Subpart C sets strategy, depth and effectiveness checks for recalls [6].

Withdraw and inform

EU operators withdraw unsafe food and inform the authority (Art. 19) [9]. Canada requires traceability documents within 24 hours of request in most cases [12].

WHERE V5 FITS

Lots link at receipt, weighing, rework, manufacture, packing and shipment, so genealogy can be followed forward from an ingredient lot or back from a complaint, and recall scope listed with customers and quantities. Recall and notification decisions stay with your team.

SUSTAIN / 05

Time a mock recall, honestly.

A mock recall is only useful if it is hard. Pick an ingredient lot nobody expects, start the clock, and measure how long it takes to account for every kilo.

- 0:00 ● Start: SP-40 named; QA lead opens the trace
- 0:06 ● Batches found: RM-0612, RM-0614
- 0:11 ● Packs and quantities per batch
- 0:19 ● Customers and shipped quantities listed
- 0:27 ● Stock on site found and placed on hold
- 0:41 ● Mass balance: received vs used vs stock vs waste

MASS BALANCE FOR SP-40 (WORKED EXAMPLE)

Received	25.0 kg in 1 sack
Used in RM-0612	8.4 kg
Used in RM-0614	8.2 kg
In stock (held)	8.1 kg
Recorded waste / sample	0.3 kg
Unaccounted	0.0 kg

Times are an example of what to measure, not a benchmark. Practise with your customers' contacts too: a trace that stops at your dock does not get product off a shelf.

WHERE V5 FITS

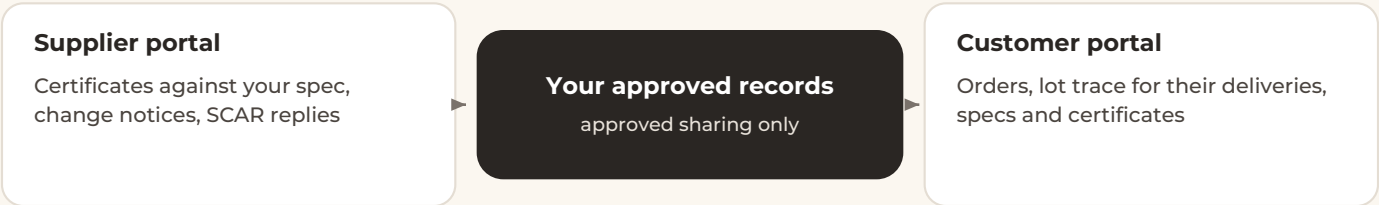
Trace reports list batches, packs, customers and quantities from an ingredient or finished lot, and stock can be held from the trace. Mock recalls can be logged as exercises with times and findings that feed CAPA.

Sources: [1], [6] (linked on pages 33–35)

SUSTAIN / 06

Share the right records, safely.

Retail customers ask for specs, certificates, audit reports and lot information. Suppliers send certificates and answer SCARs. Each should see only what you approve.



Co-packers and brand owners

Agree who owns the recipe, specs, label approval, release and complaints, and how fast lot data is shared in a recall.

Share the approved version

Retailers want current specs and certificates. Share approved revisions, linked to what they bought.

Supplier evidence

Let suppliers upload certificates and change notices to the right material, then review them before they count.

A SHARING POLICY TO AGREE BEFORE ANYONE LOGS IN

Product specification	Approved revision only	Customer
Certificate or test summary	After release	Customer
Lot trace for their deliveries	On request or always on	Customer
Open deviations and holds	Not by portal; agreed notification	Quality contacts
Supplier certificates and SCARs	Reviewed before they count	Your QA

WHERE V5 FITS

A portal foundation gives customers and suppliers branded, read-only access to what you approve. Portal scope and permissions depend on configuration; check the current plan comparison for inclusion. Nothing is shared automatically from an open record.

SUSTAIN / 07

Trustworthy records. Honest AI.

Electronic food safety records only help if they are made at the time, by a known person, with actual values, and if AI stays a helper under human control.

Electronic is allowed

117.305(a): records may be original, true copies or electronic records [1].

Part 11 and Part 117

Records that meet Part 117 are exempt from 21 CFR Part 11; records also required under other rules stay subject to it [1].

Made at the time

117.305(d): records created concurrently with the activity, with the person's signature or initials (f) [1].

