meet under section 412(b)(1) of the act. If the formula fails to comply with any regulation in subpart E of this part, it will be deemed to be adulterated under section 412(a)(2) of the act.

(c) The criteria set forth in subpart F of this part implement the record retention requirements established in section 412(b)(4) of the act. Failure to comply with any regulation in subpart F of this part is a violation of section 301(e) of the act.

(d) The criteria set forth in subpart G of this part describe the circumstances in which infant formula manufacturers are required to register with, submit to, or notify the Food and Drug Administration, and the content of those registrations, submissions, or notifications, under section 412(c), (d), and (e) of the act. Failure to comply with any regulation in subpart G of this part is a violation of section 301(s) of the act.

4. Section 106.3 is revised to read as follows:

§ 106.3 Definitions.

The definitions in this section and the definitions contained in section 201 of the Federal, Food, Drug, and Cosmetic Act (the act) shall apply to infant formula requirements in 21 CFR part 106 and part 107 of this chapter.

(a) *Batch* means a specific quantity of an infant formula or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

(b) *Final-product-stage* means the point in the manufacturing process, before distribution of an infant formula, at which the infant formula is homogeneous and is not subject to further degradation due to processing.

(c) *Indicator nutrient* means a nutrient whose concentration is measured during the manufacture of an infant formula to confirm complete addition and uniform distribution of a premix or other substance of which the indicator nutrient is a part.

(d) *Infant* means a person not more than 12 months of age.

(e) *Infant formula* means a food which 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.

(f) *In-process batch* means a combination of ingredients at any point in the manufacturing process before packaging.

(g) *Lot* means a batch, or a specifically identified portion of a batch, having uniform character and quality within specified limits; or, in the case of an infant formula produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within specified limits.

(h) *Lot number, control number, or batch number* means any distinctive combination of letters, numbers, symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of infant formula or other material can be determined.

(i) *Major change* in an infant formula means any new formulation, or any change of ingredients or processes where experience or theory would predict a possible significant adverse impact on levels of nutrients or bioavailability of nutrients, or any change that causes an infant formula to differ fundamentally in processing or in composition from any previous formulation produced by the manufacturer. Examples of infant formulas deemed to differ fundamentally in processing or in composition include:

(1) Any infant formula produced by a manufacturer who is entering the U.S. market;

(2) Any infant formula powder processed and introduced for commercial or charitable distribution by a manufacturer who previously only produced liquids (or vice versa);

(3) Any infant formula having a significant revision, addition, or substitution of a macronutrient (i.e., protein, fat, or carbohydrate), with which the manufacturer has not had previous experience;

(4) Any infant formula manufactured on a new processing line or in a new plant;

(5) Any infant formula manufactured containing a new constituent not listed in section 412(i) of the act, such as taurine or L-carnitine;

(6) Any infant formula processed by a manufacturer on new equipment that utilizes a new technology or principle (e.g., a change from terminal sterilization to aseptic processing); and

(7) An infant formula for which there has been a fundamental change in the type of packaging used (e.g., changing from metal cans to plastic pouches).

(j) *Manufacturer* means a person who prepares, reconstitutes, or otherwise changes the physical or chemical characteristics of an infant formula or packages or labels the product in a container for distribution.

(k) *Microorganisms* means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance.

(l) *New infant formula* means:

(1) An infant formula manufactured by a person that has not previously manufactured an infant formula for the U.S. market, and

(2) An infant formula manufactured by a person that has previously manufactured infant formula and in which there is a major change in processing or formulation from a current or any previous formulation produced by such manufacturer.

(m) *Nutrient* means any vitamin, mineral, or other substance or ingredient that is required in accordance with the table set out in section 412(i)(1) of the act or by regulations issued under section 412(i)(2) or that is identified as essential for infants by the Food and Nutrition Board of the National Research Council through its development of a Recommended Dietary Allowance or an Estimated Safe and Adequate Daily Dietary Intake range, or that has been identified as essential for infants by the Food and Drug Administration through a Federal Register publication.

(n) *Nutrient premix* means a combination of ingredients containing two or more nutrients received from a supplier or prepared by an infant formula manufacturer.

