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(Original Signature of Member)

119TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act to require notification to the Food and Drug Administration prior to use of substances as generally recognized as safe, reassessment of the safety of certain substances marketed as generally recognized as safe, provide resources for reviews and reassessments, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. PALLONE introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require notification to the Food and Drug Administration prior to use of substances as generally recognized as safe, reassessment of the safety of certain substances marketed as generally recognized as safe, provide resources for reviews and reassessments, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Grocery Reform And Safety Act'' or the ''GRAS Act''.

SEC. 2. REMOVAL OF GRAS EXEMPTION FROM FOOD ADDITIVE DEFINITION.

(a) IN GENERAL.—Section 201(s) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(s)) is amended—

(1) by redesignating subparagraphs (1) through (6) as clauses (A) through (G), respectively;

(2) by striking ''The term 'food additive' '' and inserting ''(1) The term 'food additive' '';

(3) by striking '', if such substance is'' and all that follows through ''of its intended use;'' and inserting '', including a substance that is generally recognized as safe,''; and

(4) by adding at the end the following:

''(2) The term 'generally recognized as safe' means, with respect to a substance used in food as described in subparagraph (1), that such substance is generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on

common use in food) to be safe under the conditions of its intended use.''.

(b) CONFORMING AMENDMENT.—Section 408(k)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.346a(k)(2)) is amended by striking ''section 201(s)(4)'' and inserting ''section 201(s)(1)(D)''.

SEC. 3. GRAS NOTIFICATIONS.

Section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348) is amended—

(1) in subsection (a)—

(A) in paragraph (2), by striking the ''or'' at the end;

(B) in paragraph (3), by striking the period at the end and inserting ''; or''; and

(C) by adding at the end the following:

''(4) the food additive is generally recognized as safe, and the procedural requirements of subsection (l) have been met with respect to the food additive.''; and

(2) by adding at the end the following:

''(l) NOTICES REGARDING USE OF GRAS SUBSTANCES.—

''(1) IN GENERAL.—Any person that manufactures, introduces, delivers for introduction, or receives a food substance in interstate commerce that

is intending to treat such food substance as generally recognized as safe (in this subsection referred to as 'GRAS') shall, with respect to any new use of such substance or use of a food substance that was not marketed for use in foods in the United States before the date of enactment of this subsection, submit to the Secretary a notice prescribing the conditions under which such person determined such substance is GRAS.

''(2) REQUIRED INFORMATION.—A notice submitted under paragraph (1) with respect to a food substance shall include publicly available supporting data and information sufficient to demonstrate the identity and composition, the manufacturing process, the intended effect, and the safety of the food substance, used as the basis of the GRAS determination, including full reports of investigations made with respect to the safety for use of such substance, including—

''(A) information as to the methods and controls used in conducting such investigations;

''(B) information on the cumulative effects of such substance;

''(C) information on hazard, dose response, and exposure;

''(D) information on the application of adequately protective safety factors to ensure an appropriate margin of safety to take into account uncertainties in hazard identification, dose response, exposure, and sensitivities;

''(E) information demonstrating the analysis that the weight of the evidence shows that such substance has not been found to be carcinogenic;

''(F) information demonstrating the analysis that the weight of the evidence shows that such substance has not been found to induce reproductive toxicity or developmental toxicity in humans or animals, including through an endocrine mode of action; and

''(G) such other information that forms the recognition of safety as the Secretary may publicly specify.

''(3) FORM OF NOTICE.—A notice submitted under paragraph (1) with respect to a food substance shall be submitted in such form and manner as specified in subpart E of part 170 of title 21, Code of Federal Regulations (or successor regulations).

''(4) STATEMENT NOT TO OBJECT TO USE.—A person may use a substance subject to a notice under paragraph (1) only if the Secretary has issued a written statement to not object to the determination that the substance is GRAS under the conditions prescribed in the notice.

''(5) STATEMENT TO OBJECT.—The Secretary shall issue a written statement objecting to use of a substance subject to a notice under paragraph (1) if the Secretary determines that—

''(A) the notice does not contain the supporting data and information described in paragraph (2);

''(B) with respect to any such supporting data and information that was provided by an expert, such expert appears to have a conflict of interest, as determined pursuant to guidance issued by the Secretary; or

''(C) such supporting data and information does not adequately support a determination that the substance is GRAS under the conditions prescribed in the notice.

