



THE DAIRY & CHILLED MANUFACTURING GUIDE

Every tank traced. Every chilled pack accounted for.

From milk tanker to chilled shelf, and back again in a recall

A practical evaluation guide for dairy and chilled food manufacturers: which rules shape each record, how one tank becomes many pack lots, how to investigate a late or failed temperature record, and what the person deciding release should be able to see.



PMO / NCIMS

21 CFR 117

EU 853/2004

PEOPLE DECIDE RELEASE

U.S. edition with EU scope notes / October 2026

v5ultimate.com

Scope: practical orientation, not legal advice. Photos are staged; loads, lots and results are worked examples.

INSIDE THE GUIDE

One tank, two pack lots.

Dairy and chilled plants turn a few large lots into many small ones, within hours, under temperature control. This guide follows tank lot PT-0417 into two yogurt pack lots and shows what each rule expects the record to hold.

01 / FRAME

pp. 03–04

Which rules apply

Grade "A" milk under the PMO, Part 117 for other dairy and chilled foods, and the EU hygiene package.

02 / RECEIVE

pp. 05–06

Milk and tank genealogy

Tanker loads, residue screens, receipt temperatures, silos and the tank lot that joins them.

03 / MAKE

pp. 07–09

Process, changeover, pack

Process verification records, cultures and allergens, pack codes and use-by dates.

04 / HOLD

pp. 10–12

Cold chain and disposition

Chilled storage, a late cold-room record worked end to end, and the person who decides.

05 / RESPOND

pp. 13–16

Test, trace, recall

Testing and environmental monitoring, FSMA 204, recall and the software you rely on.

06 / APPLY

pp. 17–22

V5 fit, worksheets, sources

Where V5 fits and does not, two worksheets, a four-week evaluation and twelve sources.

Who it is for. Plant, quality and food safety managers, milk procurement and intake leads, laboratory leads, cold-chain and distribution managers, and anyone choosing a production and quality system for a dairy or chilled operation.

How to read it. Operational pages end with a teal Where V5 fits panel. Everything above it is regulation and practice; practice is labelled as such. Statements cite numbered sources; always check the current text.

WHERE V5 FITS

V5 records the receiving, processing, packing, storage, testing and quality work your procedures define. It does not run or validate pasteurizers, set critical limits, judge product safety, release lots or decide recalls. Those decisions stay with your qualified people.

FRAME / 01

Which rules apply to you?

"Dairy" covers very different legal routes. A Grade "A" fluid milk plant, a cheese plant, a chilled ready-meal kitchen and an EU yogurt plant each start from a different rulebook. Decide the route per product before you design the record.

PRODUCT ROUTE	STARTING POINT
Grade "A" milk and milk products (U.S.)	PMO as adopted by your state, NCIMS program [2]
Milk in final package form (U.S.)	Pasteurized or from pasteurized dairy ingredients, 1240.61 [1]
Cheese and other non-Grade "A" dairy (U.S.)	Part 117, standards of identity, state rules [3][4]
Chilled prepared foods (U.S.)	Part 117 CGMP and preventive controls, as applicable [3]
Soft and semi-soft cheeses (U.S.)	Also on the Food Traceability List [5][6]
Dairy products made in the EU	852/2004 and 853/2004 Annex III Section IX [9][10]

Exemptions are specific

1240.61 allows alternatives to pasteurization only where a regulation provides them, such as curing certain cheeses under Part 133 [1].

Grade "A" and Part 117

Part 117 has specific provisions for Grade "A" plants that comply with the PMO. Confirm with your regulator which parts apply to each product [3].

Not universal food law

This guide covers U.S. federal rules and EU regulations. State, national and customer requirements add to them; check each market you sell into.

PRACTICE: ONE ROUTE PER PRODUCT, WRITTEN DOWN

For each product, record its route, the rules your team concluded apply, who confirmed it and when. Review it when the recipe, process, market or customer changes, and keep the reasoning with the specification.

WHERE V5 FITS

Product master data in V5 can carry the product's category, route and your regulatory notes, so records and reports follow the right template. V5 does not decide which rules apply to a product.

FRAME / 02

The PMO: a model with state force.