(o) *Quality factors* mean those factors necessary to demonstrate that the infant formula, as prepared for market, provides nutrients in a form that is bioavailable and safe as shown by evidence that demonstrates that the formula supports healthy growth when fed as a sole source of nutrition.

(p) *Representative sample* means a sample that consists of a number of units that are drawn based on rational criteria, such as random sampling, and intended to ensure that the sample accurately portrays the material being sampled.

(q) *Shall* is used to state mandatory requirements.

(r) *Should* is used to state recommended or advisory procedures or to identify recommended equipment.

5. Part 106 is amended by redesignating subparts B, C, and D as subparts C, F, and G, respectively, and adding new subparts B, D, and E; and by revising newly redesignated subparts C and G to read as follows:

* * * * *

Subpart B—Current Good Manufacturing Practice

§ 106.5 Current good manufacturing practice.

(a) The regulations set forth in this subpart and, for liquid infant formulas, in part 113 of this chapter define the minimum current good manufacturing practices that are to be used in, and the facilities or controls that are to be used for, the manufacture, processing, packing, or holding of an infant formula. Compliance with these provisions is necessary to ensure that such infant formula provides the nutrients required under § 107.100 of this chapter and is manufactured in a manner designed to prevent its adulteration.

(b) The failure to comply with any regulation set forth in this subpart or, for liquid infant formulas, in part 113 of this chapter in the manufacture, processing, packing, or holding of an infant formula shall render such infant formula adulterated under section 412(a)(3) of the Federal Food, Drug, and Cosmetic Act (the act).

§ 106.6 Production and in-process control system.

(a) Manufacturers shall conform to the requirements of this subpart by implementing a system of production and in-process controls. This production and in-process control system shall cover all stages of processing, from the receipt and acceptance of the raw materials, ingredients, and components through the storage and distribution of the finished product and shall be designed to ensure that all the requirements of this subpart are met.

(b) The production and in-process control system shall be set out in a written plan, or set of procedures, that is designed to ensure that an infant formula is manufactured in a manner that will prevent adulteration of the infant formula.

(c) At any point, step, or stage in the production process where control is necessary to prevent adulteration, the manufacturer shall:

(1) Establish standards or specifications to be met;

(2) Monitor the production and in-process control point, step, or stage;

(3) Establish corrective action plans for use when a standard or specification established in accordance with paragraph (b)(1) of this section is not met;

(4) Review the results of the monitoring required by paragraph (c)(2) of this section, and review and evaluate the public health significance of any deviations from standards or specifications that have been established in accordance with paragraph (c)(1) of this section. This review shall be conducted by an individual qualified by training and experience to conduct such reviews; and

(5) Establish recordkeeping procedures, in accordance with § 106.100(e)(3), that ensure that compliance with the requirements of this section is documented.

§ 106.10 Controls to prevent adulteration by workers.

(a) There shall be sufficient personnel, qualified by training and experience, to perform all operations, including all required recordkeeping, in the manufacture, processing, packing, and holding of each infant formula and to supervise such operations to ensure that they are correctly and fully performed.

(b) Personnel working directly with infant formula, infant formula raw materials, infant formula packaging, or infant formula equipment or utensil contact surfaces shall practice good personal hygiene to protect the infant formula against contamination. Good personal hygiene includes, but is not limited to:

(1) Wearing clean outer garments and, as necessary, protective apparel such as head, face, hands, and arm coverings; and

(2) Washing hands thoroughly in a hand washing facility with soap and running water at a suitable temperature before starting work, after each absence from the work station, and at any other time when the hands may become soiled or contaminated.

(c) Any person who reports that he or she has, or appears by medical examination or supervisory observation to have, an illness, open lesion, including boils, sores, or infected wounds, or any other source of microbial contamination that creates a reasonable possibility that the safety of an infant formula may be adversely affected, shall be excluded from direct contact with ingredients, containers, closures, in-process materials, equipment, utensils, and infant formula product until the condition is corrected or determined by competent medical personnel not to jeopardize the safety of the infant formula.

§ 106.20 Controls to prevent adulteration caused by facilities.

(a) Buildings used in the manufacture, processing, packing, or holding of infant formula shall be maintained in a clean and sanitary condition and shall have space for the separation of incompatible operations, such as the handling of raw materials, the manufacture of the product, and packaging and labeling operations.

