No. 17-71636

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS, et al.,

Petitioners,

STATE OF NEW YORK, et al.,

Petitioner-Intervenors,

v.

SCOTT PRUITT, Administrator, United States Environmental Protection Agency, and THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondents.

ON PETITION FOR JUDICIAL REVIEW OF ACTION BY THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

ANSWERING BRIEF OF RESPONDENTS

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STATEMENT OF JURISDICTION

League of United Latin American Citizens, Pesticide Action Network North America ("PANNA"), Natural Resources Defense Council ("NRDC"), California Rural Legal Assistance Foundation, Farmworker Association of Florida, Farmworker Justice, GreenLatinos, Labor Council for Latin American Advancement, Learning Disabilities Association of America, National Hispanic Medical Association, Pineros y Campesinos Unidos del Noroeste, and United Farm Workers (collectively "Petitioners"), challenge the order issued by Respondent Environmental Protection Agency ("EPA" or "Agency"), entitled "Chlorpyrifos: Order Denying PANNA and NRDC's Petition to Revoke Tolerances," issued March 29, 2017, and published at 82 Fed. Reg. 16,581 (Apr. 5, 2017) (hereinafter "Denial Order"). For the reasons stated below, this Court does not have jurisdiction to review this order under 21 U.S.C. § 346a(h) and 40 C.F.R. § 178.65, as Petitioners have failed to exhaust mandatory administrative remedies.

STATEMENT OF THE ISSUES

1. Whether an order denying a petition to revoke a tolerance for a pesticide under the Federal Food, Drug, and Cosmetic Act is subject to judicial review if administrative objections to that order have not been addressed in a final order issued pursuant to 21 U.S.C. § 346a(g)(2)(C).
2. Whether, if the Court determines it has jurisdiction, EPA should be permitted to first address Petitioners' objections to the Denial Order

through the administrative objections process, rather than in this Court, where EPA's final order will further develop the record for judicial review, if not moot the need for judicial review.

3. Whether Petitioners are entitled to mandamus relief where they raised their mandamus arguments in an opening brief in support of their petition for review without following the procedures set forth in Federal Rule of Appellate Procedure 21(a).

PERTINENT STATUTES AND REGULATIONS

Pertinent statutes and regulations are reproduced in the addendum to this brief.

STATEMENT OF THE CASE

A. Statutory and Regulatory Background

EPA regulates pesticides under both the Federal Food, Drug, and Cosmetic Act ("FFDCA"), *see* 21 U.S.C. § 346a, and the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y.

1. The Federal Food, Drug, and Cosmetic Act

The FFDCA authorizes EPA to establish "tolerances," which are maximum levels of pesticide residue allowed in or on food. 21 U.S.C. § 346a. Without a tolerance or exemption, pesticide residues in or on food are considered unsafe. *Id.* § 346a(a). EPA may establish a tolerance for a pesticide if EPA determines that the tolerance is "safe," but EPA must revoke or modify a tolerance if EPA determines that the tolerance is not "safe." *Id.* § 346a(b)(2)(A)(i). An unsafe food is considered

"adulterated" and may not be moved in interstate commerce legally. *Id.* §§ 331(a), 342(a)(2)(B), 346a(a).

In 1996, Congress amended the FFDCA with the Food Quality Protection Act, which, among other things, created a new safety standard for pesticide residues, requiring EPA to determine that there is a reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residues in order to establish or leave a tolerance in effect. *Id.* § 346a(b)(2)(A)(ii). Congress also amended the FFDCA to require that EPA re-assess by August 3, 2006, the existing tolerances and exemptions for all pesticide chemical residues that were in effect on August 3, 1996. *Id.* § 346a(q)(1).

The FFDCA sets forth a multi-stage procedural framework for the establishment, modification, or revocation of tolerances. The first stage may be initiated by EPA acting on its own accord or in response to an administrative petition. *Id.* § 346a(d)(1), (e)(1). "Any person may file with [EPA] a petition proposing the issuance of a regulation . . . establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food." *Id.* § 346a(d)(1)(A). EPA must then give "due consideration" to the petition and take one of three actions: (i) issue a final regulation establishing, modifying, or revoking a tolerance; (ii) issue a proposed regulation under the separate provisions of 21 U.S.C. § 346a(e), and thereafter issue a final regulation after additional public notice and comment; or (iii) issue an order denying the petition. *Id.* § 346a(d)(4)(A).

When EPA issues a regulation or order establishing, modifying, or revoking a tolerance, any person may file written objections with EPA and may also request an evidentiary hearing on those objections. *Id.* § 346a(g)(2)(A)-(B). After considering any objections and any hearing, if held, EPA must issue a final order with respect to the objection. *Id.* § 346a(g)(2)(C). Such an order is subject to judicial review in the United States Courts of Appeals. *Id.* § 346a(h). Judicial review is only available for final orders responding to objections; the statute does not provide for judicial review of tolerance regulations or orders in advance of the final order on objections. *Id.*

2. The Federal Insecticide, Fungicide, and Rodenticide Act

EPA also regulates pesticides under FIFRA. While the FFDCA authorizes the establishment of legal limits for pesticide residues in food, FIFRA requires EPA approval of pesticides prior to their distribution or sale and establishes a registration regime for regulating the use of pesticides. 7 U.S.C. § 136a(a). EPA must approve an application for pesticide registration if, among other things, the pesticide will not cause "unreasonable adverse effects on the environment." *Id.* § 136a(c)(5). As part of the application process, FIFRA requires EPA to review and approve pesticide labeling, and provides that use of a registered pesticide inconsistent with its labeling is illegal. *Id.* § 136j(a)(2)(G).

FIFRA also requires periodic reevaluation of pesticides. Section 4 of FIFRA, 7 U.S.C. § 136(a)-1, requires EPA to make reregistration determinations for all pesticides first registered prior to November 1, 1984. Following the reregistration

process for these older pesticides (which is now largely complete), FIFRA directs EPA to re-evaluate through a process known as "registration review" all currently registered pesticides by the later of October 1, 2022, or 15 years after the date on which the first pesticide containing a new active ingredient is registered, and at 15-year intervals thereafter. *Id.* § 136a(g)(1)(A)(iii)–(iv).

FIFRA also explicitly requires EPA to address the FFDCA's safety standard for pesticides when completing registration or registration review of a pesticide. FIFRA does this by defining "[t]he term 'unreasonable adverse effects on the environment'" to include "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of Title 21." 7 U.S.C. § 136(bb). Thus, Congress set forth a process by which EPA would establish or re-assess a pesticide's tolerances under the FFDCA at the same time it addressed the pesticide's registration or conducted a registration review under FIFRA.

B. Factual Background

EPA set forth a concise background of chlorpyrifos in its Denial Order.

> Chlorpyrifos (0,0-diethyl-0-3,5,6-trichloro-2-pyridyl phosphorothioate) is a broad-spectrum, chlorinated organophosphate (OP) insecticide that has been registered for use in the United States since 1965. By pounds of active ingredient, it is the most widely used conventional insecticide in the country. Currently registered use sites include a large variety of food crops (including tree fruits and nuts, many types of small fruits and vegetables, including vegetable seed treatments, grain/oilseed crops, and cotton, for example), and non-food use settings (e.g., ornamental and agricultural seed production, non-residential turf, industrial sites/rights of way, greenhouse and nursery production, sod farms, pulpwood production, public health and wood protection). For some of these

> crops, chlorpyrifos is currently the only cost-effective choice for control of certain insect pests. In 2000, the chlorpyrifos registrants reached an agreement with EPA to voluntarily cancel all residential use products except those registered for ant and roach baits in child-resistant packaging and fire ant mound treatments.

82 Fed. Reg. at 16,584 (ER 28).[1]

In 2006, EPA "completed FIFRA section 4 reregistration and FFDCA tolerance reassessment for chlorpyrifos and the OP class of pesticides," concluding that the pesticide was eligible for reregistration under FIFRA and that the tolerances met the safety standard under Section 408(b)(2) of the FFDCA, 21 U.S.C. § 346a(b)(2). *See id.*

C. Procedural Background

1. Administrative Petition to EPA Regarding Chlorpyrifos and *In re PANNA.*

In September 2007, PANNA and NRDC submitted to EPA a joint petition to revoke all FFDCA tolerances and cancel all FIFRA registrations for chlorpyrifos (hereinafter the "Administrative Petition"). Petition to Revoke All Tolerances and Cancel All Registrations for the Pesticide Chlorpyrifos, filed September 2007 (ER 1-24). The Administrative Petition raised ten claims. *Id.* EPA provided PANNA and NRDC with two interim responses on July 16, 2012, and July 15, 2014, which stated EPA's intention to deny six of their ten claims in full, and granted in part and denied

[1] "ER" citations refer to the Excerpts of Record submitted by Petitioners. *See* Dkt. 29 (Jan. 23, 2018).

in part a seventh claim.[2] 82 Fed. Reg. at 16,585-90 (ER 29-34). "The remaining claims (7-9) all related to same issue: Whether the potential exists for chlorpyrifos to cause neurodevelopmental effects in children at exposure levels below EPA's existing regulatory standard (10% cholinesterase inhibition)." *Id.* at 16,583 (ER 27).

In September 2014, PANNA and NRDC filed a petition for writ of mandamus. *See generally In re PANNA*, No. 14-72794 (9th Cir.). This Court ordered EPA to "issue either a proposed or final revocation rule or a full and final response" to the Administrative Petition by October 31, 2015. *In re PANNA*, 798 F.3d 809, 815 (9th Cir. 2015). The Court then ordered EPA to take final action on the Administrative Petition by March 31, 2017. *In re PANNA*, 808 F.3d 402, 402-03 (9th Cir. 2015); *In re PANNA*, 840 F.3d 1014, 1015 (9th Cir. 2016).

2. EPA's Decision to Deny the Administrative Petition.

In November 2015, EPA initially proposed to respond to the Administrative Petition by "revok[ing] all chlorpyrifos tolerances based in part on uncertainty surrounding the potential for chlorpyrifos to cause neurodevelopmental effects--the issue raised in petition claims 7-9." 82 Fed. Reg. at 16,583 (ER 27). A year later, "EPA published a notice of data availability that released for public comment EPA's

[2] In both interim responses, EPA made clear that, at PANNA and NRDC's request, it would issue a denial order under FFDCA § 346a(d)(4)(A)(iii) for these claims and that absent such a request, it would defer issuing a denial order until it addressed the remaining petition claims.

revised risk assessment that proposed a new regulatory point of departure based on the potential for chlorpyrifos to result in adverse neurodevelopmental effects." *Id.*

EPA reviewed the voluminous comments received on the revocation proposal and on the notice of data availability, and on March 29, 2017, EPA denied the Administrative Petition. *Id.* at 16,581 (ER 25). EPA, in the Denial Order, stated that it had determined that comments "suggest that there continue to be considerable areas of uncertainty with regard to what the epidemiology data show and deep disagreement over how those data should be considered in EPA's risk assessment." *Id.* at 16,590 (ER 34). "EPA . . . concluded that, despite several years of study, the science addressing neurodevelopmental effects remains unresolved and that further evaluation of the science during the remaining time for completion of registration review is warranted to achieve greater certainty as to whether the potential exists for adverse neurodevelopmental effects to occur from current human exposures to chlorpyrifos." *Id.* at 16,583 (ER 27).

3. The Ninth Circuit's Denial of Further Mandamus Relief and the Instant Judicial Petition for Review of the Denial Order.

Following the issuance of the Denial Order, PANNA and NRDC moved for further relief concerning both the Denial Order and the administrative objections process in the separate mandamus action. *In re PANNA*, Case No. 14-72794, Dkt. No. 55 (Mot. for Further Mandamus Relief, Apr. 5, 2017). This Court denied the motion, stating "[n]ow that EPA has issued its denial, substantive objections must

first be made through the administrative process mandated by [the FFDCA]" and, once EPA issues a final order, only then can the Court "consider the merits of EPA's 'final agency action.'" *In re PANNA*, 863 F.3d 1131, 1132-33 (9th Cir. 2017) (citations omitted). In other words, "'[f]iling objections and awaiting their resolution by the EPA Administrator is a prerequisite to obtaining judicial review' of EPA's final response to the petition." *Id.* at 1133.

On June 5, 2017, Petitioners filed this case, seeking judicial review of the Denial Order. On the same day, they also filed with EPA written objections to the denial order under the FFDCA (hereinafter "Administrative Objections"). On August 21, 2017, EPA filed a Motion to Dismiss for lack of jurisdiction on the grounds that, under the FFDCA, judicial review is only available following the Administrator's response to the administrative objections to a denial order. Dkt. No. 23. On December 20, 2017, this Court denied the motion to dismiss without prejudice to EPA renewing the arguments in its merits brief. Dkt. No. 31.

On December 21, 2017, EPA filed its certified index to the administrative record. Dkt. No. 32. On January 18, 2018, EPA filed a supplemental certified index to the administrative record. Dkt. No. 36.

On January 23, 2018, Petitioners filed their opening brief in this matter. Dkt. No. 38-1 ("Petrs.' Br."). On that same day, Petitioners also moved to "complete" EPA's administrative record or, in the alternative, for the Court to consider extra-record evidence. Dkt. No. 37. On February 2, 2018, Petitioners moved the Court to

assign this case to the panel in *In re PANNA*. Dkt. No. 51. EPA filed responses to both motions (Dkt. Nos. 50 & 62-1). On March 6, 2018, this Court denied Petitioners' request to assign this case to the panel in *In re PANNA* and referred the motion to complete the administrative record to the merits panel. Dkt. No. 68.

4. Involvement of Intervenors and *Amicus Curiae*.

Several states have moved to intervene in this case on behalf of Petitioners. The Court granted the request for intervention by several states on December 20, 2017. Dkt. No. 31. The Court granted the request for intervention by two additional states on March 6, 2018. Dkt. No. 68. Intervenors submitted their brief in support of Petitioners on February 6, 2018 (Dkt. No. 54), which was accepted by the Court on February 8, 2018 (Dkt. No. 58).

Two parties also moved to submit amicus briefs in this matter in support of Petitioners. A group of health professional organizations and former Congressman Henry Waxman both submitted proposed amicus briefs for review on February 13, 2018. Dkt. Nos. 64 & 65.

SUMMARY OF ARGUMENT

The FFDCA sets forth a clear process for judicial review. An order by EPA denying a petition to revoke a pesticide's tolerance under the FFDCA is not subject to judicial review. 21 U.S.C. § 346a(h)(1). Instead, a party objecting to EPA's decision must first file administrative objections. *See* 21 U.S.C. § 346a(g)(2)(A). EPA must then issue a "[f]inal decision," *id.* § 346a(g)(2)(C), which is then subject to judicial review, *id.*

§ 346a(h)(1). Here, however, Petitioners ask this Court to do precisely what the FFDCA prohibits—review an order by EPA denying a petition to revoke a pesticide's tolerance—rather than wait and review EPA's final decision after the administrative objections process.