The Grade "A" Pasteurized Milk Ordinance is a model ordinance maintained through the National Conference on Interstate Milk Shipments (NCIMS). States adopt it, inspect plants and rate them for the interstate milk shippers program [2].

Model document	FDA lists the 2025 PMO revision on its NCIMS model documents page, posted June 2026, after the 2023 revision [2]	PMO
How it binds	Legal force comes from state adoption and the NCIMS cooperative program, not from the PMO alone	NCIMS
What it covers	Grade "A" raw milk for pasteurization, processing plants, pasteurization equipment and records, labs, sanitation	PMO
Drug residues	Bulk milk tanker screening and the follow-up when a load tests positive	PMO
Federal floor	Milk in final package form must be pasteurized, with regulated alternatives (1240.61) [1]	21 CFR
Revision cycle	Changes are agreed at NCIMS conferences and published in a new revision; check the one your state has adopted	NCIMS

Read the revision your state uses. This guide deliberately does not restate PMO temperatures, times or test frequencies; they are set out in detail in the ordinance and its appendices, and they change between revisions. Your records should carry the values from the revision your regulator applies.

WHERE V5 FITS

V5 can hold your PMO-based procedures as controlled documents and record the checks they call for against each load, tank and lot. It does not interpret the ordinance, rate plants or report to regulators.

Sources: [1], [2] (linked on pages 21–22)

RECEIVE / 01

Every load held until it is accepted.

Raw milk arrives in large, mixed loads from many farms. What you record at the intake bay decides whether you can later say which loads went into which tank, and why each was accepted.



Screen before you pump

Record the drug residue screen your program requires for each tanker load, the test used and who ran it. A load waits until the result is in [2].

Temperature on arrival

In the EU, raw milk must arrive at no more than 10 °C and be cooled to no more than 6 °C at the plant, with stated exceptions (853/2004, Annex III, Section IX, as published) [9].

Identity of the load

Tanker, compartments, farm or route, sample identity, time and silo. Ingredients, cultures and packaging get supplier lots too.

LOAD STATUS	MEANING	PUMP TO SILO?
Pending	Sampled, screen not yet recorded	HOLD
Accepted	Screen negative, checks in limit	YES
Rejected	Positive screen or failed check	DO NOT USE
Accepted with note	Deviation recorded and approved	YES

WORKED EXAMPLE: A POSITIVE SCREEN

Load RM-223 screens positive. It is not pumped and stays rejected in the tanker. The follow-up steps your program requires are recorded against the load; for Grade "A" milk the PMO sets them. A trace confirms no silo or product contains RM-223.