AI CAN HELP

- Read certificate values for a person to confirm
- Draft a recipe or SOP from an uploaded sheet for approval
- Suggest a deviation classification or draft a summary
- Explain a lot's history in plain language
- Find records and screens faster

AI NEVER

- Writes your hazard analysis or sets critical limits
- Releases a lot or decides food is safe
- Decides to recall or notify an authority
- Approves a label or allergen statement
- Predicts failures today (forecasting is coming soon)

WHERE V5 FITS

Every record keeps who, what and when in an audit trail every plan can view; tamper-evident trails, electronic signatures designed for Part 11 and a validation pack are available where your plan includes them. AI features need configured provider access and human review.

Sources: [1] (linked on pages 33–35)

APPLY / 01

Evidence map.

A one-page check that every theme an inspector or auditor may ask about has an owner and a record. Section numbers refer to U.S. rules [1][2][5]; adapt them for other markets.

THEME	TYPICAL EVIDENCE	WHERE IT LIVES IN V5	OWNER
Qualified people (117.4)	Training records, hygiene	Skills matrix, training	HR + QA
Food safety plan (117.126)	Signed plan, revisions	Document control	PCQI
Hazard analysis (117.130)	Written analysis	Document control	PCQI
Process controls (117.135)	Limits, monitoring values	Recipes, kiosk checks	Production
Allergen controls	Changeovers, label checks	Checklists, label preview	QA
Sanitation controls	Cleaning, swab results	Cleaning, Lab & QC	Hygiene
Supply chain (Subpart G)	Approval, verification	Suppliers, scorecards	QA + purchasing
Recall plan (117.139)	Plan, mock recall times	Trace reports, CAPA	QA
Corrective actions (117.150)	Records, reviews	Deviations, CAPA	QA
Verification (117.165)	Calibration, tests, reviews	Equipment, LIMS, queue	PCQI
Records (117.305/.315)	Values, time, person, 2 yrs	Audit trail, retention	QA + IT
One-up one-down (Subpart J)	Source and recipient	Receiving, shipments	Logistics
FTL records (Subpart S)	Plan, KDEs, spreadsheet	Genealogy, exports	QA + logistics
Complaints	Log, link, outcome	Complaints, CAPA	QA

Plan inclusion varies; some areas need Professional or Enterprise. Confirm against the current plan comparison before you scope a project.

WORKSHEET 01

Would yesterday's records pass review?

Pick one recent production day on one line. Mark Yes, Partly or No, then note the gap.

	YES	PARTLY	NO
Recipe revision The batch record shows the recipe and revision made.	☐	☐	☐
Lots traced Every ingredient and rework lot used, with quantity and status at use.	☐	☐	☐
Critical values Actual values recorded for each process control, with time and person.	☐	☐	☐
Changeover Allergen changeover steps, verification result and sign-off are recorded.	☐	☐	☐
Pack checks Detector tests, label, date code and weight checks at the planned frequency.	☐	☐	☐
Corrections Every out-of-limit value has a correction or corrective action record.	☐	☐	☐
Held product Product affected by a failed check is identified, held and dispositioned.	☐	☐	☐
Instruments Probes, scales and detectors used were in calibration.	☐	☐	☐
Review in time Monitoring and corrective action records reviewed within 7 working days.	☐	☐	☐
Shipments Each shipped lot links to its customer and quantity.	☐	☐	☐

NOTES AND OWNERS

WORKSHEET 02

Is your allergen control joined up?

Follow one allergen from supplier spec to the label. Use one row per allergen and line if you need to.

	YES	PARTLY	NO
Supplier specs Every ingredient spec states allergens and cross-contact risks.	☐	☐	☐
Change notice Suppliers must tell you when a recipe, site or line changes.	☐	☐	☐
Storage Allergen-containing materials are segregated and labelled in storage.	☐	☐	☐
Recipe data Allergens flow from ingredient specs into sub-recipes and recipes.	☐	☐	☐
Rework rule Rework is only used into products with a compatible allergen profile.	☐	☐	☐
Scheduling Runs are sequenced to reduce allergen changeovers where possible.	☐	☐	☐
Changeover Clean, inspect, verify and sign-off before the next profile runs.	☐	☐	☐
Label check The label on the line matches the product and its allergen statement.	☐	☐	☐
Each market Allergen lists and emphasis rules for each market you sell into are applied.	☐	☐	☐

NOTES AND OWNERS

WORKSHEET 03

Ask to see it work.