This Court should decline Petitioners' request and instead let EPA address Petitioners' Administrative Objections to the Denial Order in the first instance. First, this Court may not review EPA's Denial Order because the FFDCA's bar on judicial review is jurisdictional and not subject to waiver. Second, even if this Court could waive the administrative exhaustion requirement in the FFDCA, it should decline to do so. The arguments Petitioners raise in this case are identical to the Administrative Objections they have raised before EPA in the administrative objections process. EPA should be allowed to address those objections first in the manner set forth by the FFDCA, prior to this Court doing so, especially where, as here, Petitioners fail to meet the high bar of showing that further administrative proceedings are futile. Lastly, Petitioners have asked this Court—if it finds it lacks jurisdiction to review the underlying Denial Order—to issue a writ of mandamus directing EPA to issue a final decision on their Administrative Objections by a time certain. This request should be rejected as failing to comply with the Federal Rules of Appellate Procedure and, in any event, is wholly based upon a misreading of a letter sent by EPA which Petitioners use to argue that EPA is engaged in unreasonable delay.

STANDARD OF REVIEW

EPA's decisions setting forth tolerances for pesticides under the FFDCA are reviewed under the Administrative Procedure Act ("APA"). *Nw. Coal. for Alts. to Pesticides v. EPA*, 544 F.3d 1043, 1047 (9th Cir. 2008). "Under the APA, [this Court should] set aside an agency's decision if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Id.* (quoting 5 U.S.C. § 706(2)(A)). "'The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency.'" *Id.* at 1048 (quoting *Mfrs' Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983)).

"Unless exceptional circumstances are present, judicial review can only take place once administrative action is final and all administrative remedies have been exhausted." *Peter Kiewit Sons' Co. v. U.S. Army Corps of Eng'rs*, 714 F.2d 163, 167 (D.C. Cir. 1983). Finality is a jurisdictional requirement and "'no one is entitled to judicial relief for a supposed or threatened injury until the prescribed administrative remedy has been exhausted.'" *Id.* at 167 (quoting *Myers v. Bethlehem Shipbuilding Corp.*, 303 U.S. 41, 50-51 (1938)); *see also Sierra Club v. U.S. Nuclear Regulatory Comm'n*, 825 F.2d 1356, 1359 (9th Cir. 1987) (explaining the "jurisdictional bar" applied to "petitions filed before a final order has been entered."); *Peter Kiewit Sons' Co.*, 714 F.2d at 167 (citing). Where a statute and agency regulations create a mandatory administrative process that must be pursued before judicial review, courts must enforce exhaustion of the administrative remedies requirements strictly. *Darby v. Cisneros*, 509 U.S. 137 (1993).

With respect to mandamus requests, "[m]andamus is an extraordinary remedy and one that will be employed only in extreme situations." *Clorox Co. v. U.S. Dist. Court for N. Dist. of Cal.*, 779 F.2d 517, 519 (9th Cir. 1985) (citations omitted). The circumstances that will justify interference with non-final agency action must be truly extraordinary, because this Court's supervisory province as to agencies is not as direct as its supervisory authority over trial courts. *Pub. Util. Comm'r of Or. v. Bonneville Power Admin.*, 767 F.2d 622, 630 (9th Cir. 1985). The party seeking a writ of mandamus bears the burden of proving that its right to issuance of the writ is "clear and indisputable." *In re Cal. Power Exch. Corp.*, 245 F.3d 1110, 1120 (9th Cir. 2001) (internal quotation marks and citation omitted).

ARGUMENT

I. This Court Lacks Jurisdiction Over the Petition for Review Because EPA Has Not Issued a Final Order Subject to Judicial Review.

This Court has already acknowledged that the FFDCA's administrative objections process is a statutory prerequisite to judicial review of an order on a petition to revoke a tolerance. *In re PANNA*, 863 F.3d at 1132-33. In their brief, Petitioners do not contend that they have exhausted the FFDCA's administrative remedies. Rather, they argue that exhaustion is not a jurisdictional bar. Petrs.' Br. at 41-43. Petitioners are incorrect. Under the FFDCA, filing objections to a denial of a petition to revoke the tolerances of a pesticide is a prerequisite to judicial review, and only the final order issued at the conclusion of the administrative objections process is

reviewable in the Courts of Appeals. 21 U.S.C. § 346a(h); 40 C.F.R. §§ 178.65, 180.30. Moreover, Petitioners are not entitled to seek judicial review under FIFRA because the FFDCA provides the exclusive remedy to address arguments raised under both statutes.

A. The FFDCA's Exhaustion Requirement Is Jurisdictional and May Not Be Waived.

Despite acknowledging that the administrative objections process is designed to be a prerequisite to judicial review—and in fact filing such objections here—Petitioners nonetheless ask this Court to review the Denial Order before that administrative process is complete. But Petitioners' exclusive remedy is to seek review of the final order issued at the conclusion of the administrative proceedings. Moreover, even if the FFDCA did not expressly prohibit review of the Denial Order, this Court would also lack jurisdiction under the APA to review the Denial Order because that order is not "final agency action." *See* 5 U.S.C. § 704. Indeed, this Court, in the prior mandamus action, noted that PANNA and NRDC, two of the Petitioners in this case, acknowledged that "'[f]iling objections and awaiting their resolution by the EPA Administrator is a prerequisite to obtaining judicial review' of EPA's final response to the petition." *See In re PANNA*, 863 F.3d at 1133.

1. Congress Changed the FFDCA's Judicial Review and Administrative Objections Provisions Such That EPA's Actions Would Not Be Subject to Both Proceedings at the Same Time.

Prior versions of the FFDCA permitted certain actions by EPA to be subject to *either* further administrative review or judicial review. *See* 21 U.S.C. § 346a(e), (i) (1982) (revised in 1996). In 1996 Congress amended the statute in the Food Quality Protection Act and eliminated the opportunity for judicial review without the completion of the administrative process. Pub. L. No. 104–170, 110 Stat. 1489. Oddly, Petitioners point this Court to a D.C. Circuit case addressing the *prior version* of the FFDCA. Petrs.' Br. at 44. There, EPA issued a regulation "following notice and comment and pursuant to § 346a(e), which permits EPA on its own initiative to establish tolerances for pesticides and provides that '[r]egulations issued under this subsection shall upon publication be subject to paragraph (5) of subsection (d).'" *Nat'l Coal. Against the Misuse of Pesticides v. Thomas*, 809 F.2d 875, 879 (D.C. Cir. 1987) (quoting 21 U.S.C. § 346a(e) (prior version)). That subsection, 21 U.S.C. § 346a(d)(5), permitted petitioners to seek an administrative hearing on their objections to EPA's regulation. *Id.* EPA argued that § 346a(d)(5) required petitioners to seek an administrative hearing before invoking judicial review. *Id.*

The D.C. Circuit rejected this argument, noting the language used in the judicial review provision of the then-applicable statute.

> Section 346a(i)(1) provides for judicial review of 'any order under subsection (d)(5), (e), or (*l*).' As we observed previously, EPA's final rule

> of February 14, 1986 and the extension of September 1986 both qualify as 'order[s] under subsection ... (e).' If we accept EPA's argument that judicial review under § 346a(i)(1) can only follow formal hearings under subsection (d)(5) of § 364a, then the reference in § 346a(i)(1) to orders under subsection (e) is rendered surplusage. Both the language and structure of § 346a therefore indicate that resort to a formal hearing is unnecessary before repairing to the courts.

Id. (citation omitted). Thus petitioners had the option to seek further administrative review or to seek judicial review first under this prior version of the statute.

After that 1987 decision, Congress *changed* the FFDCA such that EPA actions under § 346a are either subject directly to judicial review or, as is the case here, subject to an administrative objections process, the outcome of which is subject to judicial review. 21 U.S.C. §§ 346a(g)(2)(A), (h)(1). No longer could an action be subject immediately to both types of review. The statute clearly states that only decisions under §§ 346a(e)(1)(C), (f)(1)(C), and (g)(2)(C) are subject to judicial review. 21 U.S.C. § 346a(h)(1). EPA's Denial Order was issued in response to an Administrative Petition under § 346a(d)(4)(A)(iii), which, unlike the regulation in *National Coalition Against the Misuse of Pesticides*, is not listed as an order subject to judicial review. Indeed, Congress's revision of the statute seems designed to prohibit the very situation Petitioners' ask the Court to permit here: simultaneous review of an EPA decision under the FFDCA in both further administrative and judicial proceedings.

2. The FFDCA's Exhaustion Requirement Sets Forth the Sort of Detailed Process Indicating That It Is a Jurisdictional Requirement.

The determination that the FFDCA's judicial review provision is jurisdictional is confirmed by the specific language of the judicial review provision at issue. In *McBride Cotton*, this Court differentiated general exhaustion requirements in statutes (which are not jurisdictional) from statutory exhaustion provisions setting forth detailed administrative procedures (which are jurisdictional). *McBride Cotton & Cattle Corp. v. Veneman*, 290 F.3d 973, 978-80 (D.C. Cir. 2002). For instance, the Court compared general, non-jurisdictional, exhaustion provisions such as "No action shall be brought . . . until such administrative remedies as are available are exhausted," with the "sweeping and direct" exhaustion provision in *Gallo Cattle Co. v. United States Department of Agriculture*, 159 F.3d 1194 (9th Cir. 1998). There, the statute detailed a petition process, a hearing before the Secretary, and a final ruling by the Secretary, which would only then vest the court with jurisdiction. *McBride Cotton*, 290 F.3d at 979-80. The Court held that this exhaustion requirement was jurisdictional because it "explicitly granted the district court jurisdiction over only those claims which had previously been presented to the Secretary by administrative petition." *Id.* (citing *Gallo*, 159 F.3d at 1197-98).

FFDCA section 346a details an administrative process similar to the one at issue in *Gallo Cattle* that this Court held required exhaustion prior to vesting jurisdiction. To establish jurisdiction to challenge a pesticide tolerance determination,

Petitioners had to file objections with the EPA Administrator within 60 days after the order was issued, which they did, and the objections process then allows requestors to seek a public evidentiary hearing. 21 U.S.C. § 346a(g)(2)(A)-(B). "As soon as practicable after receiving the arguments of the parties," EPA must describe the actions taken in response to the objections, and any warranted revisions to the determination, in a final order. *Id.* § 346a(g)(2)(C). Only then may a petitioner seek judicial review of the final order in a Court of Appeals. *Id.* § 346a(h)(1). Moreover, the FFDCA provides that "[a]ny issue as to which review is or was obtainable under [Section 346a] shall not be the subject of judicial review under any other provision of law." *Id.* § 346a(h)(5). In sum, for EPA actions "subject to the objection procedure in FFDCA section [346a], *judicial review is not available unless an adversely affected party exhausts these objection procedures*, and any petition procedures preliminary thereto." 40 C.F.R. § 180.30(b) (emphasis added).

In one of the few cases to examine the FFDCA's exhaustion requirement, the Southern District of New York held, and the Second Circuit affirmed, that Section 346a(h)(5) "forecloses [judicial] review prior to exhaustion of administrative remedies." *State of New York v. EPA*, 350 F. Supp. 2d 429, 438 (S.D.N.Y. 2004), *aff'd sub nom. Nat. Res. Def. Council v. Johnson*, 461 F.3d 164 (2d Cir. 2006). The Southern District of New York explained that Section 346a(h) "constitutes the type of language courts have insisted upon in demonstrating congressional intention to require exhaustion of administrative remedies," and "Congress's intent to preclude review in

any other forum is apparent in the text of the statute, which provides that challenges brought pursuant to subsection (h) 'shall not be the subject of judicial review under any other provision of law.'" *Id.* at 438-39. Accordingly, judicial review "would be precluded" absent exhaustion of the internal procedures set forth in the statute. *Id.* at 439.

In their brief, Petitioners conflate varying types of exhaustion provisions and their jurisdictional effects. Petrs.' Br. at 42-44. But none of the cases cited by Petitioners in support of their exhaustion arguments concerned the FFDCA, nor do they deal with exhaustion of remedies where Congress statutorily prescribes a detailed administrative process that must be satisfied prior to judicial review.

Petitioners additionally urge the Court to waive the FFDCA's exhaustion requirement as futile because they do not expect to obtain relief from the administrative process. But futility cannot defeat statutorily-mandated procedures. Where, as here, exhaustion is a "statutorily specified jurisdictional prerequisite" and not just "simply a codification of the judicially developed doctrine of exhaustion," it "may not be dispensed with merely by a judicial conclusion of futility." *Weinberger v. Salfi*, 422 U.S. 749, 766 (1975); *Sun v. Ashcroft*, 370 F.3d 932, 941 (9th Cir. 2004). While common law exhaustion has judicially-defined exceptions and can be waived for futility, the Supreme Court has instructed that courts should "not read futility or

other exceptions into statutory exhaustion requirements." *Sun*, 370 F.3d at 941 (citing *Booth v. Churner*, 532 U.S. 731, 741 & n.6 (2001)).[3]

B. EPA's Denial Order Is Not Subject to Judicial Review Under FIFRA.

Petitioners argue that, even if judicial review is not obtainable under the FFDCA, the Denial Order is subject to judicial review under FIFRA. Petrs.' Br. at 47. However, under the express terms of the FFDCA, judicial review of any challenge to a tolerance – even if styled as a FIFRA action – is precluded unless petitioners have exhausted the statutory administrative procedures set forth in the FFDCA.

As explained above, Congress precluded judicial review of EPA's tolerance determinations except in compliance with the provisions of Sections 346a(g) and (h). And Section 346a(h)(5) explicitly states that the FFDCA provides the exclusive path to judicial review of tolerance-related decisions: "Any issue as to which review is or was obtainable under this subsection *shall not be the subject of judicial review under any other provision of law*." 21 U.S.C. § 346a(h)(5) (emphasis added). This exclusive jurisdiction clause means that "FIFRA's grant of jurisdiction" is "irrelevant" here. *See Nat. Res. Def. Council*, 461 F.3d at 176; *see also Geertson Farms, Inc. v. Johanns*, 439 F. Supp. 2d 1012, 1019 (N.D. Cal. 2006) (holding that the FFDCA forecloses jurisdiction under

[3] Moreover, even if futility could be considered, as discussed *infra* at Argument II.B, Petitioners have provided no support for a claim of futility here.

other statutes for "[a]ny issue as to which review is or was obtainable" under Section 346a).

Here, the petition for review challenges the merits of EPA's Denial Order, in which EPA declined to revoke the tolerances for chlorpyrifos at this time. The practical effect of the petition for review is to challenge the substance of the existing tolerances established by EPA pursuant to its authority under the FFDCA. Petitioners are therefore barred from raising their claims in this Court under any other statute unless and until they have exhausted the FFDCA's administrative procedures. *See Nat. Res. Def. Council*, 461 F.3d at 174 ("[A] challenge to a decision to leave a tolerance in effect is *an issue* for which review *was obtainable* under Section 346a(h). As such, [appellants] are precluded from obtaining 'judicial review under any other provision of law.'") (emphasis in original) (citing 21 U.S.C. § 346a(h)(5)). Petitioners do not suggest, nor could they, that any of the issues raised in their administrative petition could not be raised in the context of the administrative objections process under Section 346a(g). Because Petitioners could have obtained (and in fact are obtaining) administrative review pursuant to Section 346a(g), the plain language of Section 346a(h)(5) precludes jurisdiction over their current challenge to the tolerance determinations in this Court.

