



THE INFANT FORMULA MANUFACTURING GUIDE

Every nutrient checked. Every can traceable.

21 CFR 106 and 107 in practice, from premix to recall

A practical evaluation guide for U.S. infant formula manufacturers and the teams around them: how the CGMP, quality control, records, notification and recall rules shape each production aggregate, and what a connected record should show a qualified reviewer before anything is released.



21 CFR 106

21 CFR 107

PEOPLE DECIDE RELEASE

U.S. edition / October 2026

v5ultimate.com

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

INSIDE THE GUIDE

One production aggregate, start to finish.

Infant formula is often the sole source of nutrition for the people who consume it, and U.S. law treats it differently from other foods. This guide follows one powdered aggregate and shows what each rule expects the record to hold.

01 / FRAME

pp. 03–04

What counts, which rules

The legal definition, exempt formulas, how Parts 106 and 107 fit together, and what is not covered.

02 / CONTROL

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The control system and materials

Control points under 106.6, ingredients, containers and closures, premixes and nutrient testing.

03 / MAKE

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Manufacture, micro, pack

Identification and process controls, water and temperature records, Cronobacter and Salmonella, labels and codes.

04 / DECIDE

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Release, records, systems

Quarantine and documented disposition, stability, record retention, and validating automatic systems.

05 / RESPOND

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Notify, recall, audit

New formula submissions, prompt notification, 24-hour recall contact, audits and complaints.

06 / APPLY

pp. 17–22

V5 fit, worksheets, sources

Where V5 fits and does not, release readiness and demo worksheets, a four-week evaluation, ten sources.

Who it is for. Quality, regulatory and laboratory leads, production and packing managers, supply chain and purchasing, and anyone choosing a production and quality system for a U.S. infant formula operation.

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

WHERE V5 FITS

V5 records the receiving, weighing, production, testing, packing and quality work your procedures define. It does not formulate products, judge nutrient adequacy, decide release, notify FDA, or decide recalls. Those decisions stay with your qualified people.

FRAME / 01

What counts as infant formula?

The definition is narrow on purpose. Being sold for babies is not enough; the product must be represented for special dietary use solely as a food for infants because it simulates human milk or substitutes for it.

THE STATUTORY TEST [4]

A food that purports to be, or is represented for, special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk. (FD&C Act sec. 201(z), paraphrased.)

PRODUCT	WHAT APPLIES
Infant formula (standard)	Parts 106 and 107 apply in full [1][2]
Exempt infant formula	Special medical needs; terms in 107.50, some rules differ [2][3]
Baby food (purees, cereals, snacks)	Not infant formula; ordinary food rules, e.g. Part 117 [8]
Toddler or 'growing-up' drinks	Not infant formula unless represented as above; check claims
Medical foods	A separate category; do not assume Part 106 applies

Classify each product

Decide, with regulatory advice, whether each product is infant formula, exempt formula or something else, and record why. Labels and claims can change the answer.

New formula, new duties

A new infant formula needs a submission at least 90 days before interstate introduction (106.120(a)) and quality factor requirements (106.96) [1][3].

Liquid formula adds rules

Liquid formula also follows Part 113 for low-acid canned foods and Part 114 for acidified foods, as appropriate (106.55(b)) [1][7].

WHERE V5 FITS

Product master data in V5 can carry a product category and your regulatory notes, so records, labels and reports follow the right template. V5 does not classify products or decide which rules apply.

Sources: [1], [2], [3], [4], [7], [8] (linked on pages 21–22)

FRAME / 02

Two parts, one record.

Part 106 says how formula must be made, tested, recorded and notified. Part 107 says what the label must say, which nutrients are required and how recalls run. The statute, section 412, sits above both.

106 Subpart B	CGMP: control system, workers, facilities, equipment, automatic systems, ingredients, manufacture, micro, packing, release, traceability, audits	106.5–106.90
106 Subpart C	Quality control: nutrient testing of premixes, in-process and finished product; stability	106.91–106.92
106 Subpart D–E	Audit plans; quality factors (normal physical growth, protein quality)	106.94–106.96
106 Subpart F	Records, including retention periods	106.100
106 Subpart G	Registration, new formula and verification submissions, change notices, notification of adulterated formula	106.110–106.150
107 Subpart B–C	Nutrient information and directions on the label; exempt formulas	107.10–107.50
107 Subpart D	Nutrient specifications (minimums, and maximums where set)	107.100
107 Subpart E	Recalls: FDA-required and firm-initiated, notification, termination, records	107.200–107.280

Other food rules still apply. Part 106 records provisions refer to Parts 106, 107, 109, 110, 113 and 117 together [1]. FDA's infant formula pages summarise current requirements and contacts [5][6]. Read the eCFR text, not this summary, before you rely on any requirement.