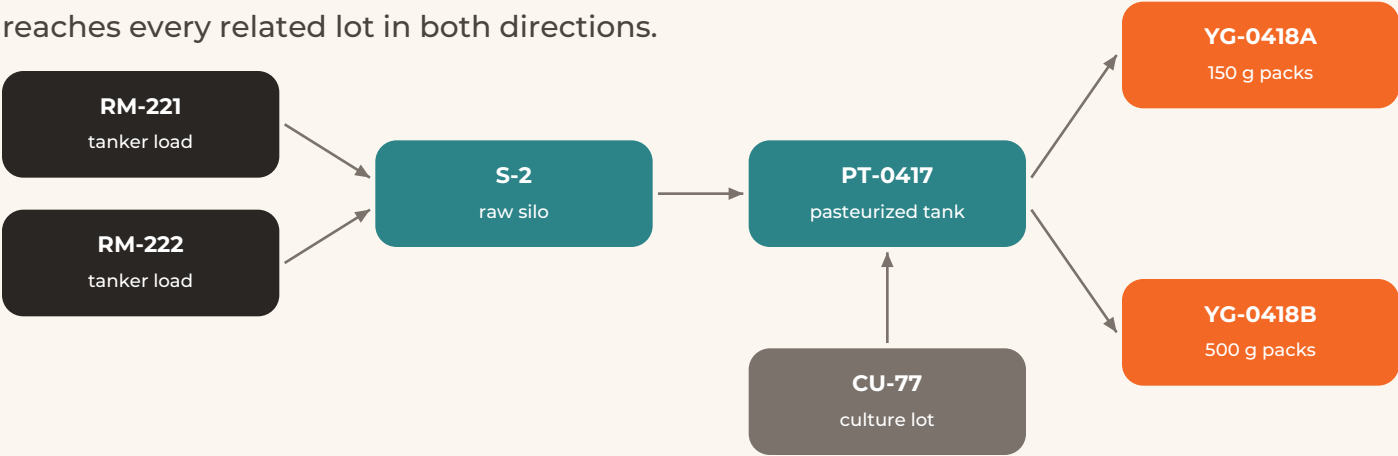
WHERE V5 FITS

V5 receiving records loads and ingredient lots with supplier identity, checks and results, records each as pending and keeps its checks and status visible; your team accepts a load before it moves on. Your program sets the tests, limits and who may accept a load.

RECEIVE / 02

One tank joins many lots.

Silos and tanks mix loads; fillers split tanks. Genealogy is the record of every one of those joins and splits, with quantities, so a question about one lot reaches every related lot in both directions.



FROM	TO	QUANTITY	NOTE (WORKED EXAMPLE)
RM-221 + RM-222	S-2	28,400 L in	Two loads, both accepted
S-2	PT-0417	12,000 L	Rest of silo to other tanks
PT-0417 + CU-77	YG-0418A	4,800 L	150 g pots, room CR-1
PT-0417 + CU-77	YG-0418B	6,950 L	500 g pots, room CR-2
PT-0417	Loss / rinse	250 L	Recorded, not sold

Siblings matter. YG-0418A and YG-0418B share a tank, a silo and two loads. A problem traced to the tank touches both; a problem in one cold room touches only the lot stored there. The record should let you tell those apart quickly.

WHERE V5 FITS

V5 traceability records each transfer, blend and fill with lots and quantities, and shows the tree forward and back from any lot. Accuracy depends on recording every transfer, including partial silo draws and rework.

MAKE / 01

Verify the process, don't replace it.

Pasteurizers, their controls, recording devices and divert systems are designed, tested and sealed under the rules that apply to your plant. The production record's job is to show that someone checked the evidence for each run [1][2][3].

VERIFICATION RECORD (WORKED EXAMPLE)	EVIDENCE	DONE?
Recording chart or file attached	PT-0417, run 1	YES
Chart reviewed and signed by operator	Signed 06:52	YES
Diversion events noted on chart	None noted	YES
Indicating vs recording thermometer check	Recorded by operator	YES
Supervisor or QA review	Recorded 08:15	YES

WHAT SOFTWARE SHOULD NOT DO HERE

A production system should not set, adjust or override pasteurization parameters, and should not decide that a lethal process was achieved. It records what your validated equipment and trained people show, and makes a missing review visible.

Part 117 records

Where Part 117 applies, monitoring, verification and corrective action records are part of the food safety plan, reviewed as the rule requires [3].

Electronic records

Part 117 records that are electronic are exempt from Part 11 (117.305(g)); records kept for other rules may not be [3].

EU: HACCP-based

EU operators apply procedures based on HACCP principles (852/2004 Art. 5) and the heat-treatment rules in 853/2004 [9][10].

WHERE V5 FITS

V5 checks on tablets attach chart files or photos, capture reviews with signatures and timestamps, and hold a tank lot when a required review is missing, if configured. Connected sensor readings can be logged; V5 does not control or validate the pasteurizer.

MAKE / 02

Cultures, ingredients and clean changeovers.

Cultured and chilled products add cultures, fruit preparations, stabilisers and inclusions, each with its own lot and allergen profile. Part 117 preventive controls include food allergen controls where the hazard analysis calls for them (117.135) [3].

CHANGEOVER BEFORE PT-0417 FILL (WORKED EXAMPLE)	RECORD	OK?
Culture CU-77	Released, certificate reviewed	YES
Fruit preparation FP-310 (contains tree nuts)	Previous run; not in this one	n/a
Line cleaned after FP-310 run	Cleaned to SOP	YES
Allergen swab, filler heads	Result recorded, below your limit	YES
Changeover verified by supervisor	Signed before YG-0418A	YES



WHERE V5 FITS

V5 recipes carry ingredients and allergens by revision; production steps record ingredient lots, and changeover checklists capture cleaning, swab results and the verifying supervisor before the next product can start, if configured. Your team sets the sequence and acceptance criteria.

