(5) Solids or an appropriate nutrient to confirm proper dilution when final dilution is made after performance of the analyses in paragraph (b) (1) through (4) of this section.

§ 106.30 Finished product evaluation.

(a) The manufacturer shall establish criteria for sampling and testing to ensure that each batch of infant formula meets the nutrient requirements of section 412(g) of the act or of regulations promulgated under section 412(a)(2) of the act before release of product for commercial or charitable distribution.

(b)(1) *Immediate analysis.* Before release of product for commercial or charitable distribution, the manufacturer shall analyze representative samples of each batch of finished product for:

(i) Specific nutrient(s) to assess process degradation; and

(ii) All nutrients not previously analyzed for by the manufacturers, unless each in-process batch is analyzed for nutrients as specified in § 106.25(b) and the ingredients are analyzed as specified in § 106.20(b). No analyses are needed for linoleic acid, vitamin D, vitamin K, choline, inositol, and biotin; and for nutrients that are added as a part of a nutrient premix analyzed by the manufacturer or having a supplier's guarantee or certification and for which an indicator nutrient(s) was analyzed by the manufacturer.

(2) *Periodic analysis.* The manufacturer shall sample at least one newly processed finished product batch every 3 months and shall analyze representative samples for all nutrients except those that the manufacturers measured in the immediate analysis of that product batch.

(3) *Stability analysis.* Using representative samples collected from finished product batches, the manufacturer shall conduct stability analysis for selected nutrients with sufficient frequency to substantiate the maintenance of nutrient content throughout the shelf life of the product.

(c) The manufacturer shall evaluate new formulations and the effect of changes in ingredients or processing conditions that could affect the level of nutrients by means of a testing program designed to confirm uniformity of batches and to determine the effects of such changes. The following shall apply:

(1) A minor change is a minor reduction in nutrient levels, a minor increase in levels of nutrients that are subject to maximum limits established under section 412(g) of the act or in regulations established under section 412(a)(2) of the act, or any other change where experience or theory would not predict a possible significant adverse impact on nutrient levels or nutrient availability. After a minor change the manufacturer shall analyze representative samples for all nutrients so changed and those possibly affected by the change.

(2) A major change is 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 availability of nutrients. After a major change the manufacturer shall analyze representative samples for osmolality, all nutrients, and the biological quality of the protein. A protein biological quality analysis is not necessary for a formulation change that is not expected to have an adverse effect on the biological quality of the protein. Vitamin D shall be determined by the rat bioassay method as prescribed in ''Official Methods of Analysis of the Association of Official Analytical Chemists'' (AOAC), 13th Ed. (1980), sections 43.195–43.208, ''Vitamin D (30)—Official Final Action,'' which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2504, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. Before release of the product for commercial or charitable distribution, the manufacturer shall have completed all appropriate analyses except that shipment of the product need not be delayed until results of the vitamin D bioassay and, if required, a protein biological quality bioassay are complete, provided such bioassays have been initiated, and if another analysis for the vitamin D has been run and the protein content has

been determined by a suitable method. The biological quality of the protein shall be determined by an appropriate modification of the AOAC bioassay method of analysis. The manufacturer shall analyze additional samples from the same batch for vitamin D, by any suitable method, and for the biological quality of the protein. The manufacturer shall perform such analyses at least annually for a period not to exceed the expected shelf life of the product.

(d) A simple adjustment in the level of an ingredient to accommodate inconsistencies in processing is considered to be neither a minor nor a major change.

[47 FR 17025, Apr. 20, 1982, as amended at 54 FR 24891, June 12, 1989; 63 FR 14035, Mar. 24, 1998]

§ 106.90 Coding.

The manufacturer shall code all infant formulas in conformity with the coding requirements that are applicable to thermally processed low-acid foods packaged in hermetically sealed containers as prescribed in § 113.60(c).

Subpart C—Records and Reports

§ 106.100 Records.

(a) Every manufacturer of infant formula shall maintain the records specified in this regulation in order to permit the Food and Drug Administration to determine whether each manufacturer is in compliance with section 412 of the Federal Food, Drug, and Cosmetic Act (the act).

(b) The manufacturer shall maintain all records that pertain to food-packaging materials subject to § 174.5 of this chapter and that bear on whether such materials would cause an infant formula to be adulterated within the meaning of section 402(a)(2)(C) of the act.

(c) The manufacturer shall maintain all records that pertain to nutrient premix testing that it generates or receives. Such records shall include, but are not limited to:

(1) Any results of testing conducted to ensure that each nutrient premix is in compliance with the premix certificate and guarantee and specifications that have been provided to the manufacturer by the premix supplier, including tests conducted when nutrients exceed their expiration date or shelf life (retest date).

(2) All certificates and guarantees given by premix suppliers concerning the nutrients required by section 412(i) of the act and § 107.100 of this chapter.

(d) The premix supplier shall maintain the results of all testing conducted to provide all certificates and guarantees concerning nutrient premixes for infant formulas. Such records shall include but are not limited to:

(1) The results of tests conducted to determine the purity of each nutrient required by section 412(i) of the act or § 107.100 of this chapter and any other nutrient listed in the certificate and guarantee;

(2) The weight of each nutrient added;

(3) The results of any quantitative tests conducted to determine the amount of each nutrient certified or guaranteed; and

(4) The results of any quantitative tests conducted to identify the nutrient levels present when nutrient premixes exceed their expiration date or shelf life (retest date).

(e) The manufacturer shall maintain all records necessary to ensure proper nutrient quality control in the manufacture of infant formula products. Such records shall include the results of any testing conducted to verify that each nutrient required by section 412(i) of the act or § 107.100 of this chapter is present in each batch of infant formula at the appropriate concentration. This requirement pertains to ingredients, in process batch and finished product from the time of manufacture through its expiration date.

(f) The manufacturer shall maintain all records necessary to ensure required nutrient content at the final product stage. Such records shall include, but are not limited to, testing results for vitamins A, B_1 (thiamine), C, and E for each batch of infant formula. ''Final product stage'' means the point in the manufacturing process prior to distribution at which the infant formula is homogenous and not subject to further degradation from the manufacturing process.