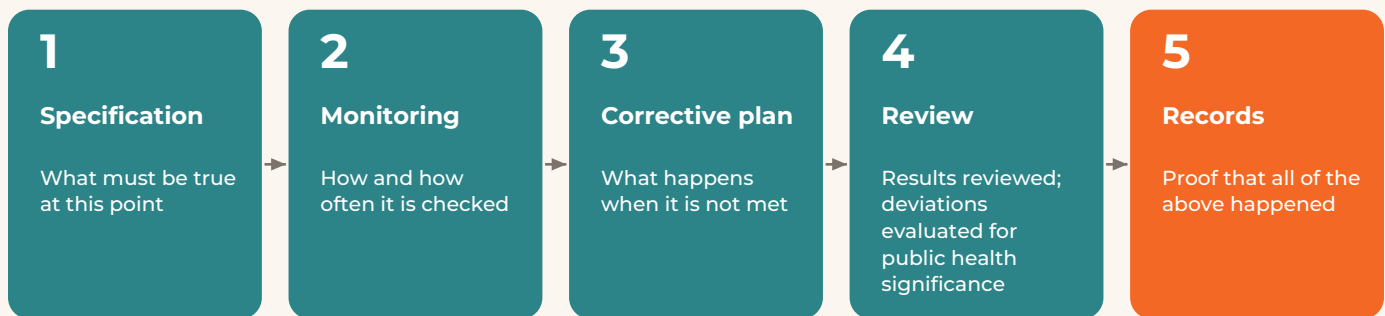
WHERE V5 FITS

V5 keeps procedures, specifications and records as controlled documents and connected records. Industry configuration adjusts screens and reports; it does not interpret regulations for you.

CONTROL / 01

Control at every point that matters.

Section 106.6 asks for a written production and in-process control system covering everything from receipt of raw materials to distribution. At each point where control is needed to prevent adulteration, five things must exist [1].



WHEN A SPECIFICATION IS MISSED

Any article that fails a specification at a control point is held under a quarantine system pending a documented review and a material disposition decision (106.6(d)). The review must evaluate public health significance, not just the number [1].

Write the points down

List each control point with its limit, method, frequency, owner and corrective plan. This list drives the batch record, not the other way round.

Separate monitor and reviewer

The person who records a value is often not the right person to judge a deviation. Name both roles.

Keep the review visible

A deviation that is closed without a recorded evaluation is the gap auditors find first.

WHERE V5 FITS

V5 lets you define steps with limits, require the check at the step, block or flag out-of-limit entries, raise a structured deviation and hold the material until a named reviewer records a disposition. Your team sets the limits and makes the decision.

Sources: [1] (linked on pages 21–22)

CONTROL / 02

Ingredients, cans and closures.

Section 106.40 covers everything that goes into or around the formula. Three habits carry most of the weight: written specifications, lot numbers, and physical or system segregation by status [1].



Safe and suitable only

Substances must be food additives used per regulation, GRAS for the use, or prior-sanctioned; packaging must meet the listed food-contact pathways (106.40(a)–(b)) [1].

A lot number on everything

Ingredients, containers and closures are identified with a lot number used to record their disposition (106.40(c)) [1].

Specifications and a test plan

Written specs plus procedures to decide whether each lot meets them. A failure goes to documented review by a qualified individual (106.40(d)) [1].

STATUS	MEANING	ISSUE TO PRODUCTION?
Pending release	Received, not yet accepted	HOLD
Released for use	Meets specification; may be issued	YES
Rejected	Cannot be used; disposition recorded	DO NOT ISSUE

Segregation can be by system. Separate areas, or a segregation system such as computerized inventory control, a card system or an automated system, clearly designated for pending, released and rejected materials (106.40(e)) [1]. If the system is your segregation, it must be reliable enough to be trusted, and validated (see page 14).