II. EPA Should Be Permitted to Address Petitioners' Objections to the Denial Order Prior to This Court Addressing Those Same Objections.

Although EPA believes the Court's inquiry should end at the plain language of the FFDCA, 21 U.S.C. § 346a(h), if the Court determines that it has discretion in this matter, it should nonetheless decline to review EPA's Denial Order prior to the conclusion of EPA's own review of Petitioners' Administrative Objections. Any merits-based review at this point would be contrary to the direction of the FFDCA and would be an inefficient use of judicial and Agency resources, as EPA is still working on completing a final agency action based on a "whole record." *See* 5 U.S.C. § 706. EPA will continue to develop its reasoning and administrative record during the FFDCA objections process, as the Administrative Objections raise arguments that were not before the Agency when it issued the Denial Order. Thus, both the Court and EPA would benefit from giving the Agency the opportunity to complete its analysis and present a full record to the Court in any future petition for review of the final decision.

A. EPA Should Address Petitioners' Arguments First in the Administrative Objections Proceedings.

The arguments Petitioners present here are *exactly the same* as those presented to EPA in their Administrative Objections to EPA's Denial Order, as shown by the following comparison.

Petitioners' Brief Point Headings	**Administrative Objections Point Headings**
EPA Lacks the Statutory Authority To Maintain Chlorpyrifos Tolerances in the Absence of an Affirmative Finding that Chlorpyrifos Is Safe (Petrs.' Br. 28)	EPA's Denial of the 2007 Petition Is Illegal Because EPA Cannot Maintain Tolerances in the Face of Its Findings that Chlorpyrifos is Unsafe (ER 149)
EPA's Findings that Chlorpyrifos Is Unsafe Compel It To Revoke the Tolerances (Petrs.' Br. 30)	EPA's Findings that Chlorpyrifos is Unsafe Compel the Administrator to Revoke All Chlorpyrifos Food Tolerances (ER 152)
A Desire to Continue Studying the Science Is Not a Legally Permissible Reason To Leave Chlorpyrifos Tolerances in Place (Petrs.' Br. 34)	Scientific Uncertainty is Not a Legally Permissible Reason to Leave Chlorpyrifos Tolerances in Place (ER 154).
The Deadline for Completing Registration Review Is Not a License To Deny the Petition and Maintain Tolerances for Unsafe Pesticides (Petrs.' Br. 38)	The Deadline for Completing Registration Review for All Older Pesticides is Not A License to Maintain Tolerances for Pesticides That are Unsafe (ER 161)

EPA is still evaluating the arguments presented by Petitioners and two other groups in their administrative objections. Until the Agency has had the opportunity to fully consider these arguments during the objections process, it would be contrary to the FFDCA's administrative exhaustion provisions for EPA to address them in this petition for review.

Petitioners' arguments made in support of their Administrative Objections were not the focus of the underlying petition to revoke tolerances for chlorpyrifos (*see* Administrative Petition (ER 1-24)), but were instead first directly raised *after* the Denial Order was entered. The Denial Order does not directly address them because they were not before the Agency at the time. These issues should be "first decided by an agency specifically equipped with expertise to resolve the regulatory issues raised."

New Mexico Ass'n for Retarded Citizens v. State of N.M., 678 F.2d 847, 850 (10th Cir. 1982) (discussing the doctrine of primary jurisdiction).

Petitioners prematurely ask this Court to wade into the legal, science and policy questions embedded in the Administrative Objections in the first instance. Petitioners assert that at the heart of the objections is a legal claim—that EPA may not leave chlorpyrifos tolerances in place pending the completion of registration review without making a safety finding in response to the Petition—and that the objections process would therefore not be informed or advanced by EPA's ruling on this subject. Petrs.' Br. at 45-46. The objections provisions of FFDCA in 21 U.S.C. § 346a(g)(2)(A) and EPA's implementing regulations at 40 C.F.R. §§ 178.20-.25 do not limit the objections process to only factual issues. While EPA will only grant a request for an *evidentiary hearing* to resolve factual disputes, purely legal and policy issues may appropriately be raised in the objections process and – whether or not an evidentiary hearing is necessary – EPA must consider and address those issues in its response. *See* 40 C.F.R. §§ 178.20(c), 178.30. Accordingly, the administrative objections process is the appropriate forum for the Agency to develop and present its views with respect to Petitioners' objections.

Not only is EPA considering the objections raised by Petitioners in the administrative process, but EPA is also considering the implications of Petitioners' proposed approach on the interplay between the statutorily mandated 15-year registration review process in FIFRA and a petition to revoke a pesticide's tolerance

under the FFDCA. EPA is statutorily required to complete a registration review of approximately 700 chemicals (including chlorpyrifos) every fifteen years. *See* EPA Website, Registration Review Process, https://www.epa.gov/pesticide-reevaluation/registration-review-process ("As of July 1, 2017, there are about 725 registration review 'cases' that include approximately 1,140 pesticide active ingredients."). This 15-year interval reflects Congress' effort to balance the need for EPA to assure that chemicals are safe for use, while at the same time recognizing the enormity of the task of reevaluating over 1,000 active ingredients[4] and EPA's limited resources.

Petitioners contend, however, that EPA, when responding to an administrative petition to revoke a chemical's tolerance under the FFDCA, must affirmatively find that a pesticide is safe under the FFDCA, which is the same as completing a partial registration review for that pesticide.[5] Petrs.' Br. at 28-30. Requiring EPA to do so in all instances may be unworkable, as *anyone* can file an administrative petition to revoke a chemical's tolerance at *any time*. 21 U.S.C. § 346a(d)(1). Moreover, Petitioners'

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[4] During a registration review EPA is required to "[a]ssess changes since a pesticide's last [registration] review," including new risk assessment methods, new studies, and new data on pesticides, to name a few. 40 C.F.R. § 155.53(a).

[5] The registration review process under FIFRA requires that a pesticide not have "unreasonable adverse effects on the environment," which has two subcomponents, (1) an unreasonable risk to humans or the environment and (2) a human dietary risk consistent with the FFDCA. 7 U.S.C. § 136(bb). Thus a full reassessment of a pesticide's tolerances under the FFDCA would satisfy the second subcomponent of the registration review process under FIFRA.

approach "would effectively give petitioners under the FFDCA the authority to re-order scheduling decisions regarding the FIFRA registration review process that Congress has vested in the administrator." 82 Fed Reg. at 16,590 (ER 34).

Petitioners objected to the Denial Order and have timely raised those objections with EPA through their Administrative Objections, which EPA is currently considering. Regardless of EPA's eventual response and final decision, this Court should let EPA address those objections in the first instance. The Agency's final decision could obviate the need for any judicial review, either in whole or in part, but even if Petitioners believe some judicial review is still necessary at that point, the Court will have the benefit of a more complete administrative record tailored to Petitioners' objections and the Agency's responses thereto.

B. The Administrative Objections Process Is Not Futile.

While the FFDCA's bar on judicial review is jurisdictional, such that no futility exception applies, Petitioners also fail to show that the administrative objections process is futile. First, Petitioners argue that exhaustion would be futile because EPA has decided to "leave Chlorpyrifos tolerances in place in the absence of a safety finding for five or more years." Petrs.' Br. at 45. This is not only inaccurate, but also based on a misreading of a December 2017 letter that EPA sent to Senator Udall. As set forth in the declaration of Charlotte Bertrand, EPA never asserted in the letter that its response to the administrative objections would be delayed for several years. *See* EPA Resp. to Petrs.' Mot. to Assign Panel, Bertrand Decl. ¶¶ 4-5 (Dkt. No. 62-2).

EPA has also not stated that it will delay its response to the administrative objections until the registration review process for chlorpyrifos is due in October 2022. *Id.* EPA will issue a final order subject to judicial review once it has completed its review of the administrative objections, at which point Petitioners are entitled to judicial review of that final order. Further, even if Petitioners were not pinning their delay argument specifically to this mistaken interpretation of the letter to Senator Udall, the amount of time needed to complete the objections process is not, in any event, relevant to the futility inquiry. By definition, *any* exhaustion requirement will delay judicial review. The question is not whether the specified administrative process will take some time, but rather, whether there is reason to believe that that investment of time will be pointless in a particular case. *See, e.g., Tesoro Refining & Marketing Co.,* 552 F.3d 868, 874 (D.C. Cir. 2009) ("The futility exception is 'quite restricted' and limited to situations 'when resort to administrative remedies [would be] 'clearly useless.'") (citations omitted).

Second, Petitioners have not presented clear evidence that the decision to be reached at the conclusion of the administrative objections process has already been determined. *See Diaz v. United Agric. Employee Welfare Benefit Plan & Trust*, 50 F.3d 1478, 1485-86 (9th Cir. 1995) (denying futility exception because "bare assertions" of futility are insufficient and "record contains nothing but speculation to suggest that the administrators would have reached a preconceived result"). A finding of futility "require[s] the 'certainty of an adverse decision' or indications that pursuit of

administrative remedies would be 'clearly useless.'" *UDC Chairs Chapter v. Bd. of Trustees of Univ. of D.C.*, 56 F.3d 1469, 1475 (D.C. Cir. 1995) (citation omitted). "The mere 'probability of administrative denial of the relief requested does not excuse failure to pursue' administrative remedies." *Id.* (citation omitted). Petitioners, a group of States, and a separate non-profit organization each filed administrative objections to the denial order. *See* Objections to March 29, 2017 Order Denying PAN/NRDC Petition to Revoke All Tolerances and Cancel All Registrations for the Pesticide Chlorpyrifos (June 5, 2017) (ER 121-64); Objections of the States of New York, et al., to EPA's March 29, 2017 Order Denying Petition to Revoke Tolerances for Chlorpyrifos and Leaving Tolerances in Effect (June 5, 2017) (ER 165-83); Objection of North Coast Rivers Alliance (June 2, 2017), EPA-HQ-OPP-2007-1005-0516 (Administrative Record Index No. 206). Petitioners have offered no evidence to suggest that the Agency will simply ignore these objections, particularly when, as noted above, many of the arguments presented were not before EPA when it issued the Denial Order. Just because Petitioners are unsatisfied with the Denial Order does not mean that there is "certainty of an adverse decision" in the ongoing administrative objections process.

Third, Petitioners argue that a Court may "dispense[] with exhaustion when it would deny review of a claim that the agency acted in derogation of clear statutory prohibitions or in excess of its statutory authority if doing so would leave parties without recourse." Petrs.' Br. at 46. Importantly, Petitioners have a clear course of

redress under the FFDCA through the administrative objections process. None of the cases cited by Petitioners is remotely similar to the case here. *See Leedom v. Kyne*, 358 U.S. 184, 187-89 (1958) (plaintiff was not limited to judicial review under the Wagner act, which contained exhaustion requirements, where plaintiff showed that "unlawful action of the Board has inflicted an injury on the petitioners for which the law, *apart from the review provisions of the Wagner Act*, affords a remedy") (emphasis added); *Oestereich v. Selective Serv. Sys. Local Bd. No. 11*, 393 U.S. 233, 238 (1968) (draft board's decision to induct divinity student into military despite clear statutory bar on induction of such students was subject to pre-induction review, rather than requiring divinity student to "be inducted and raise his protest through habeas corpus or defy induction and defend his refusal in a criminal prosecution"); *Chamber of Commerce of U.S. v. Reich*, 74 F.3d 1322, 1328 (D.C. Cir. 1996) (challenge to executive order alleged to be in violation of the National Labor Relations Act where the government conceded and did not argue that "Congress precluded non-statutory judicial review").

Indeed, contrary to Petitioners' assertions that EPA has "exceed[ed] its statuory authority," (Petrs.' Br. at 46) (citing *Bowen v. Mich. Academy of Family Physicians*, 476 U.S. 667, 681 (1986)), EPA is in fact "obey[ing] [Congress's] statutory commands" with respect to the FFDCA by reviewing the administrative objections raised by Petitioners. *See Bowen,* 476 U.S. at 680. *Bowen* is also inapposite as, there, "Respondents' attack on the regulation [was] not subject to such a requirement because there [was] no hearing, and thus no administrative remedy, to exhaust." *Id.* at

679 n.8. Here, of course, Petitioners have properly sought an administrative remedy from EPA, but still ask this Court to rule prior to EPA answering the Administrative Objections.

Accordingly, the Court should decline to exercise any discretion it has to review EPA's Denial Order prior to the conclusion of EPA's own review of Petitioners' (and others') objections to the Denial Order.

III. Petitioners' and Intervenors' Requests for Mandamus Relief Are Improper and Should Be Rejected.

Petitioners—for the first time in their opening brief—suggest to the Court that "if this Court determines it lacks jurisdiction, it should issue a writ of mandamus directing EPA to decide LULAC's objections within 60 days." Petrs.' Br. at 50. Intervenors also seek different mandamus relief, specifically an order requiring EPA to finalize the proposed revocation rule.[6] Intervenor Br. at 63 (Dkt. No. 55). These requests for mandamus relief have not been properly put before the Court pursuant to Federal Rule of Appellate Procedure 21(a). Moreover, the entire request for

[6] Intervenors' separate mandamus request is also improper because they have not established Article III standing in this matter, *see* EPA Response to Mot. Intervene (Dkt. No. 15), and, as such, may not "pursue relief that is different from that which is sought by a party with standing." *Town of Chester N.Y. v. Laroe Estates, Inc.*, 137 S. Ct. 1645, 1651 (2017) (discussing intervention under Fed. R. Civ. P. 24). Moreover, although EPA initially proposed to revoke tolerances for chlorpyrifos, it has no obligation to finalize that proposed rule. *Envtl. Integrity Project v. McCarthy*, 139 F. Supp. 3d 25, 39 (D.D.C. 2015) ("An agency may decide not to proceed with a proposed rule . . . .").

mandamus appears to be based upon nothing more than Petitioners' own misreading of a letter sent from EPA to a member of Congress. Accordingly, these mandamus requests should be summarily rejected by this Court.

A. Petitioners and Intervenors Must Request Mandamus Relief Through the Process Set Forth in Rule 21(a).

The Federal Rules of Appellate Procedure are clear. In order to request mandamus relief from a Court of Appeals, a party should petition the Court for a writ. Fed. R. App. P. 21(a). Then, after the petition has been lodged with the Court, the Court "may deny the petition without an answer. Otherwise, it must order the respondent, if any, to answer within a fixed time." *Id.* at 21(b)(1). To date, Petitioners have not filed a Rule 21 petition, nor has this Court issued any orders treating this part of Petitioners' brief as such a petition or directing EPA to file a response.