''(6) DETERMINATION TIMELINE.—

''(A) IN GENERAL.—The Secretary shall—

''(i) not later than 180 days after the acceptance of a notice under paragraph (1), issue a written statement under paragraph (4) or (5); or

''(ii) provide written notice to extend the 180-day period described in subparagraph (A) for one additional 90-day period, as specified in regulations.

''(B) CORRECTIONS.—The timeline set forth in subparagraph (A) shall not be construed to limit the authority of the Secretary to correct a statement of the Secretary to not object to the determination that the substance is GRAS if new evidence is subsequently presented or discovered.

''(7) PUBLIC AVAILABILITY AND COMMENT.—The Secretary shall—

''(A) upon acceptance of a notice under paragraph (1)—

''(i) make such notice, and the supporting data and information described in paragraph (2), publicly available in a single location on the website of the Food and Drug Administration; and

''(ii) provide an opportunity for public comment for a period of not less than 60 days; and

''(B) upon close of the comment period, make any written statement issued under paragraph (4) or (5) publicly available in the same location.

''(8) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be necessary to carry out this subsection.''.

SEC. 4. REASSESSMENTS.

Section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348), as amended by section 3, is further amended by adding at the end the following:

''(m) REASSESSMENTS.—

''(1) IN GENERAL.—Not later than 3 years after the date of enactment of this subsection, and at least every 3 years thereafter, the Secretary shall systematically reassess the safety (including the safety of conditions of use), within the meaning of section 409, of at least 10 of the following substances (or classes thereof):

''(A) Food additives marketed pursuant to an order under subsection (c).

''(B) Any substance which was, before the date of the enactment of this subsection, considered generally recognized as safe.

''(C) Color additives.

''(D) Prior-sanctioned substances (as described in subparagraph (D) of section 201(s)(1)).

''(E) Food contact substances.

''(2) SAFETY EVALUATIONS.—In conducting the reassessments under this subsection, the Secretary may require any person that manufactures, introduces, delivers for introduction, or receives a food substance described in paragraph (1) in interstate commerce to conduct, and submit to the Secretary, safety evaluations of such substance. Such a safety evaluation shall include, with respect to such substance, updated information on—

''(A) estimates of dietary exposure among the United States population;

''(B) the cumulative effects of such substance;

''(C) hazard, dose response, and exposure;

''(D) the application of adequately protective safety factors to ensure an appropriate margin of safety to take into account uncertain-

ties in hazard identification, dose response, exposure, and sensitivities;

''(E) whether the weight of the evidence shows that such substance has not been found to be carcinogenic;

''(F) whether the weight of the evidence shows that such substance has not been found to induce reproductive toxicity or developmental toxicity in humans or animals, including through an endocrine mode of action; and

''(G) such other information as the Secretary may specify in regulation.

''(3) REVOKING STATEMENT TO NOT OBJECT.—If the Secretary determines, with respect to a substance described in paragraph (1)(B), based on information received under paragraph (2) and publicly available information, that a concern about the safety of the substance, or the intended use of the substance, exists, the Secretary—

''(A) may revoke a written statement previously issued by the Secretary to not object to a determination that the substance is generally recognized as safe; and

''(B) shall post such revocation in the location on the website of the Food and Drug Administration referred to in subsection (l)(7).

''(4) NOTICES OF SUBSTANCES MARKETED AS GRAS.—The Secretary may require a person that manufactures, introduces, delivers for introduction, or receives a food substance described in paragraph (1) in interstate commerce that was marketed as generally recognized as safe before, on, and after the date of enactment of this subsection to submit to the Secretary a notification that such person so marketed the substance as generally recognized as safe.

''(5) CIVIL MONETARY PENALTIES.—In the case of a violation of this subsection, the Secretary shall assess a civil penalty in accordance with section 307.

''(6) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be necessary to carry out this subsection.''.

SEC. 5. DEFINITIONS.