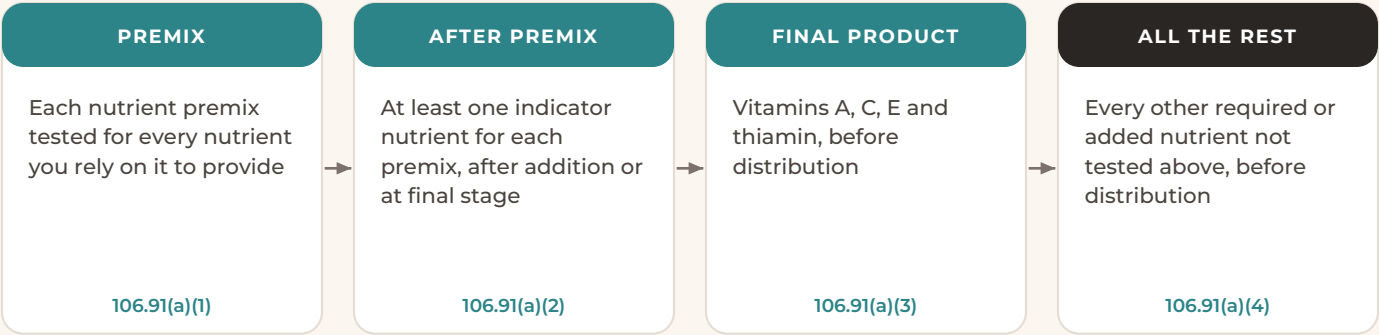
WHERE V5 FITS

V5 receiving records supplier and internal lots, holds each lot in a pending status, and only allows released lots to be issued to production. Approved supplier lists and certificate review are recorded against your specifications. Your team decides what testing a certificate can replace.

CONTROL / 03

Nutrients, tested at four stages.

Section 106.91(a) sets a layered nutrient testing scheme for every production aggregate. The point is simple: prove each premix delivered what you relied on it for, and prove the finished product meets Part 107 [1][2].



Weigh the premix exactly

Premixes are small additions carrying many nutrients. The right scale, a checked tolerance and a scanned lot are what make the indicator test meaningful.

If a result is low

If finished-product testing shows a required nutrient below Part 107 levels, 106.91(b)(4) requires you to evaluate, address released and pending aggregates, and act [1].

WHERE V5 FITS

Formulas in V5 carry the premix and its nutrient contribution; weighing steps check the scale, tolerance and lot; laboratory sample plans and results are recorded per aggregate with pending tests visible. V5 does not set nutrient levels or judge adequacy.

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

MAKE / 01

Know what is in every vessel.

Section 106.50 requires complete production and control records for each aggregate, reviewed by a qualified individual, and an identification system for every compounding and storage container, line and major piece of equipment [1].

Identify contents

Each tank, line and major equipment shows the product, aggregate and status at all times (106.50(c)). Mix-ups start where identification stops.

Review the record

An individual qualified by education, training or experience reviews the production record (106.50(b)). Name the role and keep the review on the record.

Water as an ingredient

Potable water meets EPA primary drinking water standards, tested at the point of use at least annually, with results kept (106.20(f)) [1].

TEMPERATURE AND TIME RECORDS (106.30)

Thermal processing and cold storage have their own provisions. In-process or final formula may be held cold at no more than 45 °F (7.2 °C) for a defined time only with scientific data supporting that time and temperature; cold-storage temperatures are monitored and recorded [1]. A calibration failure at a control point needs a written evaluation of all affected product (106.30) [1].



WHERE V5 FITS

V5 records steps, equipment, times and temperatures as the aggregate is made, shows equipment and line status, links calibration and cleaning records, and lists aggregates that used an instrument after a calibration failure, for your team to evaluate.

Sources: [1] (linked on pages 21–22)

MAKE / 02

Cronobacter and Salmonella: none detected.

Section 106.55 requires a process control system against microorganisms across all stages, and sets a finished-product test for every aggregate of powdered infant formula before distribution [1].

MICROORGANISM	SAMPLES (N)	SAMPLE SIZE	M VALUE
Cronobacter spp.	30	10 g	None detected
Salmonella spp.	60	25 g	None detected

Powdered formula containing a microorganism above these M values is deemed adulterated. FDA determines compliance using the latest edition of the Bacteriological Analytical Manual [1][9]. Liquid formula instead follows Parts 113 and 114, as appropriate [7].