Sources: [3] (linked on pages 21–22)

MAKE / 03

Right code, right date, right pot.

A chilled pack's code and date are the link between the shelf and your records. A wrong date or a missing code breaks the trace and can mean a recall on its own.

PACK CHECK AT START AND CHANGE (WORKED EXAMPLE)	RECORD	OK?
Lot code printed and legible	YG-0418A / YG-0418B	YES
Use-by date matches the lot record	2026-10-30 on both	YES
Label version and allergen statement	Approved revision	YES
Correct lid or sleeve for the SKU	150 g / 500 g checked	YES
Labels issued, used, destroyed	Counts reconcile	YES

Date from evidence

Shelf life comes from your own studies and product knowledge, set by your team, not by software. Record which basis applies to each product.

Check the printed pack

Verify a printed sample from the line against the lot record at start-up, after any change and at intervals your procedure sets.

EU: raw milk words

Retail labels of products made with raw milk must say so (853/2004, Annex III, Section IX, Chapter IV) [9].

PRACTICE: ONE DATE SOURCE

Print the date from the lot record rather than typing it at the coder. If a date must be keyed in, have a second person check the first printed pack and record it.

WHERE V5 FITS

V5 label design prints lot codes, dates and allergen statements from the lot and recipe records, and pack checks record what was verified, with counts. Date rules and label wording are approved by your team.

HOLD / 01

Chilled storage is part of the lot record.

For chilled products, where a lot was stored, for how long and at what temperature belongs with the lot. Rules and customers set the limits; your records show whether they were met.



- Location by lot**

Record which room, zone or truck each lot was in, from when to when. Without it, a room excursion cannot be mapped to lots.
- Records arrive late**

Logger downloads, carrier files and third-party store reports often arrive hours or days later. Plan for it: who reviews them, and when.
- Calibrated sensors**

Probes and loggers need their own calibration records, or the evidence will not stand up.

LOCATION	LOTS AND TIMES (WORKED EXAMPLE)	RECORD
Room CR-1	YG-0418A, day 1 21:30 to dispatch	In limit
Room CR-2	YG-0418B, day 1 22:10 onward	PENDING
Truck TR-14	YG-0418A, day 2 06:00	In limit
Logger LG-CR2	Calibration current	YES

PRACTICE: NAME WHO READS LATE RECORDS

List every storage record that does not arrive live: logger downloads, carrier files, third-party stores. For each, name who reviews it, by when, and what happens to the lots stored there until it is reviewed.

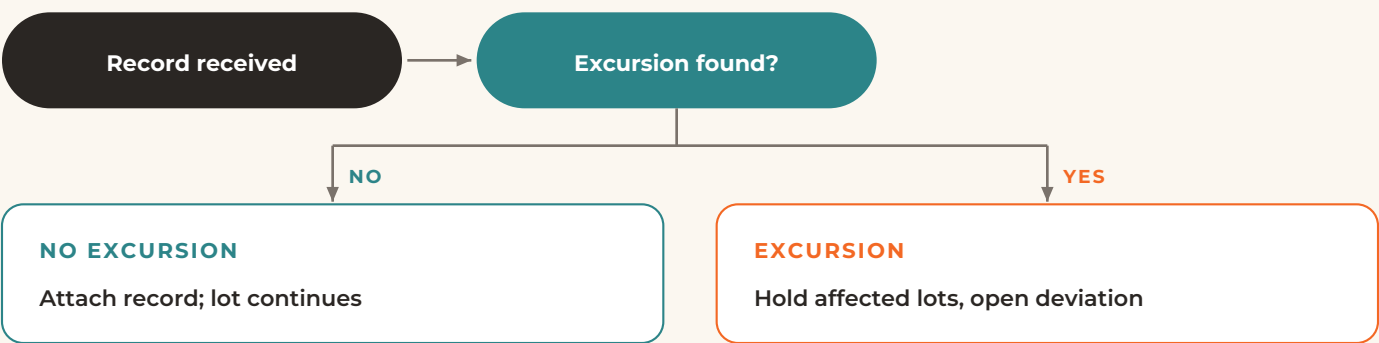
WHERE V5 FITS

V5 storage zones and transfers record where each lot is. Where sensors are connected, temperature readings are logged with alerts; files can also be attached. V5 does not control refrigeration, and whether storage was acceptable is your team's decision.

