Sec. 412. [21 U.S.C. 350a] of the Public Health Service Act

(a) An infant formula, including an infant formula powder, shall be deemed to be adulterated if—

(1) such infant formula does not provide nutrients as required by subsection (i),

(2) such infant formula does not meet the quality factor requirements prescribed by the Secretary under subsection (b)(1), or

(3) the processing of such infant formula is not in compliance with the good manufacturing practices and the quality control procedures prescribed by the Secretary under subsection (b)(2).

(b)(1) The Secretary shall by regulation establish requirements for quality factors for infant formulas to the extent possible consistent with current scientific knowledge, including quality factor requirements for the nutrients required by subsection (i).

(2)(A) The Secretary shall by regulation establish good manufacturing practices for infant formulas, including quality control procedures that the Secretary determines are necessary to assure that an infant formula provides nutrients in accordance with this subsection and subsection (i) and is manufactured in a manner designed to prevent adulteration of the infant formula.

(B) The good manufacturing practices and quality control procedures prescribed by the Secretary under subparagraph (A) shall include requirements for—

(i) the testing, in accordance with paragraph (3) and by the manufacturer of an infant formula or an agent of such manufacturer, of each batch of infant formula for each nutrient required by subsection (i) before the distribution of such batch,

(ii) regularly scheduled testing, by the manufacturer of an infant formula or an agent of such manufacturer, of samples of infant formulas during the shelf life of such formulas to ensure that such formulas are in compliance with this section,

(iii) in-process controls including, where necessary, testing required by good manufacturing practices designed to prevent adulteration of each batch of infant formula, and

(iv) the conduct by the manufacturer of an infant formula or an agent of such manufacturer of regularly scheduled audits to determine that such manufacturer has complied with the regulations prescribed under subparagraph (A).

In prescribing requirements for audits under clause (iv), the Secretary shall provide that such audits be conducted by appropriately trained individuals who do not have any direct responsibility for the manufacture or production of infant formula.

(3)(A) At the final product stage, each batch of infant formula shall be tested for vitamin A, vitamin B1, vitamin C, and vitamin E to ensure that such infant formula is in compliance with the requirements of this subsection and subsection (i) relating to such vitamins.

(B) Each nutrient premix used in the manufacture of an infant formula shall be tested for each relied upon nutrient required by subsection (i) which is contained in such premix to ensure that such premix is in compliance with its specifications or certifications by a premix supplier.

(C) During the manufacturing process or at the final product stage and before distribution of an infant formula, an infant formula shall be tested for all nutrients required to be included in such formula by subsection (i) for which testing has not been conducted pursuant to subparagraph (A) or (B). Testing under this subparagraph shall be conducted to—

(i) ensure that each batch of such infant formula is in compliance with the requirements of subsection (i) relating to such nutrients, and

(ii) confirm that nutrients contained in any nutrient premix used in such infant formula are present in each batch of such infant formula in the proper concentration.

(D) If the Secretary adds a nutrient to the list of nutrients in the table in subsection (i), the Secretary shall by regulation require that the manufacturer of an infant formula test each batch of such formula for such new nutrient in accordance with subparagraph (A), (B), or (C).

(E) For purposes of this paragraph, the term "final product stage" means the point in the manufacturing process, before distribution of an infant formula, at which an infant formula is homogenous and is not subject to further degradation.

(4)(A) The Secretary shall by regulation establish requirements respecting the retention of records. Such requirements shall provide for—

(i) the retention of all records necessary to demonstrate compliance with the good manufacturing practices and quality control procedures prescribed by the Secretary under paragraph (2), including records containing the results of all testing required under paragraph (2)(B),

(ii) the retention of all certifications or guarantees of analysis by premix suppliers,

(iii) the retention by a premix supplier of all records necessary to confirm the accuracy of all premix certifications and guarantees of analysis,

(iv) the retention of—

(I) all records pertaining to the microbiological quality and purity of raw materials used in infant formula powder and in finished infant formula, and

(II) all records pertaining to food packaging materials which show that such materials do not cause an infant formula to be adulterated within the meaning of section 402(a)(2)(C),

(v) the retention of all records of the results of regularly scheduled audits conducted pursuant to the requirements prescribed by the Secretary under paragraph (2)(B)(iv), and

(vi) the retention of all complaints and the maintenance of files with respect to, and the review of, complaints concerning infant formulas which may reveal the possible existence of a hazard to health.