(b) Separate areas shall be designated for holding raw materials, in-processing materials, and final product infant formula:

(1) Pending release for use in infant formula production or pending release of the final product,

(2) After rejection for use in infant formula and before disposition, and

(3) After release for use in infant formula production or after release of the final product.

(c) Lighting shall allow easy identification of raw materials,

packaging, labeling, in-process materials, and finished products that have been released for use in infant formula production and shall permit the easy reading of instruments and controls necessary in processing, packaging, and laboratory analysis. Any lighting fixtures directly over or adjacent to exposed raw materials, in-process materials, or bulk (unpackaged) finished product shall be protected to prevent glass from contaminating the product in the event of breakage.

(d) Air filtration systems, including prefilters and particulate matter air filters, shall be used on air supplies to production areas where ingredients or infant formula are directly exposed to the atmosphere.

(e) All rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents shall be stored and used in a manner that protects against contamination of infant formula.

(f)(1) Potable water used in the manufacture of infant formula shall meet the standards prescribed in the Environmental Protection Agency's (EPA's) Primary Drinking Water Regulations set forth in 40 CFR part 141, except that the fluoride level of the water used in infant formula manufacturing shall be as low as possible. The water shall be supplied under continuous positive pressure in a plumbing system that is free of defects that could contaminate an infant formula.

(2) Manufacturers shall test representative samples of the potable water drawn at a point in the system at which the water is in the same condition that it will be when it is used in infant formula manufacturing.

(3) Manufacturers shall conduct the tests required by paragraph (f)(2) of this section with sufficient frequency to ensure that the water meets the EPA's Primary Drinking Water Regulations but shall not conduct these tests less frequently than annually for chemical contaminants, every 4 years for radiological contaminants, and weekly for bacteriological contaminants.

(4) Manufacturers shall make and retain records, in accordance with § 106.100(f)(1), of the frequency and results of testing of the water used in the production of infant formula.

(g) There shall be no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for infant formula manufacturing.

(h) When steam comes in direct contact with infant formula, it shall be safe and free of rust and other particulate matter that may contaminate the formula. Boiler water additives in the steam shall be used in accordance with § 173.310 of this chapter.

(i) Each infant formula manufacturing site shall provide its employees with readily accessible toilet facilities and hand washing facilities that include hot and cold water, soap or detergent, and single-service towels and that are maintained in good repair and in a sanitary condition at all times, and that these facilities provide for proper disposal of the sewage. Doors to the toilet facility shall not open into areas where infant formula ingredients, containers, or closures are stored, or where infant formula is processed or stored.

§ 106.30 Controls to prevent adulteration caused by equipment or utensils.

(a) Equipment used in the manufacture, processing, packing or holding of an infant formula shall be of appropriate design and shall be installed to facilitate its intended function and its cleaning and maintenance.

(b) Equipment and utensils used in the manufacture, processing, packing, or holding of an infant formula shall be constructed so that surfaces that contact ingredients, in-process materials, or infant formula are made of nontoxic materials and are not reactive or absorptive. Such equipment and utensils shall be designed to be easily cleanable and to withstand the environment of their intended use. All surfaces that contact ingredients, in-process materials, or infant formula shall be cleaned, sanitized, and maintained to protect infant formula from being contaminated by any source. Sanitizing agents used on food-contact surfaces must comply with § 178.1010 of this chapter.

(c) Manufacturers shall ensure that substances, such as lubricants or coolants, that are required for operation of infant formula manufacturing equipment, but that would render the infant formula adulterated if they contaminated the formula, do not come in contact with formula ingredients, containers, closures, or in-process materials or with infant formula itself.

(d)(1) Manufacturers shall ensure that instruments used for measuring, regulating, or controlling mixing time and speed, temperature, pressure, moisture, water activity, or other parameters at points where control is deemed necessary to prevent adulteration in the processing of an infant formula are accurate, easily read, properly maintained, and present in sufficient number for their intended use. The instruments and controls shall be tested for accuracy (calibrated) against a known reference standard before first use and thereafter at routine intervals, as specified in writing by the manufacturer of the instrument or control, or as otherwise deemed necessary to ensure the accuracy of the instrument. The known reference standard shall be certified for accuracy at routine intervals specified in writing by the manufacturer of the instrument, or as otherwise deemed necessary to ensure the accuracy of the instrument. Manufacturers shall make and retain records of the accuracy checks in accordance with § 106.100(f)(2).