HOLD / 02

A late record, worked end to end.

Day 2, 09:40: the CR-2 logger file is downloaded and shows the room above your limit from 01:20 to 04:55. YG-0418B was stored there; YG-0418A was not. Here is the decision path.



TIME	STEP (WORKED EXAMPLE, DAY 2)	STATUS
09:40	CR-2 file received; period above limit found	Done
09:45	YG-0418B on hold; deviation DV-1207 opened	Done
10:05	Location check: YG-0418B 1,240 cases all on site	Done
10:20	Sibling check: YG-0418A in CR-1, record in limit	Done
11:30	QA evaluates excursion against procedure	Done
11:45	QA manager records disposition	Done

Why the sibling check matters. YG-0418A came from the same tank, so a tank problem would affect it. A room excursion does not, but only its own storage record can show that. Check, record, then close.

WHERE V5 FITS

V5 can place lots on hold when your team links a deviation to them, lists siblings and shipments from the same tank, and keeps the investigation with the lot. V5 does not decide whether an excursion made product unsafe.

HOLD / 03

A person decides, and the record says who.

Where Part 117 applies, corrective actions include evaluating affected food for safety and preventing unsafe food from entering commerce (117.150) [3]. The decision belongs to a qualified person, with the evidence in front of them.

Release	Rework or divert	Reject or destroy
Evidence shows the product meets your criteria. Record the basis and who decided.	Only where your procedures and the applicable rules allow, with the destination recorded.	Product cannot be sold. Record quantities, method and witness.
DISPOSITION RECORD FIELD	WORKED EXAMPLE	
Lot	YG-0418B, 1,240 cases, on hold	
Evidence	CR-2 file, location log, DV-1207 investigation	
Sibling	YG-0418A: CR-1 record in limit, shipped	
Decision	Rejected for sale (worked example)	
Decided by	QA manager, e-signature, day 2 11:45	
Follow-up	CR-2 door alarm repair; CAPA CA-0331	

The example is not a rule. Another team, with other data, might reach a different decision for the same excursion. What matters is that the decision, its basis and its owner are recorded and reviewable.

PRACTICE: CLOSE THE LOOP

Record what happened to the product (quantities destroyed, by whom, witnessed), close the deviation with its root cause, and link any corrective action so the next excursion review can see it.

WHERE V5 FITS

V5's QC release queue shows each lot's results, holds, deviations and storage records in one view. A named reviewer records the decision with an electronic signature. V5 never releases or rejects product automatically.

RESPOND / 01

Test results and environmental swabs.

Dairy and chilled plants test incoming milk, finished product and the environment. Which tests, how often and against what limits come from your program, your regulator and, in the EU, the microbiological criteria regulation [2][3][11].



Pending is a status

A result that is not back yet stays visibly pending, so no one reads a partial record as complete.

Environment, not only product

Ready-to-eat chilled foods need environmental monitoring where your hazard analysis identifies it; link swab sites to lines and dates.

EU: Listeria criteria

2073/2005 sets food safety criteria for Listeria monocytogenes in ready-to-eat foods, among others [11].

TEST (WORKED EXAMPLE)	RESULT	COMPLETE?
Finished product, YG-0418A	In specification	YES
Finished product, YG-0418B	Not tested; lot rejected	n/a
Filler zone swabs, day 1	Below your action limit	YES
Shelf-life samples, YG-0418A	Enrolled, day 7 pull due	PENDING

PRACTICE: AN ENVIRONMENTAL POSITIVE

Link the swab site to the line, zone and date, list the lots made on that line since the last negative result, and follow your procedure for corrective cleaning, follow-up sampling and any product holds. People decide what is held.

WHERE V5 FITS

V5 laboratory sample plans record results against your specifications, keep pending tests visible and escalate out-of-limit results to a deviation. Methods, limits and sampling plans stay with your lab and food safety team.

RESPOND / 02

Traceability records for listed cheeses.

