To amend the Federal Food, Drug, and Cosmetic Act to require that genetically engineered food and foods that contain genetically engineered ingredients be labeled accordingly.

IN THE SENATE OF THE UNITED STATES

Mrs. Boxer introduced the following bill; which was read twice and referred to the Committee on ____________

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require that genetically engineered food and foods that contain genetically engineered ingredients be labeled accordingly.

Be it enacted by the Senate and House of Representa-

tives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Genetically Engineered

Food Right-to-Know Act”.

SEC. 2. PURPOSE AND FINDINGS.

(a) PURPOSE.—The purpose of this Act is to estab-

lish a consistent and enforceable standard for labeling of
foods produced using genetic engineering, including fish,
thereby providing consumers with knowledge of how their
food is produced.

(b) FINDINGS.—Congress finds that—

(1) the process of genetically engineering food
organisms results in material changes to food de-
derived from those organisms;

(2) the Food and Drug Administration requires
the labeling of more than 3,000 ingredients, addi-
tives, and processes;

(3) individuals in the United States have a
right to know if their food was produced with ge-
netic engineering for a variety of reasons, including
health, economic, environmental, religious, and eth-
ical;

(4) more than 60 countries, including the
United Kingdom and all other countries of the Euro-
pean Union, South Korea, Japan, Brazil, Australia,
India, China, and other key United States trading
partners have laws or regulations mandating disclo-
sure of genetically engineered food on food labels;

(5) in 2011, Codex Alimentarius, the food
standards organization of the United Nations,
adopted a text that indicates that governments can
decide on whether and how to label foods produced with genetic engineering; and

(6) mandatory identification of food produced with genetic engineering can be a critical method of preserving the economic value of exports or domestically sensitive markets with labeling requirements for genetically engineered foods.

SEC. 3. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) IN GENERAL.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

“(z)(1) If it is a food that has been genetically engineered or contains 1 or more genetically engineered ingredients, unless such information is clearly disclosed, as determined by the Secretary.

“(2) This paragraph does not apply to food that—

“(A) is served in restaurants or other similar eating establishments, such as cafeterias and carryouts;

“(B) is a medical food (as defined in section 5(b) of the Orphan Drug Act);

“(C) is a food that would be subject to this paragraph solely because it was produced using a genetically engineered vaccine; or
“(D) is a food or processed food that would be subject to this paragraph solely because it includes the use of a genetically engineered processing aid (including yeast) or enzyme.

“(3) In this paragraph:

“(A) The term ‘genetic engineering’ means a process involving the application of—

“(i) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or

“(ii) fusion of cells beyond the taxonomic family that—

“(I) overcome natural physiological reproductive or recombinant barriers; and

“(II) are not techniques used in traditional breeding and selection.

“(B) The term ‘genetically engineered’, used with respect to a food, means a material intended for human consumption that is—

“(i) an organism that is produced through the intentional use of genetic engineering; or

“(ii) the progeny of intended sexual or asexual reproduction (or both) of 1 or more or-
organisms that is the product of genetic engineering.

“(C) The term ‘genetically engineered ingredient’ means a material that is an ingredient in a food that is derived from any part of an organism that has been genetically engineered, without regard to whether—

“(i) the altered molecular or cellular characteristics of the organism are detectable in the material; and

“(ii) the organism is capable for use as human food.”.

(b) GUARANTY.—

(1) IN GENERAL.—Section 303(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(d)) is amended—

(A) by striking “(d)” and inserting “(d)(1)”; and

(B) by adding at the end the following:

“(2)(A) No person shall be subject to the penalties of subsection (a)(1) for a violation of subsection (a), (b), or (c) of section 301 involving food that is misbranded within the meaning of section 403(z) if such person (referred to in this paragraph
as the ‘recipient’) establishes a guaranty or undertaking that—

“(i) is signed by, and contains the name and address of, a person residing in the United States from whom the recipient received in good faith the food (including the receipt of seeds to grow raw agricultural commodities); and

“(ii) contains a statement to the effect that the food is not genetically engineered or does not contain a genetically engineered ingredient.

“(B) In the case of a recipient who, with respect to a food, establishes a guaranty or undertaking in accordance with subparagraph (A), the exclusion under such subparagraph from being subject to penalties applies to the recipient without regard to the manner in which the recipient uses the food, including whether the recipient is—

“(i) processing the food;

“(ii) using the food as an ingredient in a food product;

“(iii) repacking the food; or

“(iv) growing, raising, or otherwise producing the food.
“(C) No person may avoid responsibility or liability for a violation of subsection (a), (b), or (c) of section 301 involving food that is misbranded within the meaning of section 403(z) by entering into a contract or other agreement that specifies that another person shall bear such responsibility or liability, except that a recipient may require a guaranty or undertaking as described in this subsection.

“(D) In this subsection, the terms ‘genetically engineered’ and ‘genetically engineered ingredient’ have the meanings given the terms in section 403(z).”.

(2) False guaranty.—Section 301(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(h)) is amended by inserting “or 303(d)(2)” after “section 303(e)(2)”.

(c) Unintended contamination.—Section 303(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(d)), as amended by subsection (b), is further amended by adding at the end the following:

“(3)(A) No person shall be subject to the penalties of subsection (a)(1) for a violation of subsection (a), (b), or (c) of section 301 involving food that is misbranded within the meaning of section 403(z) if—
“(i) such person is an agricultural producer and the violation occurs because food that is grown, raised, or otherwise produced by such producer, which food does not contain a genetically engineered material and was not produced with a genetically engineered material, is contaminated with a food that contains a genetically engineered material or was produced with a genetically engineered material; and

“(ii) such contamination is not intended by the agricultural producer.

“(B) Subparagraph (A) does not apply to an agricultural producer to the extent that the contamination occurs as a result of the negligence of the producer.”.

(d) PROMULGATION OF REGULATIONS.—Not later than 1 year after the date of enactment of this Act, the Secretary shall promulgate proposed regulations establishing labeling requirements for compliance in accordance with section 403(z) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).