

One Hundred Fifth Congress
of the
United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Tuesday,
the twenty-seventh day of January, one thousand nine hundred and ninety-eight*

An Act

To amend the Federal Food, Drug, and Cosmetic Act to clarify the circumstances in which a substance is considered to be a pesticide chemical for purposes of such Act, 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 “Antimicrobial Regulation Technical Corrections Act of 1998”.

SEC. 2. DEFINITION OF PESTICIDE CHEMICAL UNDER FEDERAL FOOD, DRUG, AND COSMETIC ACT.

(a) IN GENERAL.—Section 201(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(q)) is amended by striking “(q)(1)” and all that follows through the end of subparagraph (1) and inserting the following:

“(q)(1)(A) Except as provided in clause (B), the term ‘pesticide chemical’ means any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act, including all active and inert ingredients of such pesticide. Notwithstanding any other provision of law, the term ‘pesticide’ within such meaning includes ethylene oxide and propylene oxide when such substances are applied on food.

“(B) In the case of the use, with respect to food, of a substance described in clause (A) to prevent, destroy, repel, or mitigate microorganisms (including bacteria, viruses, fungi, protozoa, algae, and slime), the following applies for purposes of clause (A):

“(i) The definition in such clause for the term ‘pesticide chemical’ does not include the substance if the substance is applied for such use on food, or the substance is included for such use in water that comes into contact with the food, in the preparing, packing, or holding of the food for commercial purposes. The substance is not excluded under this subclause from such definition if the substance is ethylene oxide or propylene oxide, and is applied for such use on food. The substance is not so excluded if the substance is applied for such use on a raw agricultural commodity, or the substance is included for such use in water that comes into contact with the commodity, as follows:

“(I) The substance is applied in the field.

“(II) The substance is applied at a treatment facility where raw agricultural commodities are the only food treated, and the treatment is in a manner that does not change the status of the food as a raw agricultural commodity

(including treatment through washing, waxing, fumigating, and packing such commodities in such manner).

“(III) The substance is applied during the transportation of such commodity between the field and such a treatment facility.

“(ii) The definition in such clause for the term ‘pesticide chemical’ does not include the substance if the substance is a food contact substance as defined in section 409(h)(6), and any of the following circumstances exist: The substance is included for such use in an object that has a food contact surface but is not intended to have an ongoing effect on any portion of the object; the substance is included for such use in an object that has a food contact surface and is intended to have an ongoing effect on a portion of the object but not on the food contact surface; or the substance is included for such use in or is applied for such use on food packaging (without regard to whether the substance is intended to have an ongoing effect on any portion of the packaging). The food contact substance is not excluded under this subclause from such definition if any of the following circumstances exist: The substance is applied for such use on a semipermanent or permanent food contact surface (other than being applied on food packaging); or the substance is included for such use in an object that has a semipermanent or permanent food contact surface (other than being included in food packaging) and the substance is intended to have an ongoing effect on the food contact surface.

With respect to the definition of the term ‘pesticide’ that is applicable to the Federal Insecticide, Fungicide, and Rodenticide Act, this clause does not exclude any substance from such definition.”.

(b) REGULATIONS.—Section 408(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(j)) is amended by adding at the end the following paragraph:

“(4) CERTAIN SUBSTANCES.—With respect to a substance that is not included in the definition of the term ‘pesticide chemical’ under section 201(q)(1) but was so included on the day before the date of the enactment of the Antimicrobial Regulation Technical Corrections Act of 1998, the following applies as of such date of enactment:

“(A) Notwithstanding paragraph (2), any regulation applying to the use of the substance that was in effect on the day before such date, and was on such day deemed in such paragraph to have been issued under this section, shall be considered to have been issued under section 409.

“(B) Notwithstanding paragraph (3), any regulation applying to the use of the substance that was in effect on such day and was issued under this section (including any such regulation issued before the date of the enactment of the Food Quality Protection Act of 1996) is deemed to have been issued under section 409.”.

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(c) TECHNICAL AMENDMENT.—Section 201(q)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(q)(3)) is amended in the matter preceding clause (A) by striking “paragraphs (1) and (2)” and inserting “subparagraphs (1) and (2)”.

Speaker of the House of Representatives.

*Vice President of the United States and
President of the Senate.*