

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Parts 180 and 186**

[OPP-300439; FRL-5397-5]

RIN 2070-AC55

**Withdrawal of Proposed Revocations of Pesticide Tolerances****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Withdrawal of proposed revocations.

**SUMMARY:** EPA is withdrawing the proposed revocations of a number of pesticide tolerances established under the Federal Food, Drug and Cosmetic Act (FFDCA). The enactment of the Food Quality Protection Act removed the legal basis for these revocations. Accordingly, EPA is withdrawing these proposed rules. EPA is also withdrawing the various proposed decisions to retain certain tolerances because the obligation to make decisions on these tolerances has been removed.

**FOR FURTHER INFORMATION CONTACT:** By mail: Niloufar Nazmi-Glosson, Special Review Branch, (7508W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 308-8028; e-mail: nazmi-glosson.niloufar@epamail.epa.gov.

**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). 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)(C).

**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. EPA also began identifying those section 408 tolerances which would have to be revoked under EPA's coordination policy. Under the coordination policy, EPA will not permit use of a pesticide on a raw agricultural commodity if tolerances needed to prevent the adulteration of processed food can not be approved. Application of this policy was triggered by the revocation of various section 409 tolerances on Delaney clause grounds.

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 proposed and final revocation actions.

**III. Today's Action**

EPA is today withdrawing certain proposed revocations included in two separate proposals:

1. *September 21, 1995 Proposed Revocations (60 FR 49141)(FRL-4977-3)*. Proposed revocation of 36 section 409 tolerances (feed additives) for 16 pesticides (Appendix I, Group C). EPA is withdrawing the proposed revocations of 11 of these tolerances. EPA is not withdrawing the remaining 25 proposed revocations in the September 21, 1995 notice and, in the future, EPA will complete action on these proposals.

EPA is withdrawing 2 of the 11 proposed 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 9 proposed revocations because they were based on EPA's conclusion that the tolerances in question are set on not ready-to-eat foods. EPA had reasoned that once the dilution associated with final processing of ready-to-eat foods 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 to a ready-to-eat food have no basis in law and are therefore being withdrawn.

In the future, EPA will complete action on the remaining 25 proposed revocations, which were based on determinations that the pesticide does not concentrate in the processed feed or that the processed feed is no longer a significant animal feed for which a tolerance is necessary. These determinations are not affected by the enactment of the FQPA.

2. *March 1, 1996 Proposed Revocations (61 FR 8173)(FRL-5351-6)*. Proposed revocation of 9 section 408 tolerances under the coordination

policy, and the proposed decision to retain 32 section 408 tolerances.

EPA proposed to revoke 9 section 408 tolerances on the ground that the associated pesticide use needed a section 409 tolerance as well as a section 408 tolerance to prevent the adulteration of processed food and such section 409 tolerance is barred by the Delaney clause. Because the FQPA has moved authority for regulation of all pesticide residues into section 408, the Delaney clause in section 409 no longer bars the establishment of needed processed food tolerances. Thus there is no longer any basis for EPA to apply its coordination policy to this situation and the proposed revocations are withdrawn.

In the same notice, EPA proposed to retain 32 section 408 tolerances. EPA had issued a proposal to retain these tolerances because the consent decree mentioned in Unit II of this document required EPA to announce its decision regarding such tolerances and EPA believed revocation was not warranted. As provided by its own terms, the consent decree has now been superseded by the FQPA and EPA and all parties to the litigation have filed a joint motion seeking dismissal of the case and termination of the consent decree. Accordingly, EPA is withdrawing its proposed decisions to retain section 408 tolerances because there is no obligation on the Agency to

make a decision regarding those specific tolerances.

In withdrawing these proposed revocations, 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 ten years, as required under the FQPA.

#### IV. Specific Proposals Being Withdrawn

The specific actions EPA is withdrawing are presented in three tables.

Table 1 lists section 409 tolerances for which a proposed revocation was issued on Delaney grounds.