Here, Petitioners and Intervenors did not follow the proper procedures to file a petition for a writ of mandamus from this Court to order EPA to address Petitioners' administrative objections by a date certain. This Court should reject such requests absent the required petition.[7] *See United States v. Davis*, 953 F.2d 1482, 1498 (10th Cir. 1992) ("In seeking mandamus, however, we note that counsel has not complied with Fed. R. App. 21(a) concerning the requirement of filing a separate petition and proof

[7] Petitioners and Intervenors do not even attempt to provide a compelling reason why they did not comply with the Federal Rules of Appellate Procedure. Indeed, at least two of the Petitioners, PANNA and NRDC, are well aware of how to request a writ of mandamus from this Court as they did so successfully in *In re PANNA*, Case No. 14-72794 (9th Cir.).

of service on the respondent judge, as well as other parties below."); *EEOC v. Neches Butane Products Co.*, 704 F.2d 144, 152 (5th Cir. 1983) ("[A] mandamus petitioner may not fail to comply with rule 21 without providing an adequate excuse. We do not believe that it would be proper for us to consider today whether we would grant a petition for a writ of mandamus when no petition has been presented to us."); *accord Jones & Guerrero Co., Inc. v. Sealift Pac.*, 650 F.2d 1072, 1074 (9th Cir. 1981) (per curiam) ("The procedural requirements for mandamus have not been met here. *See* Fed. R. App. P. 21(a). We refuse to construe the appeal as a petition for mandamus.").

B. Petitioners' Mandamus Request Is Based on an Inaccurate Reading of an EPA Letter.

Although Petitioners' mandamus request should be rejected for failure to comply with the mandatory rules of appellate procedure, it is worth noting at this preliminary stage that Petitioners' request for mandamus relief falls woefully short of meeting the requirements set forth in *Telecommunications Research and Action Center v. FCC (TRAC)*, 750 F.2d 70 (D.C. Cir. 1984) and applied by this Court, *see e.g. Independence Mining Co. v. Babbitt*, 105 F.3d 502 (9th Cir. 1997) ("We look to the so-called TRAC factors in assessing whether relief under the APA is appropriate."). Petitioners' request is premised on a mischaracterization of a December 18, 2017 letter from EPA to Senator Tom Udall. *See* Petrs.' Br. at 50-51 (asserting that EPA intends to delay answering the administrative objections for five years). Contrary to Petitioners' suggestion, the Udall Letter did not state that EPA would wait five years

to complete the administrative objections process; it merely said that "the same individuals that support the agency's response are also working on many other competing time-sensitive deadlines and priorities." Petrs.' Br., Ordonia Decl., Ex. F at 3-4 (Dkt. No. 38-3) (Udall Letter). Petitioners appear to have conflated EPA's plans for the registration review of chlorpyrifos with EPA's plans to respond to the objections. As explained in the Declaration of Charlotte Bertrand, EPA "did not assert in the Letter that our response would be delayed for several years." Bertrand Decl. ¶ 4. "EPA's response to the administrative objections is not . . . part of [the registration review] process, nor did EPA represent in the Letter that its response to the objections will await completion of that process." *Id.* ¶ 5.

Petitioners' application of the *TRAC* factors is focused almost entirely on this mischaracterization of EPA's plans to address LULAC's administrative petition. Indeed, in assessing TRAC factor 1, Petitioners boldly and incorrectly state "EPA's plan to postpone action for five years violates the rule of reason." Petrs.' Br. at 51. But, EPA does not plan to postpone action the administrative objections for five years. Once this mistaken assumption is removed from their argument, Petitioners' rationale for being entitled to mandamus relief evaporates.[8]

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[8] Petitioners also attempt to recycle their failed argument for further mandamus relief in the *In re PANNA* case, by asking this Court to assess the delay from when the original administrative petition was filed in 2007. *See* Petrs.' Br. at 51. As this Court acknowledged, EPA "has now done what we ordered it to do," by issuing the Denial Order. *In re PANNA*, 863 F.3d at 1133.

Accordingly, Petitioners' and Intervenors' requests for mandamus relief should be rejected for failing to comply with the relevant Rules of Appellate Procedure and, in any event, fall far short of meeting their burden of proving that their right to issuance of the writ is "clear and indisputable." *In re Cal. Power Exch. Corp.*, 245 F.3d at 1120 (internal quotation marks and citation omitted).

CONCLUSION

For the foregoing reasons, this Petition should be dismissed.

Respectfully submitted,

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MARCH 8, 2018

CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(A)

I hereby certify that this brief complies with the requirements of Fed. R. App. P. 32(a)(5) and (6) because it has been prepared in 14-point Garamond, a proportionally spaced font.

I further certify that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains **8,480** words, excluding the parts of the brief exempted under Rule 32(a)(7)(B)(iii), according to the count of Microsoft Word.

s/Phillip R. Dupré
PHILLIP R. DUPRÉ

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on March 8, 2018. I certify that all participants in the case registered as CM/ECF users will receive service via the appellate CM/ECF system. I further certify that those participants listed below that are not registered as CM/ECF users will receive service via First Class Mail, postage prepaid.

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STATUTORY AND REGULATORY ADDENDUM

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"(C) As promptly as possible but in no event more than one year after submission of a State plan, the Administrator shall approve the State plan or disapprove it and indicate the reasons for disapproval. Consideration of plans resubmitted by States shall be expedited.

"(4) One year after the enactment of this Act the Administrator shall have promulgated and shall make effective regulations relating to the registration of establishments, permits for experimental use, and the keeping of books and records under the provisions of this Act.

"(d) No person shall be subject to any criminal or civil penalty imposed by the Federal Insecticide, Fungicide, and Rodenticide Act, as amended by this Act, for any act (or failure to act) occurring before the expiration of 60 days after the Administrator has published effective regulations in the Federal Register and taken such other action as may be necessary to permit compliance with the provisions under which the penalty is to be imposed.

"(e) For purposes of determining any criminal or civil penalty or liability to any third person in respect of any act or omission occurring before the expiration of the periods referred to in this section, the Federal Insecticide, Fungicide, and Rodenticide Act shall be treated as continuing in effect as if this Act had not been enacted."

SHORT TITLE OF 2012 AMENDMENT

Pub. L. 112-177, §1, Sept. 28, 2012, 126 Stat. 1327, provided that: "This Act [amending sections 136a-1 and 136w-8 of this title and section 346a of Title 21, Food and Drugs, and enacting provisions set out as notes under section 136a-1 of this title] may be cited as the 'Pesticide Registration Improvement Extension Act of 2012'."

SHORT TITLE OF 2007 AMENDMENT

Pub. L. 110-94, §1, Oct. 9, 2007, 121 Stat. 1000, provided that: "This Act [amending sections 136a, 136a-1, and 136w-8 of this title and section 346a of Title 21, Food and Drugs, and enacting provisions set out as a note under section 136a of this title] may be cited as the 'Pesticide Registration Improvement Renewal Act'."

SHORT TITLE OF 2004 AMENDMENT

Pub. L. 108-199, div. G, title V, §501(a), Jan. 23, 2004, 118 Stat. 419, provided that: "This section [enacting section 136w-8 of this title, amending sections 136a, 136a-1, 136x, and 136y of this title, and enacting provisions set out as notes under section 136a of this title and section 346a of Title 21, Food and Drugs] may be cited as the 'Pesticide Registration Improvement Act of 2003'."

SHORT TITLE OF 1996 AMENDMENT

Pub. L. 104-170, §1, Aug. 3, 1996, 110 Stat. 1489, provided that: "This Act [enacting sections 136i-2, 136r-1, and 136w-5 to 136w-7 of this title, amending this section, sections 136a, 136a-1, 136d, 136q, 136s, 136w, 136w-3, 136x, and 136y of this title, and sections 321, 331, 333, 342, and 346a of Title 21, Food and Drugs, and enacting provisions set out as notes under section 136i-2 of this title and sections 301 and 346a of Title 21] may be cited as the 'Food Quality Protection Act of 1996'."

[Another Food Quality Protection Act of 1996 was enacted by Pub. L. 104-170, title IV, 110 Stat. 1513, see section 401(a) of Pub. L. 104-170, set out as a note under section 301 of Title 21, Food and Drugs.]

SHORT TITLE OF 1988 AMENDMENT

Pub. L. 100-532, §1(a), Oct. 25, 1988, 102 Stat. 2654, provided that: "This Act [enacting section 136a-1 of this title, amending this section and sections 136a to 136d, 136f to 136q, 136s, 136v to 136w-2, and 136y of this title, and enacting provisions set out as notes under this section and sections 136m and 136y of this title] may be cited as the 'Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1988'."

SHORT TITLE OF 1978 AMENDMENT

Pub. L. 95-396, §29, Sept. 30, 1978, 92 Stat. 842, provided that: "This Act [enacting sections 136w-1 to 136w-4 of this title, amending this section and sections 136a to 136f, 136h, 136j, 136l, 136o, 136q, 136r, 136u to 136w, 136x, and 136y of this title, enacting provisions set out as notes under sections 136a, 136o, and 136w-4 of this title, and amending provisions set out as a note under this section] may be cited as the 'Federal Pesticide Act of 1978'."

SHORT TITLE

Pub. L. 92-516, §1, Oct. 21, 1972, 86 Stat. 973, provided: "That this Act [amending this subchapter generally, enacting notes set out under this section, and amending sections 1261 and 1471 of Title 15, Commerce and Trade, and sections 321 and 346a of Title 21, Foods and Drugs] may be cited as the 'Federal Environmental Pesticide Control Act of 1972'."

Act June 25, 1947, ch. 125, §1(a), as added by Pub. L. 92-516, §2, Oct. 21, 1972, 86 Stat. 973, provided that: "This Act [enacting this subchapter] may be cited as the 'Federal Insecticide, Fungicide, and Rodenticide Act'."

TERMINATION OF TRUST TERRITORY OF THE PACIFIC ISLANDS

For termination of Trust Territory of the Pacific Islands, see note set out preceding section 1681 of Title 48, Territories and Insular Possessions.

FEDERAL COMPLIANCE WITH POLLUTION CONTROL STANDARDS

For provisions relating to the responsibility of the head of each Executive agency for compliance with applicable pollution control standards, see Ex. Ord. No. 12088, Oct. 13, 1978, 43 F.R. 47707, set out as a note under section 4321 of Title 42, The Public Health and Welfare.

§ 136a. Registration of pesticides

(a) Requirement of registration

Except as provided by this subchapter, no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this subchapter and that is not the subject of an experimental use permit under section 136c of this title or an emergency exemption under section 136p of this title.

(b) Exemptions

A pesticide which is not registered with the Administrator may be transferred if—

(1) the transfer is from one registered establishment to another registered establishment operated by the same producer solely for packaging at the second establishment or for use as a constituent part of another pesticide produced at the second establishment; or

(2) the transfer is pursuant to and in accordance with the requirements of an experimental use permit.

(c) Procedure for registration

(1) Statement required

Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

(A) the name and address of the applicant and of any other person whose name will appear on the labeling;

(B) the name of the pesticide;

(C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;

(D) the complete formula of the pesticide;

(E) a request that the pesticide be classified for general use or for restricted use, or for both; and

(F) except as otherwise provided in paragraph (2)(D), if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

(i) With respect to pesticides containing active ingredients that are initially registered under this subchapter after September 30, 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide, except that such permission shall not be required in the case of defensive data.

(ii) The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after August 3, 1996, and within 7 years of the commencement of the exclusive use period, up to a total of 3 additional years for all minor uses registered by the Administrator if the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that—

(I) there are insufficient efficacious alternative registered pesticides available for the use;

(II) the alternatives to the minor use pesticide pose greater risks to the environment or human health;

(III) the minor use pesticide plays or will play a significant part in managing pest resistance; or

(IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The registration of a pesticide for a minor use on a crop grouping established by the Administrator shall be considered for purposes of this clause 1 minor use for each representative crop for which data are provided in the crop grouping. Any additional exclusive use period under this clause shall be modified as appropriate or terminated if the registrant voluntarily cancels the product or deletes from the registration the minor uses which formed the basis for the extension of the additional exclusive use period or if the Administrator determines that the registrant is not actually marketing the product for such minor uses.

(iii) Except as otherwise provided in clause (i), with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for reregistration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this

subchapter, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take action and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation.

(iv) After expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under clauses (i), (ii), and (iii), the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data.

(v) The period of exclusive use provided under clause (ii) shall not take effect until 1 year after August 3, 1996, except where an applicant or registrant is applying for the registration of a pesticide containing an active ingredient not previously registered.

(vi) With respect to data submitted after August 3, 1996, by an applicant or registrant to support an amendment adding a new use to an existing registration that does not retain any period of exclusive use, if such data relates solely to a minor use of a pesticide, such data shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application for a minor use by another person during the period of 10 years following the date of submission of such data. The applicant or registrant at the time the new minor use is requested shall notify the Administrator that to the best of their knowledge the exclusive use period for the pesticide has expired and that the data pertaining solely to the minor use of a pesticide is eligible for the provisions of this paragraph. If the minor use registration which is supported by data submitted pursuant to this subsection is voluntarily canceled or if such data are subsequently used to support a nonminor use, the data shall no longer be subject to the exclusive use provisions of this clause but shall instead be considered by the Administrator in accordance with the provisions of clause (i), as appropriate.

(G) If the applicant is requesting that the registration or amendment to the registration of a pesticide be expedited, an explanation of the basis for the request must be submitted, in accordance with paragraph (10) of this subsection.

(2) Data in support of registration

(A) In general

The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter the Administrator requires any additional kind of information under subparagraph (B) of this paragraph, the Administrator shall permit sufficient time for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, the public health and agricultural need for such minor use, and the level and degree of potential beneficial or adverse effects on man and the environment. The Administrator shall not require a person to submit, in relation to a registration or reregistration of a pesticide for minor agricultural use under this subchapter, any field residue data from a geographic area where the pesticide will not be registered for such use. In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 136h of this title, within 30 days after the Administrator registers a pesticide under this subchapter the Administrator shall make available to the public the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to the Administrator's decision.

(B) Additional data

(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person.

(ii) Each registrant of such pesticide shall provide evidence within ninety days after receipt of notification that it is taking appropriate steps to secure the additional data that are required. Two or more registrants may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise the Administrator of their intent within ninety days after notification. Any registrant who agrees to share in the

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cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of such registration. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iii) If, at the end of sixty days after advising the Administrator of their agreement to develop jointly, or share in the cost of developing, data, the registrants have not further agreed on the terms of the data development arrangement or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. All parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iv) Notwithstanding any other provision of this subchapter, if the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph, to participate in a procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend. If a hearing is requested, a hearing shall be conducted under section 136d(d) of this title. The only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this subchapter. If a hearing is held, a decision after completion of such hearing shall be final. Notwithstanding any other provision of this subchapter, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.

(v) Any data submitted under this subparagraph shall be subject to the provisions of paragraph (1)(D). Whenever such data are submitted jointly by two or more registrants, an agent shall be agreed on at the time of the joint submission to handle any subsequent data compensation matters for the joint submitters of such data.

(vi) Upon the request of a registrant the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under section 136a–1 of this title for the other uses of the pesticide established as of August 3, 1996, if—

(I) the data to support other uses of the pesticide on a food are being provided;

(II) the registrant, in submitting a request for such an extension, provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;

(III) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under section 136a–1 of this title; and

(IV) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) regarding the continued reg-

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istration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this clause, the Administrator may take action to modify or revoke the extension under this clause if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide, in writing to the registrant, a notice revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date established by the Administrator for the submission of the data.