(B)(i) Records required under subparagraph (A) with respect to an infant formula shall be retained for at least one year after the expiration of the shelf life of such infant formula. Except as provided in clause (ii), such records shall be made available to the Secretary for review and duplication upon request of the Secretary.

(ii) A manufacturer need only provide written assurances to the Secretary that the regularly scheduled audits required by paragraph (2)(B)(iv) are being conducted by the manufacturer, and

need not make available to the Secretary the actual written reports of such audits.

(c)(1) No person shall introduce or deliver for introduction into interstate commerce any new infant formula unless—

(A) such person has, before introducing such new infant formula, or delivering such new infant formula for introduction, into interstate commerce, registered with the Secretary the name of such person, the place of business of such person, and all establishments at which such person intends to manufacture such new infant formula, and

(B) such person has at least 90 days before marketing such new infant formula, made the submission to the Secretary required by subsection (d)(1).

(2) For purposes of paragraph (1), the term "new infant formula" includes—

(A) an infant formula manufactured by a person which has not previously manufactured an infant formula, and

(B) an infant formula manufactured by a person which 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.

For purposes of this paragraph, the term "major change" has the meaning given to such term in section 106.30(c)(2) of title 21, Code of Federal Regulations (as in effect on August 1, 1986), and guidelines issued thereunder.

(d)(1) A person shall, with respect to any infant formula subject to subsection (c), make a submission to the Secretary which shall include—

(A) the quantitative formulation of the infant formula,

(B) a description of any reformulation of the formula or change in processing of the infant formula,

(C) assurances that the infant formula will not be marketed unless it meets the requirements of subsections (b)(1) and (i), as demonstrated by the testing required under subsection (b)(3), and

(D) assurances that the processing of the infant formula complies with subsection (b)(2).

(2) After the first production of an infant formula subject to subsection (c), and before the introduction into interstate commerce of such formula, the manufacturer of such formula shall submit to the Secretary, in such form as may be prescribed by the Secretary, a written verification which summarizes test results and records demonstrating that such formula complies with the requirements of subsections (b)(1), (b)(2)(A), (b)(2)(B)(i), (b)(2)(B)(iii), (b)(3)(A), (b)(3)(C), and (i).

(3) If the manufacturer of an infant formula for commercial or charitable distribution for human consumption determines that a change in the formulation of the formula or a change in the processing of the formula may affect whether the formula is adulterated under subsection (a), the manufacturer shall, before the first processing of such formula, make the submission to the Secretary required by paragraph (1).

(4) The Secretary shall provide a response to a submission under this subsection not later than 45 days after receiving such submission.

(e)(1) If the manufacturer of an infant formula has knowledge which reasonably supports the conclusion that an infant formula which has been processed by the manufacturer and which has left an establishment subject to the control of the manufacturer—

(A) may not provide the nutrients required by subsection (i), or

(B) may be otherwise adulterated or misbranded,

the manufacturer shall ~~promptly~~ notify the Secretary of such knowledge*, within 24 hours of acquiring such knowledge*. If the Secretary determines that ~~the infant formula~~ *an infant formula* presents a risk to human health, the manufacturer shall immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary.

(2) If the result of any testing of a sample from any production aggregate of finished infant formula product is confirmed as a positive analytical result for any microorganism for which finished product testing is required under section 106.55(e) of title 21, Code of Federal Regulations (or any successor regulation), the manufacturer shall—

(A) within 24 hours of acquiring a confirmed positive analytical result, notify the Secretary of such knowledge, regardless of whether such product has left an establishment subject to the control of the manufacturer;

(B) promptly consult with the Secretary for proper isolation of the affected product, and, as the Secretary may require, cease distribution and properly dispose of the affected product; and

(C) promptly provide to the Secretary results and isolates from a positive sample of such product.

(3) Not later than 72 hours after receipt by the Secretary of a notification under paragraph (2)(A), the Secretary shall respond to the manufacturer of the infant formula to begin discussions regarding investigation and corrective action, and, as appropriate, share the findings of the Secretary with the manufacturer.

(4) Not later than 90 days after receipt of a notification under paragraph (1) or (2), the Secretary shall confirm, including through the collection of documentation, that the manufacturer submitting the notification performed, or is performing, an appropriate investigation and corrective action, if applicable. The Secretary shall consider, as part of the review of the root cause investigation, the analytical method used to conduct laboratory testing and, as appropriate, the potential for cross contamination of the sample by handling and testing. The manufacturer shall make such documentation available to the Secretary electronically or by other means, if requested by the Secretary.