Questions for any software demonstration. Ask the vendor to show each one with your product and line, not a slide.

	SHOWN	PARTLY	NOT SHOWN
Held lot Scan a held or expired ingredient lot at weigh-up; show the step stop.	☐	☐	☐
Critical limit Enter a cook temperature below the limit; show correction and hold.	☐	☐	☐
Rework Add rework to a batch and show its original lots in the trace.	☐	☐	☐
Allergen clash Try to add rework with an incompatible allergen profile.	☐	☐	☐
Changeover gate Start the next product before changeover sign-off; show what happens.	☐	☐	☐
Pack check fail Record a failed detector test; show which product is held.	☐	☐	☐
7-day review Show overdue monitoring record reviews and who signs them.	☐	☐	☐
Trace From an ingredient lot, list batches, packs and customers; then reverse.	☐	☐	☐
Sortable export Export trace data as a sortable spreadsheet.	☐	☐	☐
Audit trail Show who changed a recorded value, when and why.	☐	☐	☐

NOTES AND OWNERS

APPLY / 02

Roll out in phases.

Start where value is visible and risk is contained. Run paper and system in parallel until each phase is verified.

PHASE 1
Foundations

Scope, roles, document control for the food safety plan and SOPs, training records, equipment register with calibration.

PHASE 2
Materials

Specifications with allergens, approved suppliers, receiving with temperature and status, storage zones, expiry and FEFO.

PHASE 3
Make

Recipes under revision, weigh-up, kiosk process checks and rework on one line, paper kept in parallel.

PHASE 4
Control

Changeovers, pack checks, corrections and corrective actions, the review queue, lab and environmental results.

PHASE 5
Connect

Shipments and genealogy, timed mock recalls, complaints and CAPA, portals, OEE and loss review.

Reanalysis is a trigger, not an afterthought. A new line, recipe or system can change how controls are monitored. Ask your PCQI whether the food safety plan needs reanalysis under 117.170 before each phase goes live [1].

Sources: [1] (linked on pages 33–35)

WORKSHEET 04

Find your first improvement.

Score each area today: E evidenced, P partial, G gap. Start with the gap that costs you review time, held stock, complaints or audit findings.

	E	P	G
Supplier approval Approved before receipt; verification on schedule	☐	☐	☐
Goods-in Lot, temperature and condition recorded	☐	☐	☐
Storage and status Held stock blocked; FEFO; allergens segregated	☐	☐	☐
Recipes and allergens One source of truth, under revision	☐	☐	☐
Process controls Actual values, limits, corrections	☐	☐	☐
Rework Lots, rules, genealogy	☐	☐	☐
Changeovers Verified and signed before start	☐	☐	☐
Pack checks Label, code, detector, weight, holds	☐	☐	☐
Record review Within 7 working days, signed	☐	☐	☐
Calibration Schedule, look-back on failure	☐	☐	☐
Trace and recall Both ways, timed, mass balance	☐	☐	☐
Complaints and CAPA Linked to lots, effectiveness checked	☐	☐	☐

NOTES AND OWNERS

APPLY / 03

A fair evaluation in four weeks.

A practical way to test any system with your own people and one real product, without touching live records.

WEEK 1

Agree the product, the line and the five questions that matter most. Load one recipe with allergens, specs and checks.

WEEK 2

Run a day end to end with test data: receipt, weigh-up, cook, rework, changeover, pack checks and review.

WEEK 3

Break it on purpose: held lot, low temperature, allergen clash, failed detector test, overdue review.

WEEK 4

Run a timed mock trace. Review with production, QA, hygiene, engineering and IT, and decide what to do next.

Rules for the evaluation. Use test data only. Keep your current records and release process live until a verified change is approved. Record what was shown, not what was promised.

ASK V5

“We make [ready meals / sauces / soups / frozen foods] on [number] lines for [markets]. Our hardest moment is [e.g. allergen changeovers between dairy and non-dairy runs]. Which workflows should we evaluate first?”

Start a 7-day free trial, no card required, or ask V5 on v5ultimate.com.

WHERE V5 FITS

Try V5 with your own product in a trial workspace using test data. The assistant can answer questions about features and plans; it does not give regulatory advice.