(a) IN GENERAL.—Section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348), as amended by sections 3 and 4, is further amended by adding at the end the following:

''(n) DEFINITIONS.—In this section:

''(1) CARCINOGENIC.—The term 'carcinogenic' means, with respect to a substance, that such substance has been found—

''(A) to induce cancer when ingested by humans or animals; or

''(B) after evaluation through appropriate testing methods, by research or assessment conducted by an authoritative scientific body (such as the Environmental Protection Agency, the International Agency for Research on Cancer, or the National Toxicology Program), to induce cancer in humans or animals.

''(2) CLASS.—The term 'class', with respect to a substance, means a group of chemicals that are chemically similar or cause similar or related pharmacological effects.

''(3) CONFLICT OF INTEREST.—The term 'conflict of interest' means a personal or financial interest that could potentially compromise the professional judgment or objectivity of an individual in designing, conducting, reporting, or reviewing research or the applicability of research, potentially undermining the integrity of such research.

''(4) CUMULATIVE EFFECTS.—The term 'cumulative effects' means, with respect to a substance,

the combined health effects of all chemically or pharmacologically-related substances.

''(5) DEVELOPMENTAL TOXICITY.—The term 'developmental toxicity' means, with respect to the effect of exposure to a substance on a human or animal, an adverse effect on the development of such human or animal that results from such exposure—

''(A) to the mother prior to conception of, or during the prenatal period for, such human or animal; or

''(B) to such human or animal before the time of sexual maturity.

''(6) FOOD CONTACT SUBSTANCE.—The term 'food contact substance' means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.

''(7) NEW USE.—The term 'new use' means a use other than—

''(A) a use of a substance generally recognized as safe before, on, and after the date of enactment of this subsection;

''(B) a use of a substance treated as generally recognized as safe under subsection (l); or

''(C) a use of a prior-sanctioned substance (as described in subparagraph (D) of section 201(s)(1)).

''(8) REPRODUCTIVE TOXICITY.—The term 'reproductive toxicity' means, with respect to the effect of exposure to a substance on a human or animal, an adverse effect on the reproductive system of such human or animal, which may include alterations to reproductive system development, the endocrine system, fertility, pregnancy, pregnancy outcomes, or modifications in other functions that are dependent on the integrity of the reproductive system.''.

(b) CONFORMING AMENDMENTS.—

(1) Section 201(q)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(q)(1)(B)(ii)) is amended by striking ''section 409(h)(6)'' and inserting ''section 409(n)''.

(2) Section 409(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(h)) is amended by striking paragraph (6).

SEC. 6. FOOD ADDITIVE AND GRAS SUBSTANCE FEES.

Section 743 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–31) is amended—

(1) in subsection (a)(1)—

(A) in subparagraph (C), by striking ''and'' at the end;

(B) in subparagraph (D), by striking the period at the end and inserting a semicolon; and

(C) by adding at the end the following:

''(E) each person filing a petition or submitting a notice with respect to a food additive, for purposes of issuing regulations or reviewing notices under section 409 prescribing the conditions under which such food additive may be safely used; and

''(F) each person that manufactures, introduces, delivers for introduction, or receives a food substance in interstate commerce that is subject to a reassessment under subsection (m) of section 409, for purposes of conducting such reassessment.'';

(2) in subsection (b)—

(A) in paragraph (2)(A)—

(i) in clause (iii), by striking ''and'' at the end;

(ii) in clause (iv), by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following:

''(v) under subparagraph (E) or (F) of subsection (a)(1) for a fiscal year shall be based on the Secretary's estimate of 100 percent of the costs of the activities described in such subparagraph (E) or (F) for such year.'';

(B) in paragraph (3), by striking ''clause (i), (ii), (iii), and (iv)'' each place it appears and inserting ''clause (i), (ii), (iii), (iv), and (v)''; and

(3) in subsection (c)—

(A) in paragraph (1)—

(i) by striking ''fiscal year 2010'' and inserting ''fiscal year 2026''; and

(ii) by striking ''fiscal year 2009'' and inserting ''fiscal year 2025''; and

(B) in paragraph (3)(B), by striking ''fiscal year 2009'' and inserting ''fiscal year 2025''.