(vii) If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this clause in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under section 136a–1 of this title for the supported uses identified pursuant to this clause unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On the basis of such determination, the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 136d(f)(1) of this title. If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of this subparagraph regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 136d(f)(2) of this title. Notwithstanding the provisions of this clause, the Administrator may deny, modify, or revoke the temporary extension under this subparagraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(viii)(I) If data required to support registration of a pesticide under subparagraph (A) is requested by a Federal or State regulatory authority, the Administrator shall, to the extent practicable, coordinate data requirements, test protocols, timetables, and standards of review and reduce burdens and redundancy caused to the registrant by multiple requirements on the registrant.

(II) The Administrator may enter into a cooperative agreement with a State to carry out subclause (I).

(III) Not later than 1 year after August 3, 1996, the Administrator shall develop a process to identify and assist in alleviating future disparities between Federal and State data requirements.

(C) Simplified procedures

Within nine months after September 30, 1978, the Administrator shall, by regulation, prescribe simplified procedures for the registration of pesticides, which shall include the provisions of subparagraph (D) of this paragraph.

(D) Exemption

No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into the pesticide that is the subject of the application shall be required to—

(i) submit or cite data pertaining to such purchased product; or

(ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.

(E) Minor use waiver

In handling the registration of a pesticide for a minor use, the Administrator may waive otherwise applicable data requirements if the Administrator determines that the absence of such data will not prevent the Administrator from determining—

(i) the incremental risk presented by the minor use of the pesticide; and

(ii) that such risk, if any, would not be an unreasonable adverse effect on the environment.

(3) Application

(A) In general

The Administrator shall review the data after receipt of the application and shall, as expeditiously as possible, either register the pesticide in accordance with paragraph (5), or notify the applicant of the Administrator's determination that it does not comply with the provisions of the subchapter in accordance with paragraph (6).

(B) Identical or substantially similar

(i) The Administrator shall, as expeditiously as possible, review and act on any application received by the Administrator that—

(I) proposes the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that would differ in composition and labeling from such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment; or

(II) proposes an amendment to the registration of a registered pesticide that does not require scientific review of data.

(ii) In expediting the review of an application for an action described in clause (i), the Administrator shall—

(I) review the application in accordance with section 136w-8(f)(4)(B) of this title and, if the application is found to be incomplete, reject the application;

(II) not later than the applicable decision review time established pursuant to section 136w-8(f)(4)(B) of this title, or, if no review time is established, not later than 90 days after receiving a complete application, notify the registrant if the application has been granted or denied; and

(III) if the application is denied, notify the registrant in writing of the specific reasons for the denial of the application.

(C) Minor use registration

(i) The Administrator shall, as expeditiously as possible, review and act on any complete application—

(I) that proposes the initial registration of a new pesticide active ingredient if the active ingredient is proposed to be registered solely for minor uses, or proposes a registration amendment solely for minor uses to an existing registration; or

(II) for a registration or a registration amendment that proposes significant minor uses.

(ii) For the purposes of clause (i)—

(I) the term "as expeditiously as possible" means that the Administrator shall, to the greatest extent practicable, complete a review and evaluation of all data, submitted with a complete application, within 12 months after the submission of the complete application, and the failure of the Administrator to complete such a review and evaluation under clause (i) shall not be subject to judicial review; and

(II) the term "significant minor uses" means 3 or more minor uses proposed for every nonminor use, a minor use that would, in the judgment of the Administrator, serve as a replacement for any use which has been canceled in the 5 years preceding the receipt of the application, or a minor use that in the opinion of the Administrator would avoid the reissuance of an emergency exemption under section 136p of this title for that minor use.

(D) Adequate time for submission of minor use data

If a registrant makes a request for a minor use waiver, regarding data required by the Administrator, pursuant to paragraph (2)(E), and if the Administrator denies in whole or in part such data waiver request, the registrant shall have a full-time period for providing such data. For purposes of this subparagraph, the term "full-time period" means the time period originally established by the Administrator for submission of such data, beginning with the date of receipt by the registrant of the Administrator's notice of denial.

(4) Notice of application

The Administrator shall publish in the Federal Register, promptly after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern. The notice shall provide for a period of 30 days in which any Federal agency or any other interested person may comment.

(5) Approval of registration

The Administrator shall register a pesticide if the Administrator determines that, when considered with any restrictions imposed under subsection (d) of this section—

(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this subchapter;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other. In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy. If a pesticide is found to be efficacious by any State under section 136v(c) of this title, a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in such State.

(6) Denial of registration

If the Administrator determines that the requirements of paragraph (5) for registration are not satisfied, the Administrator shall notify the applicant for registration of the Administrator's determination and of the Administrator's reasons (including the factual basis) therefor, and that, unless the applicant corrects the conditions and notifies the Administrator thereof during the 30-day period beginning with the day after the date on which the applicant receives the notice, the Administrator may refuse to register the pesticide.

Whenever the Administrator refuses to register a pesticide, the Administrator shall notify the applicant of the Administrator's decision and of the Administrator's reasons (including the factual basis) therefor. The Administrator shall promptly publish in the Federal Register notice of such denial of registration and the reasons therefor. Upon such notification, the applicant for registration or other interested person with the concurrence of the applicant shall have the same remedies as provided for in section 136d of this title.

(7) *Registration under special circumstances*

Notwithstanding the provisions of paragraph (5)—

(A) The Administrator may conditionally register or amend the registration of a pesticide if the Administrator determines that (i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and (ii) approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. An applicant seeking conditional registration or amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data because it has not yet been generated, the Administrator may register or amend the registration of the pesticide under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this subchapter.

(B) The Administrator may conditionally amend the registration of a pesticide to permit additional uses of such pesticide notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that (i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. Notwithstanding the foregoing provisions of this subparagraph, no registration of a pesticide may be amended to permit an additional use of such pesticide if the Administrator has issued a notice stating that such pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure enumerated in regulations issued under this subchapter, and during the pendency of any risk-benefit evaluation initiated by such notice, if (I) the additional use of such pesticide involves a major food or feed crop, or (II) the additional use of such pesticide involves a minor food or feed crop and the Administrator determines, with the concurrence of the Secretary of Agriculture, there is available an effective alternative pesticide that does not meet or exceed such risk criteria. An applicant seeking amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data (other than data pertaining to the proposed additional use) because it has not yet been generated, the Administrator may amend the registration under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this subchapter.

(C) The Administrator may conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the condition that by the end of such period the Administrator receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this subchapter, and on such other conditions as the Administrator may prescribe. A conditional registration under this subparagraph shall be granted only if the Administrator determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.

(8) Interim administrative review

Notwithstanding any other provision of this subchapter, the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses prior to initiating a formal action to cancel, suspend, or deny registration of such pesticide, required under this subchapter, unless such interim administrative process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment. Notice of the definition of the terms "validated test" and "other significant evidence" as used herein shall be published by the Administrator in the Federal Register.

(9) Labeling

(A) Additional statements

Subject to subparagraphs (B) and (C), it shall not be a violation of this subchapter for a registrant to modify the labeling of an antimicrobial pesticide product to include relevant information on product efficacy, product composition, container composition or design, or other characteristics that do not relate to any pesticidal claim or pesticidal activity.

(B) Requirements

Proposed labeling information under subparagraph (A) shall not be false or misleading, shall not conflict with or detract from any statement required by law or the Administrator as a condition of registration, and shall be substantiated on the request of the Administrator.

(C) Notification and disapproval

(i) Notification

A registration may be modified under subparagraph (A) if—

(I) the registrant notifies the Administrator in writing not later than 60 days prior to distribution or sale of a product bearing the modified labeling; and

(II) the Administrator does not disapprove of the modification under clause (ii).

(ii) Disapproval

Not later than 30 days after receipt of a notification under clause (i), the Administrator may disapprove the modification by sending the registrant notification in writing stating that the proposed language is not acceptable and stating the reasons why the Administrator finds the proposed modification unacceptable.

(iii) Restriction on sale

A registrant may not sell or distribute a product bearing a disapproved modification.

(iv) Objection

A registrant may file an objection in writing to a disapproval under clause (ii) not later than 30 days after receipt of notification of the disapproval.

(v) Final action

A decision by the Administrator following receipt and consideration of an objection filed under clause (iv) shall be considered a final agency action.

(D) Use dilution

The label or labeling required under this subchapter for an antimicrobial pesticide that is or may be diluted for use may have a different statement of caution or protective measures for use of the recommended diluted solution of the pesticide than for use of a concentrate of the pesticide if the Administrator determines that—

(i) adequate data have been submitted to support the statement proposed for the diluted solution uses; and

(ii) the label or labeling provides adequate protection for exposure to the diluted solution of the pesticide.

(10) Expedited registration of pesticides

(A) Not later than 1 year after August 3, 1996, the Administrator shall, utilizing public comment, develop procedures and guidelines, and expedite the review of an application for registration of a pesticide or an amendment to a registration that satisfies such guidelines.

(B) Any application for registration or an amendment, including biological and conventional pesticides, will be considered for expedited review under this paragraph. An application for registration or an amendment shall qualify for expedited review if use of the pesticide proposed by the application may reasonably be expected to accomplish 1 or more of the following:

(i) Reduce the risks of pesticides to human health.

(ii) Reduce the risks of pesticides to nontarget organisms.

(iii) Reduce the potential for contamination of groundwater, surface water, or other valued environmental resources.

(iv) Broaden the adoption of integrated pest management strategies, or make such strategies more available or more effective.

(C) The Administrator, not later than 30 days after receipt of an application for expedited review, shall notify the applicant whether the application is complete. If it is found to be incomplete, the Administrator may either reject the request for expedited review or ask the applicant for additional information to satisfy the guidelines developed under subparagraph (A).

(d) Classification of pesticides

(1) Classification for general use, restricted use, or both

(A) As a part of the registration of a pesticide the Administrator shall classify it as being for general use or for restricted use. If the Administrator determines that some of the uses for which the pesticide is registered should be for general use and that other uses for which it is registered should be for restricted use, the Administrator shall classify it for both general use and restricted use. Pesticide uses may be classified by regulation on the initial classification, and registered pesticides may be classified prior to reregistration. If some of the uses of the pesticide are classified for general use, and other uses are classified for restricted use, the directions relating to its general uses shall be clearly separated and distinguished from those directions relating to its restricted uses. The Administrator may require that its packaging and labeling for restricted uses shall be clearly distinguishable from its packaging and labeling for general uses.

(B) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, will not generally cause unreasonable adverse effects on the environment, the Administrator will classify the pesticide, or the particular use or uses of the pesticide to which the determination applies, for general use.

(C) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, may generally cause, without addi-

tional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator, the Administrator shall classify the pesticide, or the particular use or uses to which the determination applies, for restricted use:

(i) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that the acute dermal or inhalation toxicity of the pesticide presents a hazard to the applicator or other persons, the pesticide shall be applied for any use to which the restricted classification applies only by or under the direct supervision of a certified applicator.

(ii) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such other restrictions as the Administrator may provide by regulation. Any such regulation shall be reviewable in the appropriate court of appeals upon petition of a person adversely affected filed within 60 days of the publication of the regulation in final form.

(2) Change in classification

If the Administrator determines that a change in the classification of any use of a pesticide from general use to restricted use is necessary to prevent unreasonable adverse effects on the environment, the Administrator shall notify the registrant of such pesticide of such determination at least forty-five days before making the change and shall publish the proposed change in the Federal Register. The registrant, or other interested person with the concurrence of the registrant, may seek relief from such determination under section 136d(b) of this title.

(3) Change in classification from restricted use to general use

The registrant of any pesticide with one or more uses classified for restricted use may petition the Administrator to change any such classification from restricted to general use. Such petition shall set out the basis for the registrant's position that restricted use classification is unnecessary because classification of the pesticide for general use would not cause unreasonable adverse effects on the environment. The Administrator, within sixty days after receiving such petition, shall notify the registrant whether the petition has been granted or denied. Any denial shall contain an explanation therefor and any such denial shall be subject to judicial review under section 136n of this title.

(e) Products with same formulation and claims

Products which have the same formulation, are manufactured by the same person, the labeling of which contains the same claims, and the labels of which bear a designation identifying the product as the same pesticide may be registered as a single pesticide; and additional names and labels shall be added to the registration by supplemental statements.

(f) Miscellaneous

(1) Effect of change of labeling or formulation

If the labeling or formulation for a pesticide is changed, the registration shall be amended to reflect such change if the Administrator determines that the change will not violate any provision of this subchapter.

(2) Registration not a defense

In no event shall registration of an article be construed as a defense for the commission of any offense under this subchapter. As long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the subchapter.

(3) Authority to consult other Federal agencies

In connection with consideration of any registration or application for registration under this section, the Administrator may consult with any other Federal agency.

(4) Mixtures of nitrogen stabilizers and fertilizer products

Any mixture or other combination of—

(A) 1 or more nitrogen stabilizers registered under this subchapter; and

(B) 1 or more fertilizer products,

shall not be subject to the provisions of this section or sections 136a–1, 136c, 136e, 136m, and 136o(a)(2) of this title if the mixture or other combination is accompanied by the labeling required under this subchapter for the nitrogen stabilizer contained in the mixture or other combination, the mixture or combination is mixed or combined in accordance with such labeling, and the mixture or combination does not contain any active ingredient other than the nitrogen stabilizer.

(g) Registration review

(1) General rule

(A) Periodic review

(i) In general

The registrations of pesticides are to be periodically reviewed.

(ii) Regulations

In accordance with this subparagraph, the Administrator shall by regulation establish a procedure for accomplishing the periodic review of registrations.

(iii) Initial registration review

The Administrator shall complete the registration review of each pesticide or pesticide case, which may be composed of 1 or more active ingredients and the products associated with the active ingredients, not later than the later of—

(I) October 1, 2022; or

(II) the date that is 15 years after the date on which the first pesticide containing a new active ingredient is registered.

(iv) Subsequent registration review

Not later than 15 years after the date on which the initial registration review is

completed under clause (iii) and each 15 years thereafter, the Administrator shall complete a subsequent registration review for each pesticide or pesticide case.

(v) Cancellation

No registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of section 136d of this title.

(B) Docketing

(i) In general

Subject to clause (ii), after meeting with 1 or more individuals that are not government employees to discuss matters relating to a registration review, the Administrator shall place in the docket minutes of the meeting, a list of attendees, and any documents exchanged at the meeting, not later than the earlier of—

(I) the date that is 45 days after the meeting; or

(II) the date of issuance of the registration review decision.

(ii) Protected information

The Administrator shall identify, but not include in the docket, any confidential business information the disclosure of which is prohibited by section 136h of this title.

(C) Limitation

Nothing in this subsection shall prohibit the Administrator from undertaking any other review of a pesticide pursuant to this subchapter.

(2) Data

(A) Submission required

The Administrator shall use the authority in subsection (c)(2)(B) of this section to require the submission of data when such data are necessary for a registration review.

(B) Data submission, compensation, and exemption

For purposes of this subsection, the provisions of subsections (c)(1), (c)(2)(B), and (c)(2)(D) of this section shall be utilized for and be applicable to any data required for registration review.

