

105<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# S. 2565

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.

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## IN THE SENATE OF THE UNITED STATES

OCTOBER 7 (legislative day, OCTOBER 2), 1998

Mr. DURBIN (for himself, Mr. WARNER, Ms. MIKULSKI, Mr. HUTCHINSON, Mr. ROBB, Mr. KENNEDY, and Mr. DEWINE) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

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## A BILL

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.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Antimicrobial Regula-  
5       tion Technical Corrections Act of 1998”.

1 **SEC. 2. DEFINITION OF PESTICIDE CHEMICAL UNDER FED-**  
2 **ERAL FOOD, DRUG, AND COSMETIC ACT.**

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

7 “(q)(1)(A) Except as provided in clause (B), the term  
8 ‘pesticide chemical’ means any substance that is a pes-  
9 ticide within the meaning of the Federal Insecticide, Fun-  
10 gicide, and Rodenticide Act, including all active and inert  
11 ingredients of such pesticide. Notwithstanding any other  
12 provision of law, the term ‘pesticide’ within such meaning  
13 includes ethylene oxide and propylene oxide when such  
14 substances are applied on food.

15 “(B) In the case of the use, with respect to food, of  
16 a substance described in clause (A) to prevent, destroy,  
17 repel, or mitigate microorganisms (including bacteria, vi-  
18 ruses, fungi, protozoa, algae, and slime), the following ap-  
19 plies for purposes of clause (A):

20 “(i) The definition in such clause for the term  
21 ‘pesticide chemical’ does not include the substance if  
22 the substance is applied for such use on food, or the  
23 substance is included for such use in water that  
24 comes into contact with the food, in the preparing,  
25 packing, or holding of the food for commercial pur-  
26 poses. The substance is not excluded under this sub-

1 clause from such definition if the substance is ethyl-  
2 ene oxide or propylene oxide, and is applied for such  
3 use on food. The substance is not so excluded if the  
4 substance is applied for such use on a raw agricul-  
5 tural commodity, or the substance is included for  
6 such use in water that comes into contact with the  
7 commodity, as follows:

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

9 “(II) The substance is applied at a treat-  
10 ment facility where raw agricultural commod-  
11 ities are the only food treated, and the treat-  
12 ment is in a manner that does not change the  
13 status of the food as a raw agricultural com-  
14 modity (including treatment through washing,  
15 waxing, fumigating, and packing such commod-  
16 ities in such manner).

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

20 “(ii) The definition in such clause for the term  
21 ‘pesticide chemical’ does not include the substance if  
22 the substance is a food contact substance as defined  
23 in section 409(h)(6), and any of the following cir-  
24 cumstances exist: The substance is included for such  
25 use in an object that has a food contact surface but

1 is not intended to have an ongoing effect on any por-  
2 tion of the object; the substance is included for such  
3 use in an object that has a food contact surface and  
4 is intended to have an ongoing effect on a portion  
5 of the object but not on the food contact surface; or  
6 the substance is included for such use in or is ap-  
7 plied for such use on food packaging (without regard  
8 to whether the substance is intended to have an on-  
9 going effect on any portion of the packaging). The  
10 food contact substance is not excluded under this  
11 subclause from such definition if any of the following  
12 circumstances exist: The substance is applied for  
13 such use on a semipermanent or permanent food  
14 contact surface (other than being applied on food  
15 packaging); or the substance is included for such use  
16 in an object that has a semipermanent or permanent  
17 food contact surface (other than being included in  
18 food packaging) and the substance is intended to  
19 have an ongoing effect on the food contact surface.  
20 With respect to the definition of the term ‘pesticide’ that  
21 is applicable to the Federal Insecticide, Fungicide, and  
22 Rodenticide Act, this clause does not exclude any sub-  
23 stance from such definition.”.

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

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

11 “(A) Notwithstanding paragraph (2), any  
12 regulation applying to the use of the substance  
13 that was in effect on the day before such date,  
14 and was on such day deemed in such paragraph  
15 to have been issued under this section, shall be  
16 considered to have been issued under section  
17 409.

18 “(B) Notwithstanding paragraph (3), any  
19 regulation applying to the use of the substance  
20 that was in effect on such day and was issued  
21 under this section (including any such regula-  
22 tion issued before the date of the enactment of  
23 the Food Quality Protection Act of 1996) is  
24 deemed to have been issued under section  
25 409.”.

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

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