(2) Instruments and controls that cannot be adjusted to agree with the reference standard shall be repaired or replaced.

(3) If calibration of an instrument (testing for accuracy against a known reference standard) shows that a specification or standard for a point where control is deemed necessary to prevent adulteration has not been met, a written evaluation of all affected product, and of any actions that need to be taken with respect to that product, shall be made, in accordance with § 106.100(f)(2).

(e)(1) The temperature in cold storage compartments that are used to store raw materials, in-process materials, or final product, and in thermal processing equipment used at points where temperature control is necessary to prevent adulteration, shall be monitored with such frequency as is necessary to ensure that temperature control is maintained.

(2) Cold storage compartments shall be maintained at a temperature of 40 °F (4.4 °C) or below.

(3)(i) Cold storage compartments and thermal processing equipment shall be equipped with easily readable, accurate temperature-indicating devices.

(ii) Thermal processing equipment shall be equipped with temperature-recording devices that will reflect the true temperature on a continuing basis. Cold storage compartments shall be equipped with either temperature-recording devices that will reflect the true temperature, on a continuing basis, within the compartment or, in lieu of a temperature-recording device, a high temperature alarm or a maximum-indicating thermometer that has been verified to function properly. If the manufacturer uses either of the latter options, it shall maintain a temperature log in which it notes temperature with such frequency as is necessary to achieve control. Manufacturers shall make and retain records, in accordance with § 106.100(f)(3), of the temperatures indicated or recorded by these devices.

(4) When a temperature-recording device is used, such device shall not read higher than the calibrated temperature-indicating device for thermal processing equipment or lower than the reference temperature-indicating device for cold storage compartments.

(f) Equipment and utensils used in the manufacture of infant formula shall be cleaned, sanitized, and maintained at regular intervals to prevent adulteration of the infant formula. An individual qualified by training or experience to conduct such a review shall check all cleaning, sanitizing, and maintenance to ensure that it has been satisfactorily completed. Manufacturers shall make and retain records on equipment cleaning, sanitizing, and maintenance, in accordance with § 106.100(f)(4).

(g) Compressed air or other gases that are mechanically introduced into infant formula, that are used to clean any equipment, or that come into contact with any other surface that contacts ingredients, in-process materials, or infant formula shall be treated in such a way that their use will not contaminate the infant formula with unlawful indirect food additives or other chemical, physical, or microbiological contaminants. When compressed gases are used at product filling machines to replace air removed from the headspace of containers, the manufacturer shall install a 0.5 micrometer or smaller filter as close to the end of the gas line that feeds gas into the space, as practical.

§ 106.35 Controls to prevent adulteration due to automatic (mechanical or electronic) equipment.

(a)(1) For the purposes of this section, "hardware" means all automatic equipment, including mechanical and electronic equipment (including computers), that is used in production or quality control of a infant formula.

(2) For the purposes of this section, "software" means any programs, procedures, rules, and associated documentation used in the operation of a system.

(3) For the purposes of this section, "system" means a collection of components (including software and hardware) organized to accomplish a specific function or set of functions in a specified environment.

(4) For the purposes of this section, "validation" means establishing documented evidence that provides a high degree of assurance that a system will consistently produce a product meeting its predetermined specifications and quality characteristics.

(b)(1) All systems shall be designed, installed, tested, and maintained in a manner that will ensure that they are capable of performing their intended function and of producing or analyzing infant formula in accordance with this subpart and subpart C of this part.

(2) The infant formula manufacturer shall ensure that hardware is routinely calibrated, inspected, and checked according to written procedures.

(3) The infant formula manufacturer shall check and document the accuracy of input into, and output generated by, any system used in the production or quality control of an infant formula. The degree and frequency of input/output verification shall be based on the complexity and reliability of the system and the level of risk associated with the safe operation of the system.

(4) The infant formula manufacturer shall ensure that all systems are validated before their first use to manufacture commercial product.