(h) Registration requirements for antimicrobial pesticides

(1) Evaluation of process

To the maximum extent practicable consistent with the degrees of risk presented by an antimicrobial pesticide and the type of review appropriate to evaluate the risks, the Administrator shall identify and evaluate reforms to the antimicrobial registration process that would reduce review periods existing as of August 3, 1996, for antimicrobial pesticide product registration applications and applications for amended registration of antimicrobial pesticide products, including—

(A) new antimicrobial active ingredients;

(B) new antimicrobial end-use products;

(C) substantially similar or identical antimicrobial pesticides; and

(D) amendments to antimicrobial pesticide registrations.

(2) Review time period reduction goal

Each reform identified under paragraph (1) shall be designed to achieve the goal of reducing the review period following submission of a complete application, consistent with the degree of risk, to a period of not more than—

(A) 540 days for a new antimicrobial active ingredient pesticide registration;

(B) 270 days for a new antimicrobial use of a registered active ingredient;

(C) 120 days for any other new antimicrobial product;

(D) 90 days for a substantially similar or identical antimicrobial product;

(E) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

(F) 120 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this paragraph.

(3) Implementation

(A) Proposed rulemaking

(i) Issuance

Not later than 270 days after August 3, 1996, the Administrator shall publish in the Federal Register proposed regulations to accelerate and improve the review of antimicrobial pesticide products designed to implement, to the extent practicable, the goals set forth in paragraph (2).

(ii) Requirements

Proposed regulations issued under clause (i) shall—

(I) define the various classes of antimicrobial use patterns, including household, industrial, and institutional disinfectants and sanitizing pesticides, preservatives, water treatment, and pulp and paper mill additives, and other such products intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms, or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime;

(II) differentiate the types of review undertaken for antimicrobial pesticides;

(III) conform the degree and type of review to the risks and benefits presented by antimicrobial pesticides and the function of review under this subchapter, considering the use patterns of the product, toxicity, expected exposure, and product type;

(IV) ensure that the registration process is sufficient to maintain antimicrobial pesticide efficacy and that antimicrobial pesticide products continue to meet product performance standards and effectiveness levels for each type of label claim made; and

(V) implement effective and reliable deadlines for process management.

(iii) Comments

In developing the proposed regulations, the Administrator shall solicit the views from registrants and other affected parties to maximize the effectiveness of the rule development process.

(B) Final regulations

(i) Issuance

The Administrator shall issue final regulations not later than 240 days after the close of the comment period for the proposed regulations.

(ii) Failure to meet goal

If a goal described in paragraph (2) is not met by the final regulations, the Administrator shall identify the goal, explain why the goal was not attained, describe the element of the regulations included instead, and identify future steps to attain the goal.

(iii) Requirements

In issuing final regulations, the Administrator shall—

(I) consider the establishment of a certification process for regulatory actions involving risks that can be responsibly managed, consistent with the degree of risk, in the most cost-efficient manner;

(II) consider the establishment of a certification process by approved laboratories as an adjunct to the review process;

(III) use all appropriate and cost-effective review mechanisms, including—

(aa) expanded use of notification and non-notification procedures;

(bb) revised procedures for application review; and

(cc) allocation of appropriate resources to ensure streamlined management of antimicrobial pesticide registrations; and

(IV) clarify criteria for determination of the completeness of an application.

(C) Expedited review

This subsection does not affect the requirements or extend the deadlines or review periods contained in subsection (c)(3) of this section.

(D) Alternative review periods

If the final regulations to carry out this paragraph are not effective 630 days after August 3, 1996, until the final regulations become effective, the review period, beginning on the date of receipt by the Agency of a complete application, shall be—

(i) 2 years for a new antimicrobial active ingredient pesticide registration;

(ii) 1 year for a new antimicrobial use of a registered active ingredient;

(iii) 180 days for any other new antimicrobial product;

(iv) 90 days for a substantially similar or identical antimicrobial product;

(v) 90 days for an amendment to an antimicrobial registration that does not require scientific review of data; and

(vi) 120 days for an amendment to an antimicrobial registration that requires scientific review of data and that is not otherwise described in this subparagraph.

(E) Wood preservatives

An application for the registration, or for an amendment to the registration, of a wood preservative product for which a claim of pesticidal activity listed in section 136(mm) of this title is made (regardless of any other pesticidal claim that is made with respect to the product) shall be reviewed by the Administrator within the same period as that established under this paragraph for an antimicrobial pesticide product application, consistent with the degree of risk posed by the use of the wood preservative product, if the application requires the applicant to satisfy the same data requirements as are required to support an application for a wood preservative product that is an antimicrobial pesticide.

(F) Notification

(i) In general

Subject to clause (iii), the Administrator shall notify an applicant whether an application has been granted or denied not later than the final day of the appropriate review period under this paragraph, unless the applicant and the Administrator agree to a later date.

(ii) Final decision

If the Administrator fails to notify an applicant within the period of time required under clause (i), the failure shall be considered an agency action unlawfully withheld or unreasonably delayed for purposes of judicial review under chapter 7 of title 5.

(iii) Exemption

This subparagraph does not apply to an application for an antimicrobial pesticide that is filed under subsection (c)(3)(B) of this section prior to 90 days after August 3, 1996.

(iv) Limitation

Notwithstanding clause (ii), the failure of the Administrator to notify an applicant for an amendment to a registration for an antimicrobial pesticide shall not be judicially reviewable in a Federal or State court if the amendment requires scientific review of data within—

(I) the time period specified in subparagraph (D)(vi), in the absence of a final regulation under subparagraph (B); or

(II) the time period specified in paragraph (2)(F), if adopted in a final regulation under subparagraph (B).

(4) Annual report

(A) Submission

Beginning on August 3, 1996, and ending on the date that the goals under paragraph (2) are achieved, the Administrator shall, not later than March 1 of each year, prepare and

submit an annual report to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

(B) Requirements

A report submitted under subparagraph (A) shall include a description of—

(i) measures taken to reduce the backlog of pending registration applications;

(ii) progress toward achieving reforms under this subsection; and

(iii) recommendations to improve the activities of the Agency pertaining to antimicrobial registrations.

(June 25, 1947, ch. 125, § 3, as added Pub. L. 92–516, § 2, Oct. 21, 1972, 86 Stat. 979; amended Pub. L. 94–140, § 12, Nov. 28, 1975, 89 Stat. 755; Pub. L. 95–396, §§ 2(a), 3–8, Sept. 30, 1978, 92 Stat. 820, 824–827; Pub. L. 100–532, title I, §§ 102(b), 103, title VI, § 601(b)(1), title VIII, § 801(b), Oct. 25, 1988, 102 Stat. 2667, 2677, 2680; Pub. L. 101–624, title XIV, § 1492, Nov. 28, 1990, 104 Stat. 3628; Pub. L. 102–237, title X, § 1006(a)(3), (b)(1), (2), (c), Dec. 13, 1991, 105 Stat. 1894–1896; Pub. L. 104–170, title I, §§ 105(b), 106(b), title II, §§ 210(b), (c)(1), (d), (e), (f)(2), 222–224, 231, 250, Aug. 3, 1996, 110 Stat. 1491, 1494–1497, 1499, 1503, 1504, 1508, 1510; Pub. L. 108–199, div. G, title V, § 501(b), Jan. 23, 2004, 118 Stat. 419; Pub. L. 110–94, §§ 2, 3, Oct. 9, 2007, 121 Stat. 1000.)

PRIOR PROVISIONS

A prior section 3 of act June 25, 1947, was classified to section 135a of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

AMENDMENTS

2007—Subsec. (c)(3)(B)(ii)(I). Pub. L. 110–94, § 2(1), substituted "review the application in accordance with section 136w–8(f)(4)(B) of this title and," for "within 45 days after receiving the application, notify the registrant whether or not the application is complete and,".

Subsec. (c)(3)(B)(ii)(II). Pub. L. 110–94, § 2(2), substituted "not later than the applicable decision review time established pursuant to section 136w–8(f)(4)(B) of this title, or, if no review time is established, not later than" for "within".

Subsec. (g)(1)(A). Pub. L. 110–94, § 3(1), designated first sentence as cl. (i) and inserted heading, designated second sentence as cl. (ii), inserted heading, and substituted "In accordance with this subparagraph, the Administrator" for "The Administrator", added cls. (iii) and (iv), designated fourth sentence as cl. (v) and inserted heading, and struck out third sentence which read as follows: "The goal of these regulations shall be a review of a pesticide's registration every 15 years."

Subsec. (g)(1)(B), (C). Pub. L. 110–94, § 3(2), (3), added subpar. (B) and redesignated former subpar. (B) as (C).

2004—Subsec. (h)(2)(F). Pub. L. 108–199, § 501(b)(1), substituted "120 days" for "90 to 180 days".

Subsec. (h)(3)(D)(vi). Pub. L. 108–199, § 501(b)(2)(A), substituted "120 days" for "240 days".

Subsec. (h)(3)(F)(iv). Pub. L. 108–199, § 501(b)(2)(B), added cl. (iv).

1996—Subsec. (c)(1)(F)(ii) to (vi). Pub. L. 104–170, § 210(b), added cls. (ii), (v), and (vi), redesignated former cls. (ii) and (iii) as (iii) and (iv), respectively, and in cl. (iv) substituted "(i), (ii), and (iii)" for "(i) and (ii)".

Subsec. (c)(1)(G). Pub. L. 104–170, § 250(1), added subpar. (G).

Subsec. (c)(2)(A). Pub. L. 104–170, §§ 210(d)(1), 231, inserted heading, inserted "the public health and agricultural need for such minor use," after "pattern of use,", and substituted "potential beneficial or adverse effects on man and the environment" for "potential exposure of man and the environment to the pesticide".

Subsec. (c)(2)(B). Pub. L. 104–170, § 210(d)(2), inserted heading.

Subsec. (c)(2)(B)(vi). Pub. L. 104–170, § 210(c)(1), added cl. (vi).

Subsec. (c)(2)(B)(vii). Pub. L. 104–170, § 210(f)(2), added cl. (vii).

Subsec. (c)(2)(B)(viii). Pub. L. 104–170, § 222, added cl. (viii).

Subsec. (c)(2)(C). Pub. L. 104–170, § 210(d)(3), inserted heading.

Subsec. (c)(2)(E). Pub. L. 104–170, § 210(d)(4), added subpar. (E).

Subsec. (c)(3)(A), (B). Pub. L. 104–170, § 210(e)(1), (2), inserted headings.

Subsec. (c)(3)(C), (D). Pub. L. 104–170, § 210(e)(3), added subpars. (C) and (D).

Subsec. (c)(9). Pub. L. 104–170, § 223, added par. (9).

Subsec. (c)(10). Pub. L. 104–170, § 250(2), added par. (10).

Subsec. (f)(4). Pub. L. 104–170, § 105(b), added par. (4).

Subsec. (g). Pub. L. 104–170, § 106(b), added subsec. (g).

Subsec. (h). Pub. L. 104–170, § 224, added subsec. (h).

1991—Subsec. (c)(1)(D). Pub. L. 102–237, § 1006(a)(3)(B), (C), added subpar. (D) and redesignated former subpar. (D) as (F).

Subsec. (c)(1)(E). Pub. L. 102–237, § 1006(a)(3)(A), (C), added subpar. (E) and struck out former subpar. (E) which read as follows: "the complete formula of the pesticide; and".

Subsec. (c)(1)(F). Pub. L. 102–237, § 1006(a)(3)(A), (B), (D), redesignated former subpar. (D) as (F), in cl. (i) substituted "With" for "with" and a period for semicolon at end, in cl. (ii) substituted "Except" for "except" and a period for semicolon at end, in cl. (iii) substituted "After" for "after" and a period for semicolon at end, and struck out former subpar. (F) which read as follows: "a request that the pesticide be classified for general use, for restricted use, or for both."

Subsec. (c)(2)(A). Pub. L. 102–237, § 1006(b)(1), (2), substituted "the Administrator" for "he" before "requires", "shall permit", "shall make", and "deems", and substituted "the Administrator's" for "his".

Subsec. (c)(2)(D). Pub. L. 102–237, § 1006(c), clarified amendment made by Pub. L. 100–532, § 102(b)(2)(A). See 1988 Amendment note below.

Subsec. (c)(3)(A). Pub. L. 102–237, § 1006(b)(2), substituted "the Administrator's" for "his".

Subsec. (c)(5). Pub. L. 102–237, § 1006(b)(1), substituted "the Administrator" for "he" before "determines".

Subsec. (c)(6). Pub. L. 102–237, § 1006(b)(1), (2), substituted "the Administrator" for "he" before "shall notify" in two places and "the Administrator's" for "his" in four places.

Subsec. (d)(1). Pub. L. 102–237, § 1006(b)(1), substituted "the Administrator" for "he" before "shall classify it for both" in subpar. (A), before "will classify" in subpar. (B), and before "shall classify" in subpar. (C).

Subsec. (d)(2). Pub. L. 102–237, § 1006(b)(1), substituted "the Administrator" for "he" before "shall notify".

1990—Subsec. (c)(2)(A). Pub. L. 101–624 inserted after third sentence "The Administrator shall not require a person to submit, in relation to a registration or reregistration of a pesticide for minor agricultural use under this subchapter, any field residue data from a geographic area where the pesticide will not be registered for such use."

1988—Subsec. (a). Pub. L. 100–532, § 601(b)(1), substituted "Requirement of registration" for "Requirement" in heading and amended text generally. Prior to amendment, text read as follows: "Except as otherwise provided by this subchapter, no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator."

Subsec. (c)(1)(D). Pub. L. 100–532, § 801(b)(1)–(4), in introductory provisions, substituted "paragraph (2)(D)"

for "subsection (c)(2)(D) of this section", in cl. (i), substituted "(i) with" for "(i) With" and ", except that" for ": *Provided*, That", in cl. (ii), substituted "clause (i)" for "subparagraph (D)(i) of this paragraph", and in cl. (iii), substituted "clauses (i) and (ii)" for "subparagraphs (D)(i) and (D)(ii) of this paragraph".

Subsec. (c)(2)(A). Pub. L. 100–532, §801(b)(5)(A), (B), substituted "(2) Data in support of registration.—

"(A) The"

for "(2)(A) Data in support of registration.—The", and directed that subpar. (A) be aligned with left margin of subsec. (d)(1)(A) of this section.

Subsec. (c)(2)(B). Pub. L. 100–532, §§102(b)(1), 801(b)(5)(C)–(F), substituted "(B)(i) If" for "(B) Additional data to support existing registration.—(1) If", directed that cls. (ii) to (v) be aligned with left margin of subpar. (A), in cls. (ii) and (iii), inserted "The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.", in cl. (iv), substituted "title. The only" for "title: *Provided*, that the only", and in cl. (v), substituted "paragraph (1)(D)" for "subsection (c)(1)(D) of this section".

Subsec. (c)(2)(C). Pub. L. 100–532, §801(b)(5)(G), (H), struck out "Simplified procedures" after "(C)" and directed that text be aligned with left margin of subpar. (A).

Subsec. (c)(2)(D). Pub. L. 100–532, §102(b)(2)(A), and Pub. L. 102–237, §1006(c), substituted "the pesticide that is the subject of the application" for "an end-use product".

Subsec. (c)(2)(D)(i). Pub. L. 100–532, §102(b)(2)(B), struck out "the safety of" after "data pertaining to".