(~~2~~ *5*) For purposes of ~~paragraph (1)~~ *paragraphs (1) and (2)*, the term "knowledge" as applied to a manufacturer means (A) the actual knowledge that the manufacturer had, or (B) the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care.

(f)(1) If a recall of infant formula is begun by a manufacturer, the recall shall be carried out in accordance with such requirements as the Secretary shall prescribe under paragraph (2) and—

(A) the Secretary shall, not later than the 15th day after the beginning of such recall and at least once every 15 days thereafter until the recall is terminated, review the actions taken under the recall to determine whether the recall meets the requirements prescribed under paragraph (2), and

(B) the manufacturer shall, not later than the 14th day after the beginning of such recall and at least once every 14 days thereafter until the recall is terminated, report to the Secretary the actions taken to implement the recall.

(2) The Secretary shall by regulation prescribe the scope and extent of recalls of infant formulas necessary and appropriate for the degree of risks to human health presented by the formula subject to the recall.

(3) The Secretary shall by regulation require each manufacturer of an infant formula who begins a recall of such formula because of a risk to human health to request each retail establishment at which such formula is sold or available for sale to post at the point of purchase of such formula a notice of such recall at such establishment for such time that the Secretary determines necessary to inform the public of such recall.

(g)(1) Each manufacturer of an infant formula shall make and retain such records respecting the distribution of the infant formula through any establishment owned or operated by such manufacturer as may be necessary to effect and monitor recalls of the formula. Such records shall be retained for at least one year after the expiration of the shelf life of the infant formula.

(2) To the extent that the Secretary determines that records are not being made or maintained in accordance with paragraph (1), the Secretary may by regulation prescribe the records required to be made under paragraph (1) and requirements respecting the retention of such records under such paragraph. Such regulations shall take effect on such date as the Secretary prescribes but not sooner than the 180th day after the date such regulations are promulgated. Such regulations shall apply only with respect to distributions of infant formulas made after such effective date.

(h)(1) Any infant formula which is represented and labeled for use by an infant—

(A) who has an inborn error of metabolism or a low birth weight, or

(B) who otherwise has an unusual medical or dietary problem,

is exempt from the requirements of subsections (a), (b), and (c). The manufacturer of an infant formula exempt under this paragraph shall, in the case of the exempt formula, be required to provide the notice required by subsection (e)(1) only with respect to adulteration or misbranding described in subsection (e)(1)(B) and to comply with the regulations prescribed by the Secretary under paragraph (2).

(2) The Secretary may by regulation establish terms and conditions for the exemption of an infant formula from the requirements of subsections (a), (b), and (c). An exemption of an infant formula under paragraph (1) may be withdrawn by the Secretary if such formula is not in compliance with applicable terms and conditions prescribed under this paragraph.

(i)(1) An infant formula shall contain nutrients in accordance with the table set out in this subsection, which shall be reviewed by the Secretary every 4 years as appropriate. In reviewing

such table, the Secretary shall consider any new scientific data or information related to infant formula nutrients, including international infant formula standards. The Secretary may revise the list of nutrients and the required level for any nutrient required by the table.

(2) The Secretary may by regulation—

(A) revise the list of nutrients in the table in this subsection, and
(B) revise the required level for any nutrient required by the table. […]

(j) Premarket Submissions To Address Shortages.—

(1) In general.—The Secretary shall waive the 90-day premarket submission requirement under subsection (c) and apply a 30-day premarket submission requirement for any person who intends to introduce or deliver for introduction into interstate commerce any new infant formula.

(2) Effective period.—The waiver authority under this subsection shall remain in effect—

(A) for 90 days beginning on the date that the Secretary distributes information under section 424(a)(2) with respect to a shortage of infant formula; or

(B) such longer period as the Secretary determines appropriate, to prevent or mitigate a shortage of infant formula.

(k) Congressional Notification of Recall.—

(1) In general.—Not later than 24 hours after the initiation of a recall of infant formula as described in subsection (e), the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a notification of such recall.

(2) Contents.—A notification under paragraph (1) shall include the following:

(A) If the recall is required by the Food and Drug Administration, a summary of the information supporting a determination that the adulterated or misbranded infant formula presents a risk to human health.