(5) The infant formula manufacturer shall ensure that any system that is modified is revalidated after the modification and before use of the modified system to manufacture commercial product. All modifications to software shall be made by a designated individual and shall be checked by the infant formula manufacturer to ensure that infant formula that is produced or analyzed using the modified software complies with this subpart and with subpart C of this part.

(c) The infant formula manufacturer shall make and retain records, in accordance with § 106.100(f)(5), concerning automatic (mechanical or electronic) equipment.

§ 106.40 Controls to prevent adulteration caused by ingredients, containers, and closures.

(a) The only substances that may be used in infant formulas are food ingredients whose use in infant formula is safe and suitable under the applicable food safety provisions of the Federal Food, Drug, and Cosmetic Act; that is, the substance is generally recognized as safe (GRAS) for such use, is used in accordance with the agency's food additive regulations, or is authorized by a prior sanction.

(b) Infant formula containers and closures shall not be reactive or absorptive so as to affect the safety of the infant formula, and all packaging material that comes in contact with infant formula shall be composed of substances that are GRAS for use in or on food, GRAS for their intended use in food packaging, authorized by a prior sanction issued by the agency, or authorized for use as an indirect food additive. Any packaging material that comes in contact with infant formula shall be used in accordance with any prescribed limitations.

(c) Ingredients, containers, and closures used in the manufacture of infant formula shall be identified with a batch or lot number to be used in recording their disposition.

(d) Infant formula manufacturers shall develop written specifications for their acceptance or rejection of ingredients, containers, and closures used in infant formula manufacture. These specifications shall stipulate the standards for acceptance or rejection of such ingredients, containers, and closures as well as the procedures for determining whether the ingredients, containers, and closures meet that standard. An individual qualified by training or experience shall conduct an investigation of a finding that any ingredients, containers, or closures used in a batch of infant formula failed to meet any of the manufacturer's specifications.

(e) Ingredients, containers and closures shall be stored in areas clearly designated for:

(1) Materials pending release for use,

(2) Materials released for use, or

(3) Materials rejected for use in infant formula production. Any lot of ingredients, containers, or closures that does not meet the manufacturer's specifications shall be rejected and controlled under a quarantine system designed to prevent its use in the manufacture of infant formula.

(f) If an ingredient, a container, or a closure that has been tested and examined is exposed to air, heat, or other conditions that may adversely affect it, the ingredient, container, or closure shall be retested or reexamined to ensure that it still meets the manufacturer's specifications.

(g) Manufacturers shall make and retain records, in accordance with § 106.100(f)(6), on the ingredients, containers, and closures used in the manufacture of infant formula.

§ 106.50 Controls to prevent adulteration during manufacturing.

(a)(1) Manufacturers shall prepare and follow a written master manufacturing order that establishes controls and procedures for the production of an infant formula.

(2) The manufacturer shall make and retain records, in accordance with § 106.100(e), that include complete information relating to the production and control of the batch. An individual qualified by training or experience shall conduct an investigation of any

deviations from the master manufacturing order and any corrective actions taken.

(3) Changes made to the master manufacturing order shall be drafted, reviewed, and approved by a responsible official and include an evaluation of the effect of the change on the nutrient content and the suitability of the formula for infants.

(b) The manufacturer shall establish controls to ensure that each raw or in-process ingredient required by the master manufacturing order is examined by one person and checked by a second person or system. This checking will ensure that the correct ingredient is added during the manufacturing process, that the ingredient has been released for use in infant formula, and that the correct weight or measure of the ingredient is added to the batch.

(c) The manufacturer shall identify the contents, including the processing stage and the lot or batch number of a batch of infant formula, of all compounding and storage containers, processing lines, and major equipment used during the production of a batch of an infant formula.

(d) The manufacturer shall establish controls to ensure that the nutrient levels required by § 107.100 of this chapter are maintained in the formula, and that the formula is not contaminated with microorganisms or other contaminants. Such controls shall include but not be limited to:

(1) The mixing time; the speed, temperature, and flow rate of product; and other critical parameters necessary to ensure the addition of required ingredients to, and the homogeneity of, the formula;

(2) The spray-drying process for powdered infant formula, including the filtering of the intake air before heating, to prevent microbial and other contamination;

(3) The removal of air from the finished product to ensure that nutrient deterioration does not occur;

(4) Ensuring that each container of finished product is properly sealed. Such controls shall involve use of established procedures, specifications, and intervals of examination that are designed by qualified individuals and are sufficient to:

(i) Detect visible closure or seal defects, and

(ii) Determine closure strength through destructive testing. Manufacturers of liquid infant formulas, which are thermally processed low-acid foods packaged in hermetically sealed containers, shall perform such closure integrity testing in accordance with § 113.60(a) of this chapter.

