(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 en-
sure that each batch of infant formula
meets the nutrient requirements of
section 412(g) of the act or of regula-
tions promulgated under section
412(a)(2) of the act before release of
product for commercial or charitable
distribution.

(b) (1) Immediate analysis. Before re-
lease of product for commercial or
charitable distribution, the manufac-
turer shall analyze representative sam-
ples of each batch of finished product
for:

(i) Specific nutrient(s) to assess proc-
cess degradation; and

(ii) All nutrients not previously ana-
lyzed for by the manufacturers, unless
each in-process batch is analyzed for
nutrients that are added as a part of a
nutrient premix analyzed by the manu-
facturer or having a supplier’s guar-
antee or certification and for which an
indicator nutrient(s) was analyzed by
the manufacturer.

(2) Periodic analysis. The manufac-
turer shall sample at least one newly
processed finished product batch every
3 months and shall analyze representa-
tive samples for all nutrients except
those that the manufacturers measured
in the immediate analysis of that prod-
uct batch.

(3) Stability analysis. Using represent-
ative samples collected from finished
product batches, the manufacturer
shall conduct stability analysis for se-
lected nutrients with sufficient fre-
quency to substantiate the mainte-
ance 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 pro-
gram 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 reduc-
tion in nutrient levels, a minor in-
crease 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 representa-
tive samples for all nutrients so
changed and those possibly affected by
the change.

(2) A major change is any new formu-
lation, or any change of ingredients or
processes where experience or theory
would predict a possible significant ad-
verse 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 qual-
ty of the protein. A protein biological
quality analysis is not necessary for a
formulation change that is not ex-
pected to have an adverse effect on the
biological quality of the protein. Vita-
min D shall be determined by the rat
bioassay method as prescribed in “Of-

cial Methods of Analysis of the Asso-
ciation of Official Analytical Chem-
ists” (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 AOAC INTERNATIONAL, 481 North
Frederick Ave., suite 500, Gaithersburg,
MD 20877, or available for inspection at
the National Archives and Records Ad-
ministration (NARA). For information
on the availability of this material at
NARA, call 202–741–6030, or go to: http://
www.archives.gov/federal_register/
code_of_federal_regulations/ibr_locations.html. Before release of the
product for commercial or charitable
distribution, the manufacturer shall
have completed all appropriate anal-
yses except that shipment of the prod-
uct need not be delayed until results of

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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.

§ 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, (thiamine),