

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 185**

[OPP-300438; FRL-5397-4]

RIN 2070-AC55

Withdrawal of Pesticide Tolerance Revocations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Rule.

SUMMARY: EPA is withdrawing final rules revoking 17 processed food tolerances. The Agency is withdrawing these revocations because they were based on two provisions of the Federal Food, Drug and Cosmetic Act that no longer are applicable to pesticide residues in food, specifically the Delaney clause and the "ready-to-eat" provision. Since the enactment of the Food Quality Protection Act, the basis for these revocations no longer exists as a matter of law. Accordingly, EPA is withdrawing these final rules.

EFFECTIVE DATE: This rule is effective September 26, 1996.

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SUPPLEMENTARY INFORMATION:**I. Statutory Background**

The Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 301 et seq.) authorizes the establishment of maximum permissible levels of pesticides in foods, which are referred to as "tolerances" (21 U.S.C. 346a). Without such a tolerance or an exemption from a tolerance, a food containing a pesticide residue is "adulterated" under section 402 of the FFDCA and may not be legally moved in interstate commerce (21 U.S.C. 342). Monitoring and enforcement of pesticide residues are carried out by the U.S. Food and Drug Administration and the U.S. Department of Agriculture.

The FFDCA's provisions governing pesticides were significantly amended on August 3, 1996 by the enactment of the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170, 110 Stat. 1489). The FQPA amendments were effective immediately.

Among other things, the FQPA amends the FFDCA to bring all EPA pesticide tolerance-setting activities

under a single section of the statute — section 408 — and added a new safety standard and new procedures in that section. Previously, regulatory authority over pesticides in the FFDCA had been divided between sections 408 and 409. The division of pesticides between sections 408 and 409 had been the subject of some controversy because of the differing safety standards in the two sections. Of particular significance was the inclusion in section 409, but not section 408, of the Delaney anti-cancer clause. The FQPA converted all existing section 409 tolerances for pesticide residues in processed food into section 408 tolerances. 21 U.S.C. 346a(j).

The FQPA also amended the so-called "flow-through" provision in section 402(a)(2) that governed whether tolerances for pesticide residues in raw agricultural commodities apply to pesticide residues in processed foods. Before being amended, the FFDCA had specified that a pesticide residue in a processed food would not render that food adulterated if, among other things, the level of the residue in the processed food "when ready to eat" is below the tolerance level for the pesticide in the precursor raw agricultural commodity. The FQPA maintained this flow-through concept that raw agricultural commodity tolerances would apply to pesticides in processed food but modified existing law by dropping the requirement that the level of residue in the processed food be evaluated at the ready-to-eat stage. 21 U.S.C. 346a(a)(2)(A).

II. Regulatory Background

In response to the decision in *Les v. Reilly*, 968 F.2d 985 (9th Cir.), cert. denied, 113 S.Ct. 1361 (1993), in which the U.S. Court of Appeals, Ninth Circuit held there was no *de minimis* exception to the Delaney clause, EPA began to initiate revocation actions against those existing section 409 tolerances which were inconsistent with the Delaney clause.

Further, on February 9, 1995, EPA entered into a court-approved consent decree in which EPA agreed to a timetable for deciding whether to revoke an extensive list of section 408 and 409 tolerances. Under the consent decree, EPA has taken a number of revocation actions. In the case of final revocations, many tolerances remain in effect because either EPA has delayed the effective date to allow for the filing of objections and hearing requests and to consider stay requests or EPA or a court has granted requests for stays of the effective date of revocation.

III. Today's Action

EPA is today withdrawing a total of 17 revocations issued in 5 separate actions. The tables in Unit IV of this notice list the specific tolerance revocations in those five actions that are being withdrawn. Revocations in those actions not listed in the table are not affected.

1. *Benomyl on tomato products and raisins.* This final revocation of section 409 tolerances (June 30, 1994, 59 FR 33685; July 14, 1993, 58 FR 37862) was stayed by the D.C. Court of Appeals and the Agency reinstated the tolerances on September 12, 1994 (59 FR 46769). EPA is withdrawing the revocations of the tolerances on tomato products and raisins. Because EPA's reinstatement rule reestablished the tomato products and raisin tolerances in full force, no amendment to the Code of Federal Regulations is necessary in conjunction with the withdrawal of these revocations.

2. *Dichlorvos in bagged and packaged processed foods.* This final revocation of the section 409 tolerance (November 10, 1993, 58 FR 59663) was stayed by EPA on March 11, 1994 (59 FR 11556). EPA styled this revocation as a revision to the tolerance because the revocation had a delayed effective date. EPA is withdrawing that revision.

3. *Dicofol on dried tea.* This final revocation of the section 409 tolerance for dicofol (March 9, 1994, 59 FR 10993) was stayed by EPA on May 9, 1994 (59 FR 23799). EPA is withdrawing this revocation.