Finished test is the last line

The 106.55 table is a minimum release test. The process control system, including environmental monitoring of the processing environment, is what keeps contamination out.

Hold until results are in

Aggregates stay in quarantine until micro results are complete and meet specification (106.70) [1].

Keep the records

Micro testing records are kept under 106.100(e)(5)(ii) and (f)(7) [1].

WHERE V5 FITS

V5 laboratory sample plans can carry your micro tests and sample counts per aggregate, record results, keep the aggregate on hold while results are pending, and escalate out-of-specification results to a deviation. Laboratory methods and decisions stay with your lab and quality team.

MAKE / 03

Right label, right date, right code.

Section 106.60 requires examining packaged and labeled formula during finishing to confirm every container in the aggregate has the correct label, use-by date and production code [1]. Part 107 sets what the label must say [2].

Check every aggregate

Correct label, correct use-by date, correct code (106.60(a)). Record who checked, when, and how many units.

Labels that last

Designed, printed and applied to stay legible and attached through processing, storage, distribution and use (106.60(b)).

Shipping packs

Multi-container packaging names product, manufacturer or shipper and the code; mixed packs list each (106.60(c)) [1].

LABEL ELEMENT	WHAT IT COVERS	SECTION
Nutrient information	Per 100 kcal, in the format 107.10 sets	107.10
Directions for use	Preparation, storage, warnings, pictograms	107.20
Exemptions	Limited cases set out in the regulation	107.30
Nutrient levels	Minimums, and maximums where set	107.100

THE PRODUCTION CODE (106.80)

Each aggregate is coded with a sequential number identifying the product and the packing establishment, permitting tracing of all stages of manufacture: the year, the day of the year, the period of that day it was packed, and the receipt and handling of the raw materials used [1].

WHERE V5 FITS

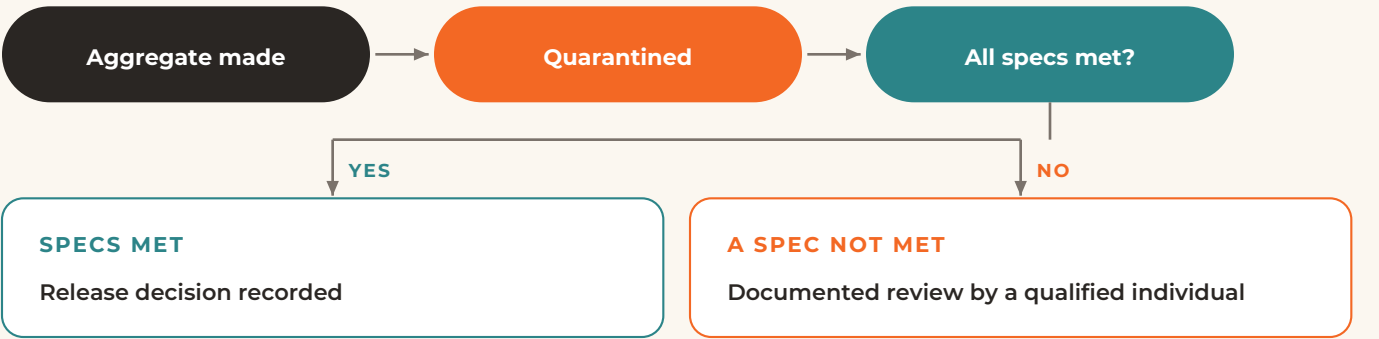
V5 label design can print the code and use-by date from the aggregate record, and pack-out checks record label, date and code verification with counts. Label content, claims and nutrient panels are approved by your regulatory team.

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

DECIDE / 01

Quarantine until a person decides.

Section 106.70 is the release rule. Every aggregate stays under a quarantine system until it meets all specifications, including micro and nutrient testing, or until a documented review of any failure is complete [1].



IF A SPECIFICATION IS NOT MET, THE DOCUMENTED DISPOSITION IS ONE OF (106.70(b))

Reject
Clearly identified as rejected and kept under quarantine so it cannot be released (106.70(c)).

Reprocess or recondition
Then re-evaluated; the reworked aggregate must still meet every requirement.

Approve and release
Only if the review finds the failure does not result in, or could not lead to, adulteration.

A hard line. An aggregate that does not meet the nutrient requirements of section 412(i), or was not made, packed, labeled and held to prevent adulteration, shall not be approved and released (106.70(d)) [1][3].