(B) If the recall is voluntarily initiated by the manufacturer, a summary of the information provided to the Food and Drug Administration by the manufacturer regarding infant formula that has left the control of the manufacturer that may be adulterated or misbranded.

(C) Specification of when the Food and Drug Administration was first made aware of the instance or circumstances surrounding the recall.

(D) An initial estimate of the disruption in domestic production that may result from the recall.

(l) Annual Report to Congress.—

(1) In general.—Not later than March 30 of each year, the Secretary shall submit a report to Congress containing, with respect to the preceding calendar year, the following information:

(A) The number of submissions received by the Secretary under subsection (d).

(B) The number of such submissions that included any new ingredients that were not included in any infant formula already on the market.

(C) The number of inspections conducted by the Food and Drug Administration or any agent thereof to evaluate compliance with the requirements for infant formulas under subsection (b).

(D) The time between any inspection referred to in subparagraph (C) and any necessary reinspection to evaluate compliance with the requirements for infant formulas under subsection (b).

(E) A breakdown of the information described in subparagraphs (A) through (D) between foreign and domestic manufacturers and facilities.

(2) Confidentiality.—The Secretary shall ensure that the reports under paragraph (1) do not include any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

(m) Waiver of Requirements for Importation of Specialty Infant Formula.—

(1) In general.—The Secretary may, during a shortage of specialty infant formula as determined by the Secretary, waive any requirement under this Act applicable to facilitate the importation of specialty infant formula. Such a waiver may be applicable to—

(A) the importation of specialty infant formula from any country that is determined by the Secretary to be implementing and enforcing requirements for infant formula that provide a similar assurance of safety and nutritional adequacy as the requirements of this Act; or

(B) the distribution and sale of such imported specialty infant formula.

(2) Rule of construction.—Nothing in paragraph (1) shall be construed to limit the authority of the Secretary to require a recall of, or otherwise impose restrictions and requirements under this Act with respect to, specialty infant formula that is subject to a waiver under paragraph (1).

(3) Definition of specialty infant formula.—In this subsection, the term "specialty infant formula" means infant formula described in subsection (h)(1).

(n) REPORTING TO IMPROVE THE SAFETY AND SUPPLY OF INFANT FORMULA.—

(1) PROGRESS REPORT.—Not later than 180 days after the date of enactment of the Protect Infant Formula from Contamination Act, the Secretary shall issue a progress report on implementation of the recommendations to improve the safety and supply of infant formula contained in the report titled, 'Immediate National Strategy to Increase the Resiliency of the U.S. Infant Formula Market', issued by the Food and Drug Administration in March 2023. Such progress report shall include additional authorities or resources that the Secretary may require for purposes of improving the safety and supply of infant formula.

(2) QUARTERLY REPORTS ON SUPPLY CHAIN.—Not later than 270 days after the date of enactment of the Protect Infant Formula from Contamination Act, and not less frequently than quarterly for the 5-year period thereafter, the Secretary shall submit a report on the most current, critical supply chain data for infant formula, including in-stock rates, to—

(A) the Committee on Health, Education, Labor, and Pensions; the Committee on Agriculture, Nutrition, and Forestry; and the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies of the Committee on Appropriations of the Senate; and

(B) the Committee on Energy and Commerce; the Committee on Agriculture; and the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies of the Committee on Appropriations of the House of Representatives.

(3) CONSULTATION.—The Secretary, in accordance with the National Strategy set forth in the report described in paragraph (1), shall engage with the Department of Agriculture and other relevant agencies of the Federal Government regarding ongoing efforts to address immediate formula needs and build long-term resiliency into the infant formula market.

(4) ANNUAL REPORTS ON ADEQUACY OF SUPPLY.—Not later than 270 days after the date of enactment of the Protect Infant Formula from Contamination Act, and not less frequently than annually for the 5-year period thereafter, the Secretary shall—

(A) engage with infant formula manufacturers to determine evidence-based practices that can be implemented to maximize infant formula supply and infant safety, including the value of high frequency testing in identifying contamination events and bracketing potentially contaminated product, the impact of corrective action on contamination events, and evidence-based recommendations for enhancing infant formula supply and safety; and

(B) submit a report to the committees described in subparagraphs (A) and (B) of paragraph (2) that identifies the modifications to manufacturer practices and actions described in subparagraph (A), if any, that could be implemented to improve infant formula supply and safety.".