SOURCES

Keep the evidence close.

Primary sources behind this guide, checked October 2026. Click a title to open the publisher's page.

- | | | |
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| [1] | <u>U.S. eCFR, 21 CFR Part 117: CGMP and preventive controls for human food</u>
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| [2] | <u>U.S. eCFR, 21 CFR Part 1 Subpart S: additional traceability records</u>
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| [3] | <u>U.S. FDA, Food Traceability Final Rule page (FTL, FAQs, updates)</u>
https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-req... | FDA INFORMATION PAGE |
| [4] | <u>Federal Register, 90 FR 38084 (7 Aug 2025): compliance date extension</u>
https://www.federalregister.gov/documents/2025/08/07/2025-14967/requirements-fo... | PROPOSED RULE (CHECK STATUS) |
| [5] | <u>U.S. eCFR, 21 CFR Part 1 Subpart J: establishment and maintenance of records</u>
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| [6] | <u>U.S. eCFR, 21 CFR Part 7: Enforcement Policy (recalls, Subpart C)</u>
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| [7] | <u>21 U.S.C. 321(qq) (FD&C Act sec. 201(qq)): major food allergens</u>
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| [8] | <u>U.S. eCFR, 9 CFR Part 417: HACCP systems (USDA FSIS, meat and poultry)</u>
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| [9] | <u>Regulation (EC) 178/2002: General Food Law (EU)</u>
https://eur-lex.europa.eu/eli/reg/2002/178/oj | BINDING EU REGULATION |

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| [11] | <u>Regulation (EU) 1169/2011: food information to consumers</u> | BINDING EU REGULATION |
| | https://eur-lex.europa.eu/eli/reg/2011/1169/oj | |
| [12] | <u>Canada, Safe Food for Canadians Regulations (SOR/2018-108)</u> | BINDING CANADIAN REGULATION |
| | https://laws-lois.justice.gc.ca/eng/regulations/SOR-2018-108/ | |
| [13] | <u>Codex Alimentarius, General Principles of Food Hygiene (CXC 1-1969, rev. 2022)</u> | VOLUNTARY INTERNATIONAL |
| | https://www.fao.org/fao-who-codexalimentarius/codex-texts/codes-of-practice/en/ | |
| [14] | <u>U.S. FDA, Proposed rule notice page on the traceability extension (Aug 2025)</u> | FDA ANNOUNCEMENT |
| | https://www.fda.gov/food/hfp-constituent-updates/fda-proposes-extend-compliance... | |
| [15] | <u>U.S. FDA, CGMPs for food and dietary supplements (Part 117 hub)</u> | FDA INFORMATION PAGE |
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| [18] | <u>European Commission, Food hygiene legislation (852/2004, 853/2004)</u> | EU COMMISSION PAGE |
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[EU COMMISSION PAGE](#)

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[20] [European Commission, Mandatory food information \(1169/2011\)](https://food.ec.europa.eu/food-safety/labelling-and-nutrition/food-information-...)

[EU COMMISSION PAGE](#)

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[CFIA GUIDANCE](#)

<https://inspection.canada.ca/en/food-safety-industry/toolkit-food-businesses/sf...>

[22] [CFIA, Preventive control plan guide](https://inspection.canada.ca/en/food-safety-industry/preventive-control-plans/g...)

[CFIA GUIDANCE](#)

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How to read the status labels. Binding regulations and statutes are law in their jurisdiction. A proposed rule is not in force until finalised; check its status. FDA web pages explain and announce but do not bind. Codex texts and certification schemes are voluntary.

SCOPE AND LIMITS

This guide is practical orientation for evaluating food processing operations and software. It is not legal or regulatory advice and does not list every requirement that applies to you; requirements depend on product, site, market and exemptions. V5 capability statements reflect the V5 product reference reviewed on 1 October 2026 and depend on plan, configuration, devices and permissions. AI forecasting and anomaly detection are coming soon. V5 does not write hazard analyses, set or validate limits, decide food safety, release product or decide recalls, and does not by itself make you compliant. Photography is illustrative; batches, lots, results and charts are worked examples, not customer data.



Safe changeovers. Right labels. Every lot traceable.

See food processing workflows at v5ultimate.com · Global edition · October 2026