WHERE V5 FITS
V5's QC release queue shows each aggregate's results, open deviations, code checks and holds in one view. A named reviewer records the decision with an electronic signature. V5 never releases product automatically and never makes the disposition decision.

DECIDE / 02

Prove it lasts to the use-by date.

Section 106.91(b) adds finished-product nutrient testing over shelf life. It is how a manufacturer shows the label stays true until the last day [1].

WHICH FORMULA	SAMPLE AND SCOPE	TIMING
New infant formula	First aggregate, each site and form	Every 4 months through shelf life
Subsequent aggregates	Each aggregate, each site and form	At end of shelf life

Exemption is possible

FDA may exempt a new formula from the 4-month schedule if stability data for similar formulas show it is unlikely to differ (106.91(b)(1)(ii)) [1].

If shelf life is not supported

Address every released and pending aggregate implicated by the results (106.91(b)(3)) [1].

Plan the samples

Retained samples, storage conditions and pull dates are a schedule to keep for years, across products and sites.

WORKED EXAMPLE

Aggregate IF-2611, powder, 18-month use-by. Retained sample pulled at month 18 and tested for the required and added nutrients except minerals, which 106.91(b)(5) leaves out of stability testing (manufacture testing under (a) is separate). Vitamin C reads close to the Part 107 minimum: the lab raises an out-of-specification investigation, quality evaluates other aggregates of the same formula, and the result feeds the next shelf-life review. The decision on released stock is quality's.

WHERE V5 FITS

V5 laboratory stability programmes schedule pulls by aggregate and product, record results against your specifications and escalate out-of-specification results. Your quality team sets shelf life and decides what to do with affected aggregates.

DECIDE / 03

Records that outlast the product.

Section 106.100 lists the records each aggregate needs and how long to keep them. Quality control records must be complete enough to permit a public health evaluation of any aggregate (106.100(o)) [1].

RETENTION (106.100(n))

Production control, product testing, test results, complaints and distribution records: keep for **1 year after the end of shelf life or 3 years from manufacture, whichever is greater** [1]. Recall distribution records under 107.280: at least 1 year after shelf-life expiry [2].

RECORD	WHAT IT HOLDS	WHERE
Production aggregate record	Complete production and control information	106.100(e)
Water testing	Frequency and results	106.100(f)(1)
Temperatures	Thermal processing and cold storage	106.100(f)(3)
Equipment	Cleaning, sanitizing, maintenance	106.100(f)(4)
Automatic systems	Validation, checks, modifications	106.100(f)(5)
Ingredients, containers, closures	Lots, specs, test results, disposition	106.100(f)(6)
Microbiology	Tests and results	106.100(f)(7)
Quality control	Nutrient testing results	106.100(e)(5)(i)

Electronic records. Where records are kept electronically, Part 11 sets controls for electronic records and signatures; how it applies to each record is for your quality and regulatory team to decide [10].

WHERE V5 FITS

V5 keeps aggregate, laboratory, equipment, receiving and distribution records connected, with an audit trail and electronic signatures, and exports them for review. Your record schedule sets retention; V5 does not decide which records you need.

Sources: [1], [2], [10] (linked on pages 21–22)

DECIDE / 04

Your software is part of the process.

Section 106.35 applies to computers and software used in production or quality control. Any system you rely on, including the one this guide describes, falls under it [1].

01 Designed and tested

Systems designed, installed, tested and maintained to perform their intended function (106.35(b)).

02 Input and output checked

Accuracy of input and output checked and documented; degree and frequency based on complexity, reliability and risk (106.35(b)(2)).

03 Validated before use

Each system validated before any formula made with it is released (106.35(b)(3)).

04 Revalidated after change

Modified systems revalidated before release; software changes made by a designated individual and checked (106.35(b)(4)).

WHO DOES WHAT

You, the manufacturer, decide the intended use, assess risk, plan and approve validation, including performance qualification, and decide when a change needs revalidation. **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. V5 is not validated for your use until you validate it; it does not make your process compliant on its own.

Sources: [1] (linked on pages 21–22)

RESPOND / 01

When FDA needs to hear from you.

Infant formula has its own submission and notification duties. They run on short clocks, so the facts must be findable fast [1][2][3].

Before first interstate introduction

Register the manufacturer and each intended establishment for the new formula (106.110(a)).