Subsec. (c)(3). Pub. L. 100–532, §103, substituted "(A) The Administrator" for "The Administrator" and added subpar. (B).

Subsec. (c)(7). Pub. L. 100–532, §801(b)(6), in introductory provisions, substituted "paragraph (5)" for "subsection (c)(5) of this section", in subpars. (A) and (B), substituted "paragraph (5). If" for "subsection (c)(5) of this section: *Provided*, That, if", and in subpar. (C), substituted "prescribe. A" for "prescribe: *Provided*, that a".

Subsec. (d)(1)(A). Pub. L. 100–532, §801(b)(7), substituted "restricted use. If" for "restricted use, provided that if" and "restricted uses. The Administrator" for "restricted uses: *Provided, however*, That the Administrator".

Subsec. (f)(2). Pub. L. 100–532, §801(b)(8), substituted "this subchapter. As" for "this subchapter: *Provided*, That as".

Subsec. (g). Pub. L. 100–532, §801(b)(9), struck out subsec. (g) which read as follows: "The Administrator shall accomplish the reregistration of all pesticides in the most expeditious manner practicable: *Provided*, That, to the extent appropriate, any pesticide that results in a postharvest residue in or on food or feed crops shall be given priority in the reregistration process."

1978—Subsec. (c)(1)(D). Pub. L. 95–396, §2(a)(1), added subpar. (D), and struck out provisions which required the applicant for registration of a pesticide to file with the Administrator a statement containing "if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, except that data submitted on or after January 1, 1970, in support of an application shall not, without permission of the applicant, be considered by the Administrator in support of any other application for registration unless such other applicant shall have first offered to pay reasonable compensation for producing the test data to be relied upon and such data is not protected from disclosure by section 136h(b) of this title. This provision with regard to compensation for producing the test data to be relied upon shall apply with respect to all applications for registration or reregistration submitted on or after October 21, 1972. If the parties cannot agree on the amount and method of payment, the Administrator shall make such determination and may fix such other terms and conditions as may be reasonable under the circumstances. The Administrator's determination shall be made on the record after notice and opportunity for hearing. If either party does not agree with said determination, he may, within thirty days, take an appeal to the Federal district court for the district in which he resides with respect to either the amount of the payment or the terms of payment, or both. Registration shall not be delayed pending the determination of reasonable compensation between the applicants, by the Administrator or by the court.".

Subsec. (c)(2). Pub. L. 95–396, §§2(a)(2)(A)–(D), 3, 4, designated existing provisions as subpar. (A), inserted in second sentence "under subparagraph (B) of this paragraph" after "kind of information", struck out from introductory text of third sentence "subsection (c)(1)(D) of this section and" after "Except as provided by", and inserted provisions relating to establishment of standards for data requirements for registration of pesticides with respect to minor uses and consideration of economic factors in development of standards and cost of development, and added subpars. (B) to (D).

Subsec. (c)(5). Pub. L. 95–396, §5, provided for waiver of data requirements pertaining to efficacy.

Subsec. (c)(7), (8). Pub. L. 95–396, §6, added pars. (7) and (8).

Subsec. (d)(1)(A). Pub. L. 95–396, §7(1), authorized classification of pesticide uses by regulation on the initial classification and registered pesticides prior to reregistration.

Subsec. (d)(2). Pub. L. 95–396, §7(2), substituted "forty-five days" for "30 days".

Subsec. (d)(3). Pub. L. 95–396, §7(3), added par. (3).

Subsec. (g). Pub. L. 95–396, §8, added subsec. (g).

1975—Subsec. (c)(1)(D). Pub. L. 94–140 inserted exception relating to test data submitted on or after January 1, 1970, in support of application, inserted provision that compensation for producing test data shall apply to all applications submitted on or after October 21, 1972, and provision relating to delay of registration pending determination of reasonable compensation, struck out requirement that payment determined by court not be less than amount determined by Administrator, and substituted "If either party" for "If the owner of the test data".

Effective Date of 2007 Amendment

Pub. L. 110–94, §6, Oct. 9, 2007, 121 Stat. 1007, provided that: "This Act [see Short Title of 2007 Amendment note set out under section 136 of this title] and the amendments made by this Act take effect on October 1, 2007."

Effective Date of 2004 Amendment

Pub. L. 108–199, div. G, title V, §501(h), Jan. 23, 2004, 118 Stat. 434, provided that: "Except as otherwise provided in this section [enacting section 136w–8 of this title, amending this section and sections 136a–1, 136x, and 136y of this title, and enacting provisions set out as notes under sections 136 of this title and section 346a of Title 21, Food and Drugs] and the amendments made by this section, this section and the amendments made by this section take effect on the date that is 60 days after the date of enactment of this Act [Jan. 23, 2004]."

Effective Date of 1988 Amendment

Amendment by Pub. L. 100–532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100–532, set out as a note under section 136 of this title.

Effective Date of 1978 Amendment

Pub. L. 95–396, §2(b), Sept. 30, 1978, 92 Stat. 824, provided that: "The amendment to section 3(c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act [subsec. (c)(1)(D) of this section] made by [subsec. (a)(1) of] this section shall apply with respect to all applications for registration approved after the date of enactment of this Act [Sept. 30, 1978]."

EFFECTIVE DATE

For effective date of section, see section 4 of Pub. L. 92-516, set out as a note under section 136 of this title.

BIOLOGICAL PESTICIDE HANDLING STUDY

Pub. L. 101-624, title XIV, §1498, Nov. 28, 1990, 104 Stat. 3631, provided that:

"(a) STUDY.—Not later than September 30, 1992, the National Academy of Sciences shall conduct a study of the biological control programs and registration procedures utilized by the Food and Drug Administration, the Animal and Plant Health Inspection Service, and the Environmental Protection Agency.

"(b) DEVELOPMENT OF PROCEDURES.—Not later than 1 year after the completion of the study under subsection (a), the agencies and offices described in such subsection shall develop and implement a common process for reviewing and approving biological control applications that are submitted to such agencies and offices that shall be based on the study conducted under such subsection and the recommendation of the National Academy of Sciences, and other public comment."

EDUCATION, STUDY, AND REPORT

Pub. L. 100-478, title I, §1010, Oct. 7, 1988, 102 Stat. 2313, provided that:

"(a) EDUCATION.—The Administrator of the Environmental Protection Agency in cooperation with the Secretary of Agriculture and the Secretary of the Interior, promptly upon enactment of this Act [Oct. 7, 1988], shall conduct a program to inform and educate fully persons engaged in agricultural food and fiber commodity production of any proposed pesticide labeling program or requirements that may be imposed by the Administrator in compliance with the Endangered Species Act [of 1973] (16 U.S.C. 1531 et seq.). The Administrator also shall provide the public with notice of, and opportunity for comment on, the elements of any such program and requirements based on compliance with the Endangered Species Act [of 1973], including (but not limited to) an identification of any pesticides affected by the program; an explanation of the restriction or prohibition on the user or applicator of any such pesticide; an identification of those geographic areas affected by any pesticide restriction or prohibition; an identification of the effects of any restricted or prohibited pesticide on endangered or threatened species; and an identification of the endangered or threatened species along with a general description of the geographic areas in which such species are located wherein the application of a pesticide will be restricted, prohibited, or its use otherwise limited, unless the Secretary of the Interior determines that the disclosure of such information may create a substantial risk of harm to such species or its habitat.

"(b) STUDY.—The Administrator of the Environmental Protection Agency, jointly with the Secretary of Agriculture and the Secretary of the Interior, shall conduct a study to identify reasonable and prudent means available to the Administrator to implement the endangered species pesticides labeling program which would comply with the Endangered Species Act of 1973, as amended, and which would allow persons to continue production of agricultural food and fiber commodities. Such study shall include investigation by the Administrator of the best available methods to develop maps and the best available alternatives to mapping as means of identifying those circumstances in which use of pesticides may be restricted; identification of alternatives to prohibitions on pesticide use, including, but not limited to, alternative pesticides and application methods and other agricultural practices which can be used in lieu of any pesticides whose use may be restricted by the labeling program; examination of methods to improve coordination among the Environmental Protection Agency, Department of Agriculture, and Department of the Interior in administration of the labeling program; and analysis of the means of implementing the endangered species pesticides labeling program or alternatives to such a program, if any, to promote the conservation of endangered or threatened species and to minimize the impacts to persons engaged in agricultural food and fiber commodity production and other affected pesticide users and applicators.

"(c) REPORT.—The Administrator of the Environmental Protection Agency in cooperation with the Secretary of Agriculture and the Secretary of the Interior shall submit a report within one year of the date of enactment of this Act [Oct. 7, 1988], presenting the results of the study conducted pursuant to subsection (b) of this section to the Committee on Merchant Marine and Fisheries and the Committee on Agriculture of the United States House of Representatives, and the Committee on Environment and Public Works and the Committee on Agriculture, Nutrition, and Forestry of the United States Senate."

§ 136a-1. Reregistration of registered pesticides

(a) General rule

The Administrator shall reregister, in accordance with this section, each registered pesticide containing any active ingredient contained in any pesticide first registered before November 1, 1984, except for any pesticide as to which the Administrator has determined, after November 1, 1984, and before the effective date of this section, that—

(1) there are no outstanding data requirements; and

(2) the requirements of section 136a(c)(5) of this title have been satisfied.

(b) Reregistration phases

Reregistrations of pesticides under this section shall be carried out in the following phases:

(1) The first phase shall include the listing under subsection (c) of this section of the active ingredients of the pesticides that will be reregistered.

(2) The second phase shall include the submission to the Administrator under subsection (d) of this section of notices by registrants respecting their intention to seek reregistration, identification by registrants of missing and inadequate data for such pesticides, and commitments by registrants to replace such missing or inadequate data within the applicable time period.

(3) The third phase shall include submission to the Administrator by registrants of the information required under subsection (e) of this section.

(4) The fourth phase shall include an independent, initial review by the Administrator under subsection (f) of this section of submissions under phases two and three, identification of outstanding data requirements, and the issuance, as necessary, of requests for additional data.

(5) The fifth phase shall include the review by the Administrator under subsection (g) of this section of data submitted for reregistration and appropriate regulatory action by the Administrator.

(c) Phase one

(1) Priority for reregistration

For purposes of the reregistration of the pesticides described in subsection (a) of this section, the Administrator shall list the active ingredients of pesticides and shall give priority to, among others, active ingredients (other

than active ingredients for which registration standards have been issued before the effective date of this section) that—

(A) are in use on or in food or feed and may result in postharvest residues;

(B) may result in residues of potential toxicological concern in potable ground water, edible fish, or shellfish;

(C) have been determined by the Administrator before the effective date of this section to have significant outstanding data requirements; or

(D) are used on crops, including in greenhouses and nurseries, where worker exposure is most likely to occur.

(2) Reregistration lists

For purposes of reregistration under this section, the Administrator shall by order—

(A) not later than 70 days after the effective date of this section, list pesticide active ingredients for which registration standards have been issued before such effective date;

(B) not later than 4 months after such effective date, list the first 150 pesticide active ingredients, as determined under paragraph (1);

(C) not later than 7 months after such effective date, list the second 150 pesticide active ingredients, as determined under paragraph (1); and

(D) not later than 10 months after such effective date, list the remainder of the pesticide active ingredients, as determined under paragraph (1).

Each list shall be published in the Federal Register.

(3) Judicial review

The content of a list issued by the Administrator under paragraph (2) shall not be subject to judicial review.

(4) Notice to registrants

On the publication of a list of pesticide active ingredients under paragraph (2), the Administrator shall send by certified mail to the registrants of the pesticides containing such active ingredients a notice of the time by which the registrants are to notify the Administrator under subsection (d) of this section whether the registrants intend to seek or not to seek reregistration of such pesticides.

(d) Phase two

(1) In general

The registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) of this section shall submit to the Administrator, within the time period prescribed by paragraph (4), the notice described in paragraph (2) and any information, commitment, or offer described in paragraph (3).

(2) Notice of intent to seek or not to seek reregistration

(A) The registrant of a pesticide containing an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) of this section shall notify the Administrator by certified mail whether the registrant intends to seek or does not intend to seek reregistration of the pesticide.

(B) If a registrant submits a notice under subparagraph (A) of an intention not to seek reregistration of a pesticide, the Administrator shall publish a notice in the Federal Register stating that such a notice has been submitted.

(3) Missing or inadequate data

Each registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) of this section and for which the registrant submitted a notice under paragraph (2) of an intention to seek reregistration of such pesticide shall submit to the Administrator—

(A) in accordance with regulations issued by the Administrator under section 136a of this title, an identification of—

(i) all data that are required by regulation to support the registration of the pesticide with respect to such active ingredient;

(ii) data that were submitted by the registrant previously in support of the registration of the pesticide that are inadequate to meet such regulations; and

(iii) data identified under clause (i) that have not been submitted to the Administrator; and

(B) either—

(i) a commitment to replace the data identified under subparagraph (A)(ii) and submit the data identified under subparagraph (A)(iii) within the applicable time period prescribed by paragraph (4)(B); or

(ii) an offer to share in the cost to be incurred by a person who has made a commitment under clause (i) to replace or submit the data and an offer to submit to arbitration as described by section 136a(c)(2)(B) of this title with regard to such cost sharing.

For purposes of a submission by a registrant under subparagraph (A)(ii), data are inadequate if the data are derived from a study with respect to which the registrant is unable to make the certification prescribed by subsection (e)(1)(G) of this section that the registrant possesses or has access to the raw data used in or generated by such study. For purposes of a submission by a registrant under such subparagraph, data shall be considered to be inadequate if the data are derived from a study submitted before January 1, 1970, unless it is demonstrated to the satisfaction of the Administrator that such data should be considered to support the registration of the pesticide that is to be reregistered.

(4) Time periods

(A) A submission under paragraph (2) or (3) shall be made—

(i) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(B) of this section, not later than 3 months after the date of publication of the listing of such active ingredient;

(ii) in the case of a pesticide containing an active ingredient listed under subsection

(c)(2)(C) of this section, not later than 3 months after the date of publication of the listing of such active ingredient; and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(D) of this section, not later than 3 months after the date of publication of the listing of such active ingredient.

On application, the Administrator may extend a time period prescribed by this subparagraph if the Administrator determines that factors beyond the control of the registrant prevent the registrant from complying with such period.

(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (3)(B) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. Upon application of a registrant, the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under this section for the other uses of the pesticide established as of August 3, 1996, if—

(i) the data to support other uses of the pesticide on a food are being provided;

(ii) the registrant, in submitting a request for such an extension provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;

(iii) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under this section; and

(iv) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 136a(c)(2)(B) of this title or other provisions of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this subparagraph, the Administrator may take action to modify or revoke the extension under this subparagraph if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.

(5) Cancellation and removal

(A) If the registrant of a pesticide does not submit a notice under paragraph (2) or (3) within the time prescribed by paragraph (4)(A), the Administrator shall issue a notice of intent to cancel the registration of such registrant for such pesticide and shall publish the notice in the Federal Register and allow 60 days for the submission of comments on the notice. On expiration of such 60 days, the Administrator, by order and without a hearing, may cancel the registration or take such other action, including extension of applicable time periods, as may be necessary to enable reregistration of such pesticide by another person.