(e) The manufacturer shall establish controls that ensure that the equipment used at points where control is deemed necessary to prevent adulteration is monitored, so that personnel will be alerted to malfunctions.

(f) The manufacturer shall establish controls that ensure that rejected in-process materials:

(1) Are clearly identified as having been rejected for use in an infant formula;

(2) Are controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable;

(3) Meet the appropriate specifications, if reprocessed, before being released for use in infant formula.

§ 106.55 Controls to prevent adulteration from microorganisms.

(a) Manufacturers of liquid infant formula shall comply with the procedures specified in part 113 of this chapter for liquid infant formula.

(b) Manufacturers of powdered infant formula shall test representative samples of every batch of the formula at the final product stage, before distribution, to ensure that the infant formula meets the microbiological quality standards listed in paragraph (c) of this section.

(c) Any powdered infant formula that contains any microorganism that exceeds the M value listed for that microorganism in Table 1 of this section will be deemed to be adulterated under sections 402 and 412 of the Federal Food, Drug, and Cosmetic Act (the act). FDA will determine compliance with the M values listed below using the *Bacteriological Analytical Manual* (BAM), 8th ed. (1995), published by the AOAC International Association of Official Analytical Chemists, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Association of Official Analytical Chemists, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or may be examined at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

Microorganism	M value[1]
Aerobic Plate Count (APC).	10,000 CFU/gram (g).[2]
Coliforms[3]	3.05 MPN/g.[4,5]
Fecal coliforms[6]	3.05 MPN/g.
Salmonella	0.[7]
Listeria monocytogenes.	0.[7]
Staphylococcus aureus.	3.05 MPN/g.
Bacillus cereus[8]	100 MPN/g or CFU/g.

[1] The M value is the maximum allowable number of microorganisms present in 1 g of dry infant formula.

[2] CFU/g, colony forming units per g.

[3] M values for coliforms greater than 3.05 are not violative if testing for fecal coliforms results in an M value equal to or less than 3.05.

[4] MPN/g, most probable number per g.

[5] The MPN value of 3.05 in this table is derived from the tables of calculated MPN values that appear in the 8th ed. of the BAM when using an inoculation series of 0.1, 0.01, and 0.001g (or ml) of the infant formula sample.

[6] No testing for fecal coliforms is required when the M value for coliforms is less than or equal to 3.05.

[7] None detected.

[8] *B. cereus* testing must be performed only if the APC exceeds 100 CFU/g.

(d) Manufacturers shall make and retain records, in accordance with § 106.100(e)(5)(ii) and (f)(7), on the testing of infant formulas for microorganisms.

§ 106.60 Controls to prevent adulteration during packaging and labeling of infant formula.

(a) Manufacturers shall examine packaged and labeled infant formula during finishing operations to ensure that containers and packages in the lot have the correct label, the correct use-by date, and the correct code established under § 106.80.

(b) Labels shall be designed, printed, and applied so that the labels remain legible and attached during the conditions of processing, storage, handling, distribution, and use.

(c) All infant formula held in a single package shall be the same product bearing the same code, established under § 106.80. Packaging used to hold multiple containers of infant formula shall be labeled with the product name, the name of the manufacturer or shipper, and the code.

§ 106.70 Controls on the release of finished infant formula.

(a) The manufacturer shall hold, or maintain under its control, each batch of infant formula until it determines that the batch meets all of its specifications, including those adopted to meet the requirements of § 106.55 on microbiological contamination and § 106.91(a) on quality control procedures, and releases the batch for distribution.

(b) Each batch of infant formula that fails to meet the manufacturer's specifications shall be rejected. Although the batch may be reprocessed, any batch of infant formula that is reprocessed shall be shown to meet the