At least 90 days before introduction

New infant formula submission (106.120(a)). The filing date is when FDA receives a complete submission; do not market before 90 days after it (106.120(e)).

After first production, before introduction

Verification submission confirming the formula complies and is not adulterated (106.130(a)); export-only formulas follow 106.120(c).

Before first processing of a changed formula

Submission when a change in formulation or processing may affect whether the formula is adulterated (106.140(a)).

Promptly

Notify FDA when you know facts that reasonably support a conclusion that formula that has left your control may not provide required nutrients or may be otherwise adulterated or misbranded (106.150). By telephone; FDA's after-hours emergency number is in the regulation.

Within 24 hours

Telephone FDA once a decision is made to recall (107.240(a)).

Within 14 days, then every 14

Initial written recall report, then written status reports until FDA terminates the recall (107.240(b)–(c)).

Check the current procedure. Contact routes and offices in these sections have changed over time; confirm the current FDA contact details on FDA's infant formula pages before you need them [5][6].

WHERE V5 FITS

V5 can pull the facts a notification needs, such as aggregates, results, codes and shipments, quickly from connected records. V5 does not decide whether to notify or recall and does not contact FDA. Those are decisions for your people.

Sources: [1], [2], [3], [5], [6] (linked on pages 21–22)

RESPOND / 02

Recall fast. Audit honestly.

Part 107 Subpart E sets out FDA-required recalls and firm-initiated removals, what a recall must include, and the distribution records that make it possible. Part 106 adds independent audits [1][2].



Elements of a recall (107.230)

Notifying consignees, effectiveness checks, and retail notice where required. Distribution records must be good enough to effect and monitor the recall (107.280) [2].

Mock recall

From one premix lot: list aggregates, codes, shipments and consignees, timed. Then from one code back to every ingredient lot.

Independent CGMP audits

Regularly scheduled, by people knowledgeable in infant formula production with no direct responsibility for what they audit (106.90) [1].

Quality control audits

Audits of quality control procedures under 106.92, to a written plan (106.94) [1].

Complaints

Complaints are among the records kept under 106.100(n). Link each to the code, the aggregate and the review [1].

WHERE V5 FITS

V5 traces from an ingredient lot to aggregates, codes and shipments and back, records mock recalls with timings, links complaints to aggregates, and schedules audits with findings and CAPA. Recall strategy, consignee notices and FDA reports stay with your people.

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

APPLY / 01

Where V5 fits, and where it does not.

A plain map from the rule 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.

RULE	V5 KEEPS THE RECORD	YOUR PEOPLE DECIDE
Ingredient status (106.40)	Receiving, lot status, issue blocks	Specs and acceptance
Control points (106.6)	Steps with limits, deviations, holds	Limits, review, disposition
Premix weighing	Weigh & dispense, tolerance, scanned lots	Formula and tolerances
Nutrient tests (106.91)	LIMS sample plans and results	Methods, specs, judgement
Micro tests (106.55)	Sample plans, results, OOS escalation	Methods, environmental plan
Codes and labels (106.60/80)	Label print, pack-out code checks	Label content and claims
Release (106.70)	QC release queue, e-signature	The release decision
Stability (106.91(b))	Stability schedules and results	Shelf life, affected stock
Records (106.100)	Connected records, audit trail, export	Record schedule
Automatic systems (106.35)	Versioned releases, change audit trail	Validation, incl. PQ
Recall (107 Subpart E)	Lot trace, mock recall, shipments	Recall decision, FDA contact

Coming soon, not available today: AI demand and yield forecasting and process anomaly detection.
Plan-dependent: IQ/OQ and validation support are Enterprise only, scoped in the accepted quote or statement of work.

WHERE V5 FITS

Nothing in V5 releases formula, decides a disposition, notifies FDA or starts a recall. It keeps the evidence connected so the qualified people who make those decisions can see it.

WORKSHEET 01

Release readiness for one aggregate.