FDA's Food Traceability List includes soft and semi-soft cheeses (other than hard cheeses), made from pasteurized or unpasteurized milk, with stated exclusions. Fluid milk and yogurt are not on the list [5][6].

TOPIC	WHAT THE RULE SAYS
Who	Persons who manufacture, process, pack or hold listed foods, with exemptions [5]
What	Key data elements for critical tracking events, linked by traceability lot code [5]
Plan	A written traceability plan, kept current [5]
On request	Records to FDA within 24 hours or an agreed time (1.1455(c)); not routine reporting [5]
When	FDA states the compliance date is July 20, 2028; reverify before relying on it [7]

Check each product

A cheese plant may make listed and unlisted cheeses on the same line. Classify each product against the current list and its exclusions [6].

Lot codes carry the trace

The traceability lot code assigned at transformation (for example, cheese making) is what customers must keep with the product [5].

One record, two uses

The same genealogy that supports recall work can supply traceability records, if the data elements are captured at the right events.

WORKED EXAMPLE: A TRANSFORMATION EVENT FOR A SOFT CHEESE (KEY DATA ELEMENTS PARAPHRASED FROM 1.1350)

New traceability lot code	CH-0503
Product description	Queso fresco, 10 kg wheels
Listed foods used as inputs	None: milk and culture are not on the list
Quantity and unit	240 wheels (2,400 kg)
Lot code source location	This plant
Date completed and reference document	Day 3; batch record BR-0503

WHERE V5 FITS

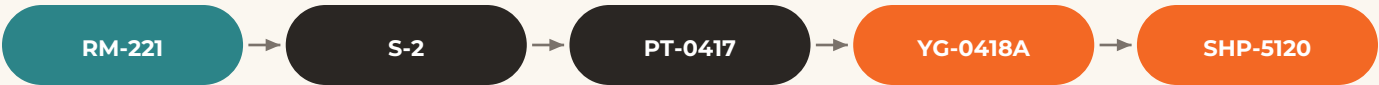
V5 records lots, transformations and shipments, and FSMA 204 / EPCIS 2.0 publishing can push critical tracking events to a traceability repository where your plan includes it. Your team decides coverage and answers FDA requests.

Sources: [5], [6], [7] (linked on pages 21–22)

RESPOND / 03

From one milk load to every customer.

If a load, a culture lot or a tank is in question, the first hours are about finding every lot it touched and every customer who received them. Part 7 Subpart C sets out FDA's recall policy and procedures [8].



WORKED EXAMPLE: ONE MILK LOAD, TWO TANKS, THREE PACK LOTS

TANK	PACK LOT	SHIPMENT	CONSIGNEE OR LOCATION
PT-0417	YG-0418A	SHP-5120	Customer A, 640 cases
PT-0417	YG-0418B	None	Rejected; on site, destroyed
PT-0419	ML-0419	SHP-5124	Customer B, 900 cases
PT-0419	ML-0419	On hand	180 cases in CR-1

Trace forward

From load RM-221 through silo S-2: every tank drawn from it, every pack lot, every shipment and customer, with quantities and dates.

Trace back

From one pack lot to every load, culture, ingredient and packaging lot, and the process and storage records.

Mock recall

Time it. Record what was found, what was missing and who did what, and repeat after changes.

WORKED EXAMPLE: MOCK RECALL TIMING FROM LOAD RM-221

09:00	Exercise started by QA
09:12	Tanks and pack lots identified
09:26	Shipments and customers listed
09:48	Stock on hand confirmed in CR-1
10:05	Review: one carrier file missing, CAPA raised

WHERE V5 FITS

V5 traces from a load or ingredient lot to tanks, pack lots and shipments and back, records mock recalls with timings and keeps distribution records. Recall strategy, customer notices and regulator contact stay with your people.

RESPOND / 04

The software you rely on.

Food rules rarely prescribe software validation the way device or drug rules do, but your records are only as good as the system that holds them. Know what it does, test it with your data and control its changes.

01 Define its job
Which records it holds, which checks it enforces and which decisions it supports.

02 Test with your data
Run your products, limits and edge cases before relying on it; keep the evidence.

03 Control change
Assess supplier releases and configuration changes before they reach production.

04 Keep a paper fallback
Decide how records are kept if the system or network is unavailable, and how they are entered later.