TABLE 1.—PROPOSED REVOCATIONS THAT WERE BASED ON DELANEY GROUNDS

Pesticide	Commodity	40 CFR citation
Simazine ...	Sugarcane molasses	186.5350

TABLE 1.—PROPOSED REVOCATIONS THAT WERE BASED ON DELANEY GROUNDS—Continued

Pesticide	Commodity	40 CFR citation
Tetrachlorvinphos.	Feed of beef, dairy cattle, and horses	186.950

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

TABLE 2.—PROPOSED REVOCATIONS THAT WERE BASED ON NOT READY-TO-EAT GROUNDS

Pesticide	Commodity	40 CFR citation
Acephate	Cottonseed hulls	186.100
Benomyl ....	Dried citrus pulp, rice hulls	186.350
Diflubenzuron.	Soybean hulls	186.2000
Imazalil .....	Dried citrus pulp	186.3650
Iprodione ...	Rice bran, rice hulls	186.3750
Mancozeb	Milled wheat fractions	186.6300
Thiodicarb	Soybean hulls	186.5650

Table 3 lists section 408 tolerances for which EPA made a proposed determination to either retain or revoke based upon its coordination policy.

TABLE 3.—PROPOSED REVOCATIONS AND DECISIONS ON SECTION 408 TOLERANCES

Pesticide	Commodity	40 CFR Citation	Proposed Action
Acephate .....	Cottonseed	180.108	Retain
Alachlor .....	Sunflower seed	180.249	Retain
Benomyl .....	Citrus	180.294	Retain
	Rice	180.294	Retain
Captan .....	Grapes, Tomatoes	180.103	Retain
Carbaryl .....	Pineapples	180.169	Retain
Dicofol .....	Apples	180.163	Revoke
	Grapes	180.163	Revoke
	Plums	180.163	Revoke
	Tomatoes	180.163	Retain
Diflubenzuron .....	Soybeans	180.377	Retain
Dimethipin .....	Cottonseed	180.406	Retain
Ethylene Oxide .....	Whole spices (direct treatment)	180.151	Retain
Iprodione .....	Peanuts	180.399	Retain
	Rice	180.399	Retain
Lindane .....	Tomatoes	180.133	Retain
Mancozeb .....	Barley	180.176	Retain
	Grapes	180.176	Retain
	Oats	180.176	Revoke
	Rye	180.176	Retain
	Wheat	180.176	Revoke
Maneb .....	Grapes	180.110	Retain
Methomyl .....	Wheat	180.253	Retain
Norflurazon .....	Grapes	180.356	Retain
Oxyfluorfen .....	Cottonseed	180.381	Retain
	Peppermint	180.381	Retain
	Spearmint	180.381	Retain
	Soybeans	180.381	Retain
PCNB .....	Tomatoes	180.319	Retain

TABLE 3.—PROPOSED REVOCATIONS AND DECISIONS ON SECTION 408 TOLERANCES—Continued

Pesticide	Commodity	40 CFR Citation	Proposed Action
Permethrin .....	Tomatoes	180.378	Retain
Propargite .....	Apples	180.259	Revoke
	Figs	180.259	Revoke
	Grapes	180.259	Retain
	Plums	180.259	Retain
Simazine .....	Sugarcane	180.213	Revoke
Thiodicarb .....	Cottonseed	180.407	Retain
	Soybeans	180.307	Retain
Triadimefon .....	Grapes	180.410	Retain
	Wheat	180.410	Revoke
	Pineapple	180.410	Retain

## List of Subjects

## 40 CFR Part 180

Environmental protection,  
Administrative practice and procedure,  
Agricultural commodities, Pesticides  
and pests, reporting and recordkeeping  
requirements.

## 40 CFR Part 186

Environmental protection, Animal  
feeds, Pesticide and pests.

Accordingly, for the reasons set out in  
the preamble above, EPA is  
withdrawing the following:

1. The proposed rule published at 61  
FR 8174, March 1, 1996 proposing  
changes to part 180 is withdrawn.

2. The amendments proposing to  
remove §§ 186.100, 186.350, 186.950,

186.2000, 186.3650, 186.3750 and  
186.5350, 186.5650, and 186.6300,  
published at 60 FR 49141, September  
21, 1995 are withdrawn.

Dated: September 19, 1996.

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

[FR Doc. 96-24603 Filed 9-25-96; 8:45 am]

BILLING CODE 6560-50-F