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

	SHOWN	PARTLY	NOT SHOWN
Ingredient lots released Every lot used was released for use before issue	☐	☐	☐
Premix tested Each premix tested for the nutrients relied on	☐	☐	☐
Indicator nutrients One per premix, after addition or final stage	☐	☐	☐
Vitamins A, C, E, thiamin Final-stage results before distribution	☐	☐	☐
Remaining nutrients All other required and added nutrients covered	☐	☐	☐
Cronobacter and Salmonella Sample plan and results for powdered formula	☐	☐	☐
Control point deviations Each evaluated, with public health significance	☐	☐	☐
Label, use-by, code Checked across the aggregate, with counts	☐	☐	☐
Qualified reviewer Named, with a documented decision	☐	☐	☐
Distribution Shipments linked to the code	☐	☐	☐

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 lot Try to issue a pending premix lot; show the block.	☐	☐	☐
Tolerance Enter an out-of-tolerance premix weight; show what happens.	☐	☐	☐
Missing result Try to release with a nutrient result pending.	☐	☐	☐
Micro failure Record a positive micro result; show hold and deviation.	☐	☐	☐
Disposition Record reject, reprocess and approve; show who signed.	☐	☐	☐
Calibration look-back Fail a calibration; list aggregates that used the instrument.	☐	☐	☐
Stability pull Show the shelf-life schedule and a late pull.	☐	☐	☐
Trace From one premix lot, list codes and consignees, timed.	☐	☐	☐
Change control Show what changed between two software versions.	☐	☐	☐
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 formula, without touching live records.

WEEK 1

Agree one formula and the five questions that matter most. Load specs, control points and sample plans.

WEEK 2

Run an aggregate end to end with test data: receipt, premix, blend, tests, pack-out, release review.

WEEK 3

Break it on purpose: pending lot, out-of-tolerance weight, positive micro, failed calibration.

WEEK 4

Run a timed mock recall. Review with QA, lab, production, warehouse and IT; plan validation.

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

ASK V5

“We make [powdered / liquid] infant formula at [number] sites. Our hardest moment is [e.g. holding aggregates for micro results]. 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 formula 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 Part 106: infant formula requirements (CGMP, quality control, records, submissions)</u>
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-106 | BINDING U.S. REGULATION |
| [2] | <u>U.S. eCFR, 21 CFR Part 107: infant formula labeling, nutrients, exempt formulas and recalls</u>
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-107 | BINDING U.S. REGULATION |
| [3] | <u>21 U.S.C. 350a (FD&C Act sec. 412): requirements for infant formulas</u>
https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section350a | BINDING U.S. STATUTE |
| [4] | <u>21 U.S.C. 321(z) (FD&C Act sec. 201(z)): definition of infant formula</u>
https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section321 | BINDING U.S. STATUTE |
| [5] | <u>U.S. FDA, Regulations and information on the manufacture and distribution of infant formula</u>
https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-informati... | FDA INFORMATION PAGE |
| [6] | <u>U.S. FDA, Information for infant formula manufacturers and retailers</u>
https://www.fda.gov/food/infant-formula-homepage/information-infant-formula-man... | FDA INFORMATION PAGE |
| [7] | <u>U.S. eCFR, 21 CFR Part 113: thermally processed low-acid foods in hermetically sealed containers</u>
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-113 | BINDING U.S. REGULATION |
| [8] | <u>U.S. eCFR, 21 CFR Part 117: CGMP and preventive controls for human food</u>
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-117 | BINDING U.S. REGULATION |

SOURCES

Sources, continued.

[9] [U.S. FDA, Bacteriological Analytical Manual, Chapter 29: Cronobacter](https://www.fda.gov/food/laboratory-methods-food/bam-chapter-29-cronobacter)

FDA LABORATORY METHOD

<https://www.fda.gov/food/laboratory-methods-food/bam-chapter-29-cronobacter>

[10] [U.S. eCFR, 21 CFR Part 11: electronic records and electronic signatures](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11)

BINDING U.S. REGULATION

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11>

How to read the status labels. Binding regulations and statutes are law in the United States. FDA web pages explain and announce; the Bacteriological Analytical Manual is FDA's laboratory method reference.

SCOPE AND LIMITS

This guide is practical orientation for evaluating U.S. infant formula operations and software. It is not legal or regulatory advice and does not list every requirement that applies to you. It covers 21 CFR 106 and 107, which apply to infant formula only, not to all foods for babies; other markets have their own rules, not covered here. Regulatory text was checked on eCFR 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 formulate products, judge nutrient adequacy, release formula, decide dispositions, notify FDA or decide recalls, is not validated for your use until you validate it, and does not by itself make you compliant. Photography is illustrative; aggregates, codes and results are worked examples, not customer data.



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