WHO DOES WHAT

You decide the intended use, test it and approve go-live, including any performance qualification your customers or certification scheme expect. **A supplier** can provide documentation and, where agreed, installation and operational qualification support. In V5's case, IQ/OQ and validation support are part of the Enterprise plan, scoped in the accepted quote or statement of work.

WHERE V5 FITS

V5 records configuration changes in an audit trail and releases software in versions, so you can see what changed. It does not make a food safety plan compliant on its own.

APPLY / 01

Where V5 fits, and where it does not.

A plain map from the area to the V5 capability that keeps its record, and the decision that stays with you. Capabilities are from the V5 product reference reviewed 1 October 2026 and depend on plan and configuration.

AREA	V5 KEEPS THE RECORD	YOUR PEOPLE DECIDE
Milk and ingredient intake	Receiving, lot status, checks, holds	Tests, limits, acceptance
Silos and tanks	Transfers, blends, fills, genealogy	Recording every transfer
Process verification	Chart attachments, reviews, signatures	Process control, validation
Allergens, changeover	Recipes, checklists, swab results	Sequence and criteria
Pack codes and dates	Label print, pack checks, counts	Shelf life, label wording
Cold chain	Zones, transfers, sensor logs if connected	Limits, acceptability
Excursions	Deviations, holds, sibling trace	Safety evaluation
Testing	LIMS sample plans and results	Methods, limits, plans
Release	QC release queue, e-signature	The decision itself
FSMA 204	Lots, events, EPCIS publishing	Coverage, FDA requests
Recall	Lot trace, mock recall, shipments	Recall decision, notices

Coming soon, not available today: AI demand and yield forecasting and process anomaly detection.
Plan-dependent: sensor integration, EPCIS publishing, and IQ/OQ and validation support (Enterprise only, scoped in the accepted quote or statement of work). **Not offered:** control of pasteurizers or refrigeration, process validation, or regulatory submissions.

WHERE V5 FITS

Nothing in V5 releases a lot, decides a disposition, judges whether food is safe, reports to a regulator or starts a recall. It keeps the evidence connected so the qualified people who make those decisions can see it.

WORKSHEET 01

Excursion and release readiness for one lot.

Use with a real (or test) pack lot record. Tick what the record shows today without asking anyone.

	SHOWN	PARTLY	NOT SHOWN
Loads accepted Every load in the tank has a recorded screen and acceptance	☐	☐	☐
Genealogy complete Loads to silo to tank to pack lots, with quantities	☐	☐	☐
Process review Chart or file attached, reviewed and signed	☐	☐	☐
Changeover Allergen changeover verified before the run	☐	☐	☐
Pack check Code, date and label version verified with counts	☐	☐	☐
Storage record Every room and truck the lot was in, with times	☐	☐	☐
Late records Records still awaited are visible as pending	☐	☐	☐
Siblings Other lots from the same tank listed and checked	☐	☐	☐
Named decision Who decided, when, on what evidence	☐	☐	☐
Distribution Shipments linked to the lot	☐	☐	☐

NOTES AND OWNERS

WORKSHEET 02

Questions for any software demo.

Ask the vendor to show, not tell, using test data. Record what you saw.

	SHOWN	PARTLY	NOT SHOWN
Pending load Try to use a load with no screen result; show the block.	☐	☐	☐
Split tank Fill one tank into two SKUs; show both pack lots.	☐	☐	☐
Partial silo Draw part of a silo into a tank; show the remainder.	☐	☐	☐
Missing review Leave a chart review unsigned; show what happens.	☐	☐	☐
Late file Attach a late cold-room file; put the right lot on hold.	☐	☐	☐
Siblings From one pack lot, list its siblings and their storage.	☐	☐	☐
Wrong date Print a pack with the wrong use-by; show the check.	☐	☐	☐
Trace From one load, list pack lots and customers, timed.	☐	☐	☐
Calibration Fail a probe calibration; list affected records.	☐	☐	☐
Audit trail Show who changed a value, when and why.	☐	☐	☐

NOTES AND OWNERS

APPLY / 02

A fair evaluation in four weeks.

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

WEEK 1

Agree one product family and the five questions that matter most. Load recipes, rooms, checks and specifications.

