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(Original Signature of Member)

119TH CONGRESS
1ST SESSION

H. R. _____

To direct the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to establish a board to review certain designations that a substance used in food is generally recognized as safe, with respect to the intended use of such substance, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

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

A BILL

To direct the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to establish a board to review certain designations that a substance used in food is generally recognized as safe, with respect to the intended use of such substance, 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 ''GRAS Oversight and Transparency Act''.

SEC. 2. GRAS REVIEW BOARD; REVOCATION OF CERTAIN GRAS DESIGNATIONS.

(a) ESTABLISHMENT.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, (in this section referred to as the ''Secretary'') shall establish a board (in this section referred to as the ''Board'') to review the validity of covered GRAS designations.

(b) MEMBERSHIP.—

(1) IN GENERAL.—

(A) VOTING MEMBERS.—The Board shall be composed of the following voting members:

(i) The Secretary of Health and Human Services.

(ii) The Secretary of Agriculture.

(iii) Two representatives of the Human Foods Program of the Food and Drug Administration, to be appointed by the Secretary.

(iv) One representative of each of the following organizations, to be appointed by the Secretary:

(I) The Office of the Chief Counsel of the Food and Drug Administration.

(II) The Office of the Chief Scientist of the Department of Agriculture.

(III) The Office of the General Counsel of the Department of Agriculture.

(IV) The Food Safety and Inspection Service of the Department of Agriculture.

(V) The Center for Nutrition Policy and Promotion of the Department of Agriculture.

(VI) The Agricultural Research Service of the Department of Agriculture.

(VII) The Public Health and Integrated Toxicology Division of the Environmental Protection Agency.

(B) NON-VOTING MEMBERS.—The Board shall be composed of the following non-voting members, to be appointed by the Secretary:

(i) An academic expert in food toxicology.

(ii) A representative from the food manufacturing industry.

(2) CHAIRPERSON.—The Secretary shall designate a chairperson of the Board from among the voting members described in paragraph (1).

(3) TERMS.—Each voting and non-voting member of the Board appointed by the Secretary shall be appointed for a term of five years.

(4) COMPENSATION.—Each member of the Board shall serve without compensation.

(c) DUTIES.—

(1) IN GENERAL.—The Board shall carry out a review of each covered GRAS designation in accordance with the requirements of this subsection.

(2) STAGES OF REVIEW.—In carrying out the review, the Board shall—

(A) identify the scope of covered GRAS designations by soliciting the participation of food manufacturers under subsection (d);

(B) categorize each covered GRAS designation so identified into a tier 1, tier 2, or tier 3 review category, with tier 1 indicating the highest priority for review;

(C) carry out a review of the covered GRAS designations in each review category to determine the validity of each such designation; and

(D) report the results of each such review in accordance with subsection (f).

(3) NOTIFICATION RECOMMENDING REVOCATION OF GRAS DESIGNATION.—Not later than 90 days after the date on which the Board completes the review of a covered GRAS designation under paragraph (2)(C), the Board shall notify the Secretary and Congress of—

(A) a determination that the substance that is the subject of such designation has not been shown to be safe; and

(B) a recommendation that the Secretary revoke such designation under subsection (e).

(d) PARTICIPATION OF FOOD MANUFACTURERS.—

(1) IN GENERAL.—The Secretary shall require a food manufacturer to provide to the Board, not later than 90 days after the date of enactment of this Act, a notice that—

(A) identifies each covered GRAS designation attributable to such manufacturer; and

(B) contains any other such information the Board determines to be appropriate.

(2) FAILURE TO COMPLY.—If a food manufacturer does not comply with paragraph (1), the Secretary may take actions to require such compliance, including—

(A) imposing a civil penalty on such manufacturer in accordance with the amounts described in section 307(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335b(a)); or

(B) with respect to a substance subject to a covered GRAS designation attributable to such manufacturer—

(i) treating such substance as an unapproved food additive under section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348); and

(ii) deeming such substance to be unsafe under such section as appropriate.

(e) REVOCATION OF CERTAIN GRAS DESIGNATIONS.—

(1) IN GENERAL.—Upon receiving a notification under subsection (c)(3), the Secretary may, using evidence before the Secretary, revoke a covered

GRAS designation in accordance with the requirements under paragraph (2).

(2) REQUIREMENTS FOR REVOCATION.—If the Secretary decides to revoke a covered GRAS designation under paragraph (1), the Secretary shall—

(A) notify the food manufacturer that provided a notice identifying such designation under subsection (d) of such decision, including a description of the evidence used in making such decision;

(B) provide 180 days for such manufacturer to provide sufficient scientific evidence that the substance subject to such designation is shown to be safe;

(C) review such decision using any such evidence; and

(D) notify such manufacturer of the outcome of such review, including a description of how the Secretary carried out such review.

(3) COMPLIANCE WITH REVOCATION.—The Secretary shall establish procedures to ensure a manufacturer complies with a revocation of a covered GRAS designation under this subsection, including an appropriate timeline for ceasing distribution of

any substance subject to such designation and recalling such substance.

(f) REPORTS.—

(1) IN GENERAL.—The Board shall submit to the Secretary and Congress, and make publicly available on the website of the Food and Drug Administration, a report containing—

(A) information related to the review carried out under subsection (c); and

(B) any recommendation related to such review, including whether the Board made a notification under subsection (c)(3).

(2) TIMING OF REPORTS.—A report shall be submitted under paragraph (1)—

(A) with respect to a covered GRAS designation the Board categorizes into tier 1, not later than 2 years after the date of enactment of this Act;

(B) with respect to a covered GRAS designation the Board categorizes into tier 2, not later than 4 years after the date of enactment of this Act; and

(C) with respect to a covered GRAS designation the Board categorizes into tier 3, not

later than 10 years after the date of enactment of this Act.

(g) DEFINITIONS.—In this section:

(1) COVERED GRAS DESIGNATION.—The term ''covered GRAS designation'' means a designation made by a manufacturer prior to 2000 that a substance used in food is generally recognized as safe, as described in section 201(s) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(s)), including any such designation made in which such manufacturer has not filed a petition under section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348) or otherwise notified the Secretary of such designation.

(2) FOOD.—The term ''food'' has the meaning given such term in section 201(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(f)).

(h) TERMINATION OF BOARD.—The Board shall terminate, and this Act shall cease to be effective, 10 years after the date of enactment of this Act.