4. *March 1996 revocations.* This group consists of final revocations of 26 section 409 tolerances for 7 pesticides (March 22, 1996, 61 FR 11993)(FRL-5357-7). The revocations of 8 tolerances were stayed by EPA (May 20, 1996, 61 FR 22153). The remaining revocations became effective on May 21, 1996. EPA is today withdrawing the revocations of the 8 tolerances for which stays were granted.

5. *July 1996 revocations.* This group consists of final revocations of six section 409 tolerances and three section 408 tolerances for four pesticides (July 29, 1996, 61 FR 39527)(FRL-5388-2). These revocations are not yet effective. EPA is today withdrawing the revocations of five section 409 tolerances. The revocations of the remaining section 409 tolerance and the section 408 tolerances will become effective on October 28, 1996.

EPA is withdrawing 16 of the 17 revocations because they were based on the Delaney clause in section 409. Under the modified FFDCA, pesticide residues are no longer governed by

section 409 or its Delaney clause and all of the section 409 tolerances which were still in effect on August 3, 1996 were converted to section 408 tolerances. A section 408 processed food tolerance cannot be revoked on the basis of the Delaney clause in section 409 and thus all pending revocations premised solely on the Delaney clause are being withdrawn as lacking any legal basis.

EPA is withdrawing one revocation (imazalil/citrus oil) because it was based on EPA's conclusion that the tolerance in question is set on a not ready-to-eat food. EPA had reasoned that once the dilution associated with final processing of the ready-to-eat food is taken into account the ready-to-eat food is unlikely to contain residues above the tolerance for the precursor raw commodity and hence no section 409 tolerance is necessary to prevent the processed food from being deemed adulterated. Because the FQPA removed the ready-to-eat factor from the flow-through provision governing the applicability of raw agricultural commodity tolerances to processed foods, revocations relying on the dilution which occurs in processing a ready-to-eat food have no basis in law and are therefore being withdrawn.

In withdrawing these actions, EPA would like to make clear two points. First, because these revocations concerned legal requirements no longer applying to pesticides, EPA will not assert a preclusive effect as to any factual findings regarding such requirements. Second, today's action should not be interpreted to mean that EPA has made a "safety finding" as to the pesticide tolerances in question under the FFDCA, as amended by the FQPA. EPA will systematically review the safety of all the tolerances within the next 10 years, as required under the FQPA.

IV. Specific Revocations Being Withdrawn

The specific actions EPA is withdrawing are presented in the two tables below.

Table 1 lists section 409 tolerances for which final rules were issued on Delaney grounds.

TABLE 1.—REVOCATIONS WHICH WERE BASED ON THE DELANEY CLAUSE

Pesticide	Commodity	40 CFR Citation
Acephate	food handling establishments	185.100
Benomyl	tomato products, raisins	185.350
Dichlorvos (DDVP).	bagged and packaged processed foods	185.1900
Dicofol	dried tea	185.410
Ethylene Oxide.	ground spices	185.2850
Iprodione	dried ginseng, raisins	185.3750
Mancozeb	bran of oats	185.6300
Propargite	dried figs, dried tea	185.5000
Propylene oxide.	cocoa, gums, processed nutmeats (except peanuts), processed spices	185.5150
Triadimefon.	milled fractions of wheat	185.800

Table 2 lists section 409 tolerances for which a final rule was issued on not ready-to-eat grounds.

TABLE 2.—REVOCATION WHICH WAS BASED ON NOT READY-TO-EAT GROUNDS

Pesticide	Commodity	40 CFR Citation
Imazalil ...	citrus oil	185.3650

List of Subjects in Part 185

Environmental protection, Food additives, Pesticides and pests

Dated: September 19, 1996.

Lynn R. Goldman,
Assistant Administrator for Prevention,
Pesticides and Toxic Substances.

Accordingly, 40 CFR chapter I, part 185 is amended as follows:

PART 185—[AMENDED]

The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

§ 185.410 [Amendment and Stay Withdrawn]

2. The amendment removing § 185.410, at 59 FR 10997, March 9, 1994 and the subsequent stay of the effective date of that amendment, at 59 FR 23800, May 9, 1994 are withdrawn.

§ 185.1900 [Amendment and Stay Withdrawn]

3. The revision of § 185.1900 at 58 FR 59667, November 10, 1993 and the subsequent stay of that revision at 59 FR 11556, March 11, 1994 are withdrawn.

§ 185.2850 [Amendment and Stay Withdrawn]

4. The amendment removing § 185.2850 published at 61 FR 11993, March 22, 1996, and the subsequent stay at 61 FR 25153, May 20, 1996 are withdrawn.

§§ 185.5000, 185.5150 and 185.6300 [Amendment Withdrawn]

5. The amendment to the text of § 185.5000, and the amended text for §§ 185.5150 and 185.6300, published at 61 FR 25153, May 20, 1996 as a result of a partial stay of the removals published at 61 FR 11993, March 22, 1996 are confirmed as final.

§§ 185.100, 185.800, 185.3650, 185.3750 [Amendment Withdrawn]

6. The amendments removing §§ 185.100, 185.800, 185.3650, and 185.3750, at 61 FR 39542, July 29, 1996 are withdrawn.

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