WEEK 2

Run a tank end to end with test data: loads, silo, tank, two pack lots, checks, storage, release review.

WEEK 3

Break it on purpose: pending load, missing chart review, late cold-room file, wrong date, failed calibration.

WEEK 4

Run a timed mock recall from one load. Review with QA, production, intake, distribution and IT.

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

ASK V5

“We make [fluid milk / yogurt / cheese / chilled foods] at [number] sites. Our hardest moment is [e.g. late cold-room records]. 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 family in a trial workspace using test data. The assistant answers questions about features and plans; it does not give regulatory advice.

SOURCES

Keep the evidence close.

Primary sources behind this guide, checked 2 October 2026. Click a title to open the publisher's page.

- | | | |
|-----|---|----------------------------|
| [1] | <u>U.S. eCFR, 21 CFR 1240.61: mandatory pasteurization of milk in final package form</u> | BINDING U.S. REGULATION |
| [2] | <u>U.S. FDA, NCIMS model documents: Grade "A" Pasteurized Milk Ordinance (PMO)</u> | MODEL ORDINANCE VIA STATES |
| [3] | <u>U.S. eCFR, 21 CFR Part 117: CGMP and hazard analysis and risk-based preventive controls</u> | BINDING U.S. REGULATION |
| [4] | <u>U.S. eCFR, 21 CFR Part 131: milk and cream (standards of identity)</u> | BINDING U.S. REGULATION |
| [5] | <u>U.S. eCFR, 21 CFR Part 1 Subpart S: additional traceability records for certain foods</u> | BINDING U.S. REGULATION |
| [6] | <u>U.S. FDA, Food Traceability List</u> | FDA INFORMATION PAGE |
| [7] | <u>U.S. FDA, FSMA final rule on requirements for additional traceability records</u> | FDA INFORMATION PAGE |
| [8] | <u>U.S. eCFR, 21 CFR Part 7: enforcement policy (recalls, Subpart C)</u> | U.S. REGULATION / POLICY |

SOURCES

Sources, continued.

[9] [Regulation \(EC\) No 853/2004: specific hygiene rules for food of animal origin](https://eur-lex.europa.eu/eli/reg/2004/853/oj)

BINDING EU REGULATION

<https://eur-lex.europa.eu/eli/reg/2004/853/oj>

[10] [Regulation \(EC\) No 852/2004: hygiene of foodstuffs](https://eur-lex.europa.eu/eli/reg/2004/852/oj)

BINDING EU REGULATION

<https://eur-lex.europa.eu/eli/reg/2004/852/oj>

[11] [Regulation \(EC\) No 2073/2005: microbiological criteria for foodstuffs](https://eur-lex.europa.eu/eli/reg/2005/2073/oj)

BINDING EU REGULATION

<https://eur-lex.europa.eu/eli/reg/2005/2073/oj>

[12] [Codex Alimentarius, General Principles of Food Hygiene \(CXC 1-1969\)](https://www.fao.org/fao-who-codexalimentarius/codex-texts/codes-of-practice/en/)

VOLUNTARY INTERNATIONAL CODE

<https://www.fao.org/fao-who-codexalimentarius/codex-texts/codes-of-practice/en/>

How to read the status labels. Binding regulations are law in their jurisdiction. The PMO is a model ordinance that takes legal force through state adoption and the NCIMS program. FDA information pages explain and announce. Codex texts are voluntary international standards. EU text was read as originally published; check the consolidated version.

SCOPE AND LIMITS

This guide is practical orientation for evaluating dairy and chilled food operations and software. It is not legal or regulatory advice and does not list every requirement that applies to you. It covers U.S. federal rules and the PMO model, with EU scope notes; state, national, customer and certification requirements add to them. Regulatory text was checked on 2 October 2026; confirm the current text before relying on it. 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 control or validate pasteurizers or refrigeration, set critical limits, judge product safety, release or reject lots, report to regulators or decide recalls, and does not by itself make you compliant. Photography is illustrative; loads, lots and results are worked examples, not customer data.



Every tank traced. Every chilled pack accounted for.

See dairy and chilled workflows at v5ultimate.com · U.S. edition · October 2026