(B)(i) If—

(I) no registrant of a pesticide containing an active ingredient listed under subsection (c)(2) of this section notifies the Administrator under paragraph (2) that the registrant intends to seek reregistration of any pesticide containing that active ingredient;

(II) no such registrant complies with paragraph (3)(A); or

(III) no such registrant makes a commitment under paragraph (3)(B) to replace or submit all data described in clauses (ii) and (iii) of paragraph (3)(A);

the Administrator shall publish in the Federal Register a notice of intent to remove the active ingredient from the list established under subsection (c)(2) of this section and a notice of intent to cancel the registrations of all pesticides containing such active ingredient and shall provide 60 days for comment on such notice.

(ii) After the 60-day period has expired, the Administrator, by order, may cancel any such registration without hearing, except that the Administrator shall not cancel a registration under this subparagraph if—

(I) during the comment period a person acquires the rights of the registrant in that registration;

(II) during the comment period that person furnishes a notice of intent to reregister the pesticide in accordance with paragraph (2); and

(III) not later than 120 days after the publication of the notice under this subparagraph, that person has complied with paragraph (3) and the fee prescribed by this section has been paid.

(6) Suspensions and penalties

The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by section 136a(c)(2)(B)(iv) of this title if the Administrator determines that (A) progress is insufficient to ensure the submission of the data required for such pesticide under a com-

mitment made under paragraph (3)(B) within the time period prescribed by paragraph (4)(B) or (B) the registrant has not submitted such data to the Administrator within such time period. If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this paragraph in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under this section for the supported uses identified pursuant to this paragraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On such a determination the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 136d(f)(1) of this title. If the Administrator grants an extension under this paragraph, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with section 136a(c)(2)(B)(iv) of this title regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 136d(f)(2) of this title. Notwithstanding this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this paragraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(e) Phase three

(1) Information about studies

Each registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) of this section who has submitted a notice under subsection (d)(2) of this section of an intent to seek the reregistration of such pesticide shall submit, in accordance with the guidelines issued under paragraph (4), to the Administrator—

(A) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing such active ingredient and considered by the registrant to be adequate to meet the requirements of section 136a of this title and the regulations issued under such section;

(B) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing such active ingredient that may not comply with the requirements of section 136a of this title and the regulations issued under such section but which the registrant asserts should be deemed to comply with such requirements and regulations;

(C) a reformat of the data from each study summarized under subparagraph (A) or (B) by the registrant concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, teratogenicity, or residue chemistry of the active ingredient that were submitted to the Administrator before January 1, 1982;

(D) where data described in subparagraph (C) are not required for the active ingredient by regulations issued under section 136a of this title, a reformat of acute and subchronic dosing data submitted by the registrant to the Administrator before January 1, 1982, that the registrant considers to be adequate to meet the requirements of section 136a of this title and the regulations issued under such section;

(E) an identification of data that are required to be submitted to the Administrator under section 136d(a)(2) of this title, indicating an adverse effect of the pesticide;

(F) an identification of any other information available that in the view of the registrant supports the registration;

(G) a certification that the registrant or the Administrator possesses or has access to the raw data used in or generated by the studies that the registrant summarized under subparagraph (A) or (B);

(H) either—

(i) a commitment to submit data to fill each outstanding data requirement identified by the registrant; or

(ii) an offer to share in the cost of developing such data to be incurred by a person who has made a commitment under clause (i) to submit such data, and an offer to submit to arbitration as described by section 136a(c)(2)(B) of this title with regard to such cost sharing; and

(I) evidence of compliance with section 136a(c)(1)(D)(ii)[1] of this title and regulations issued thereunder with regard to previously submitted data as if the registrant were now seeking the original registration of the pesticide.

A registrant who submits a certification under subparagraph (G) that is false shall be considered to have violated this subchapter and shall

[1] See References in Text note below.

be subject to the penalties prescribed by section 136*l* of this title.

(2) Time periods

(A) The information required by paragraph (1) shall be submitted to the Administrator—

(i) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(B) of this section, not later than 12 months after the date of publication of the listing of such active ingredient;

(ii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(C) of this section, not later than 12 months after the date of publication of the listing of such active ingredient; and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(D) of this section, not later than 12 months after the date of publication of the listing of such active ingredient.

(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (1)(H) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment under such paragraph. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. Upon application of a registrant, the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under this section for the other uses of the pesticide established as of August 3, 1996, if—

(i) the data to support other uses of the pesticide on a food are being provided;

(ii) the registrant, in submitting a request for such an extension provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;

(iii) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issuing a reregistration eligibility determination required under this section; and

(iv) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 136a(c)(2)(B) of this title or other provisions of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this subparagraph, the Administrator may take action to modify or revoke the extension under this subparagraph if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.

(3) Cancellation

(A) If the registrant of a pesticide fails to submit the information required by paragraph (1) within the time prescribed by paragraph (2), the Administrator, by order and without hearing, shall cancel the registration of such pesticide. If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this subparagraph in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under this section for the supported uses identified pursuant to this subparagraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On the basis of such determination, the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 136d(f)(1) of this title. If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with section 136a(c)(2)(B)(iv) of this title regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 136d(f)(2) of this title. Notwithstanding this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this subparagraph if the Administrator determines

that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(B)(i) If the registrant of a pesticide submits the information required by paragraph (1) within the time prescribed by paragraph (2) and such information does not conform to the guidelines for submissions established by the Administrator, the Administrator shall determine whether the registrant made a good faith attempt to conform its submission to such guidelines.

(ii) If the Administrator determines that the registrant made a good faith attempt to conform its submission to such guidelines, the Administrator shall provide the registrant a reasonable period of time to make any necessary changes or corrections.

(iii)(I) If the Administrator determines that the registrant did not make a good faith attempt to conform its submission to such guidelines, the Administrator may issue a notice of intent to cancel the registration. Such a notice shall be sent to the registrant by certified mail.

(II) The registration shall be canceled without a hearing or further notice at the end of 30 days after receipt by the registrant of the notice unless during that time a request for a hearing is made by the registrant.

(III) If a hearing is requested, a hearing shall be conducted under section 136d(d) of this title, except that the only matter for resolution at the hearing shall be whether the registrant made a good faith attempt to conform its submission to such guidelines. The hearing shall be held and a determination made within 75 days after receipt of a request for hearing.

(4) Guidelines

(A) Not later than 1 year after the effective date of this section, the Administrator, by order, shall issue guidelines to be followed by registrants in—

(i) summarizing studies;

(ii) reformatting studies;

(iii) identifying adverse information; and

(iv) identifying studies that have been submitted previously that may not meet the requirements of section 136a of this title or regulations issued under such section,

under paragraph (1).

(B) Guidelines issued under subparagraph (A) shall not be subject to judicial review.

(5) Monitoring

The Administrator shall monitor the progress of registrants in acquiring and submitting the data required under paragraph (1).

(f) Phase four

(1) Independent review and identification of outstanding data requirements

(A) The Administrator shall review the submissions of all registrants of pesticides containing a particular active ingredient under subsections (d)(3) and (e)(1) of this section to determine if such submissions identified all the data that are missing or inadequate for such active ingredient. To assist the review of the Administrator under this subparagraph, the Administrator may require a registrant seeking reregistration to submit complete copies of studies summarized under subsection (e)(1) of this section.

(B) The Administrator shall independently identify and publish in the Federal Register the outstanding data requirements for each active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (c)(2) of this section and that is contained in a pesticide to be reregistered under this section. The Administrator, at the same time, shall issue a notice under section 136a(c)(2)(B) of this title for the submission of the additional data that are required to meet such requirements.

(2) Time periods

(A) The Administrator shall take the action required by paragraph (1)—

(i) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(B) of this section, not later than 18 months after the date of the listing of such active ingredient;

(ii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(C) of this section, not later than 24 months after the date of the listing of such active ingredient; and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(D) of this section, not later than 33 months after the date of the listing of such active ingredient.

(B) If the Administrator issues a notice to a registrant under paragraph (1)(B) for the submission of additional data, the registrant shall submit such data within a reasonable period of time, as determined by the Administrator, but not to exceed 48 months after the issuance of such notice. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. Upon application of a registrant, the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under this section for the other uses of the pesticide established as of August 3, 1996, if—

(i) the data to support other uses of the pesticide on a food are being provided;

(ii) the registrant, in submitting a request for such an extension provides a schedule, including interim dates to measure progress, to assure that the data production will be completed before the expiration of the extension period;

(iii) the Administrator has determined that such extension will not significantly delay the Administrator's schedule for issu-

ing a reregistration eligibility determination required under this section; and

(iv) the Administrator has determined that based on existing data, such extension would not significantly increase the risk of any unreasonable adverse effect on the environment. If the Administrator grants an extension under this subparagraph, the Administrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 136a(c)(2)(B) of this title or other provisions of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provisions of this subparagraph, the Administrator may take action to modify or revoke the extension under this subparagraph if the Administrator determines that the extension for the minor use may cause an unreasonable adverse effect on the environment. In such circumstance, the Administrator shall provide written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.

(3) Suspensions and penalties

The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by section 136a(c)(2)(B)(iv) of this title if the Administrator determines that (A) tests necessary to fill an outstanding data requirement for such pesticide have not been initiated within 1 year after the issuance of a notice under paragraph (1)(B), or (B) progress is insufficient to ensure submission of the data referred to in clause (A) within the time period prescribed by paragraph (2)(B) or the required data have not been submitted to the Administrator within such time period. If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this paragraph in regard to such unsupported minor use until the final deadline established as of August 3, 1996, for the submission of data under this section for the supported uses identified pursuant to this paragraph unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On such a determination the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the registration pursuant to section 136d(f)(1) of this title. If the Administrator grants an extension under this paragraph, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with section 136a(c)(2)(B)(iv) of this title regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 136d(f)(2) of this title. Notwithstanding this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this paragraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(g) Phase five

(1) Data review

The Administrator shall conduct a thorough examination of all data submitted under this section concerning an active ingredient listed under subsection (c)(2) of this section and of all other available data found by the Administrator to be relevant.

(2) Reregistration and other actions

(A) IN GENERAL.—The Administrator shall make a determination as to eligibility for reregistration—

(i) for all active ingredients subject to reregistration under this section for which tolerances or exemptions from tolerances are required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), not later than the last date for tolerance reassessment established under section 408(q)(1)(C) of that Act (21 U.S.C. 346a(q)(1)(C)); and

(ii) for all other active ingredients subject to reregistration under this section, not later than October 3, 2008.

(B) PRODUCT-SPECIFIC DATA.—

(i) IN GENERAL.—Before reregistering a pesticide, the Administrator shall obtain any needed product-specific data regarding the pesticide by use of section 136a(c)(2)(B) of this title and shall review such data within 90 days after its submission.

(ii) TIMING.—

(I) IN GENERAL.—Subject to subclause (II), the Administrator shall require that data under this subparagraph be submitted to the Administrator not later than 8

months after a determination of eligibility under subparagraph (A) has been made for each active ingredient of the pesticide, unless the Administrator determines that a longer period is required for the generation of the data.

(II) EXTRAORDINARY CIRCUMSTANCES.—In the case of extraordinary circumstances, the Administrator may provide such a longer period, of not more than 2 additional years, for submission of data to the Administrator under this subparagraph.

(C) After conducting the review required by paragraph (1) for each active ingredient of a pesticide and the review required by subparagraph (B) of this paragraph, the Administrator shall determine whether to reregister a pesticide by determining whether such pesticide meets the requirements of section 136a(c)(5) of this title. If the Administrator determines that a pesticide is eligible to be reregistered, the Administrator shall reregister such pesticide within 6 months after the submission of the data concerning such pesticide under subparagraph (B).

(D) DETERMINATION TO NOT REREGISTER.—

(i) IN GENERAL.—If after conducting a review under paragraph (1) or subparagraph (B) of this paragraph the Administrator determines that a pesticide should not be reregistered, the Administrator shall take appropriate regulatory action.

(ii) TIMING FOR REGULATORY ACTION.—Regulatory action under clause (i) shall be completed as expeditiously as possible.

(E) As soon as the Administrator has sufficient information with respect to the dietary risk of a particular active ingredient, but in any event no later than the time the Administrator makes a determination under subparagraph (C) or (D) with respect to pesticides containing a particular active ingredient, the Administrator shall—

(i) reassess each associated tolerance and exemption from the requirement for a tolerance issued under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a);

(ii) determine whether such tolerance or exemption meets the requirements of that Act [21 U.S.C. 301 et seq.];

(iii) determine whether additional tolerances or exemptions should be issued;

(iv) publish in the Federal Register a notice setting forth the determinations made under this subparagraph; and

(v) commence promptly such proceedings under this subchapter and section 408 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 346a] as are warranted by such determinations.

(h) Compensation of data submitter

If data that are submitted by a registrant under subsection (d), (e), (f), or (g) of this section are used to support the application of another person under section 136a of this title, the registrant who submitted such data shall be entitled to compensation for the use of such data as prescribed by section 136a(c)(1)(D)[2] of this title. In determining the amount of such compensation, the fees paid by the registrant under this section shall be taken into account.

(i) Fees

(1) Maintenance fee

(A) IN GENERAL.—Subject to other provisions of this paragraph, each registrant of a pesticide shall pay an annual fee by January 15 of each year for each registration, except that no fee shall be charged for more than 200 registrations held by any registrant.

(B) In the case of a pesticide that is registered for a minor agricultural use, the Administrator may reduce or waive the payment of the fee imposed under this paragraph if the Administrator determines that the fee would significantly reduce the availability of the pesticide for the use.

(C) TOTAL AMOUNT OF FEES.—The amount of each fee prescribed under subparagraph (A) shall be adjusted by the Administrator to a level that will result in the collection under this paragraph of, to the extent practicable, an aggregate amount of $27,800,000 for each of fiscal years 2013 through 2017.

(D) MAXIMUM AMOUNT OF FEES FOR REGISTRANTS.—The maximum annual fee payable under this paragraph by—

(i) a registrant holding not more than 50 pesticide registrations shall be $115,500 for each of fiscal years 2013 through 2017; and

(ii) a registrant holding over 50 registrations shall be $184,800 for each of fiscal years 2013 through 2017.

(E) MAXIMUM AMOUNT OF FEES FOR SMALL BUSINESSES.—

(i) IN GENERAL.—For a small business, the maximum annual fee payable under this paragraph by—

(I) a registrant holding not more than 50 pesticide registrations shall be $70,600 for each of fiscal years 2013 through 2017; and

(II) a registrant holding over 50 pesticide registrations shall be $122,100 for each of fiscal years 2013 through 2017.

(ii) DEFINITION OF SMALL BUSINESS.—

(I) IN GENERAL.—In clause (i), the term "small business" means a corporation, partnership, or unincorporated business that—

(aa) has 500 or fewer employees; and

(bb) during the 3-year period prior to the most recent maintenance fee billing cycle, had an average annual global gross revenue from pesticides that did not exceed $60,000,000.

(II) AFFILIATES.—

(aa) IN GENERAL.—In the case of a business entity with 1 or more affiliates, the gross revenue limit under subclause (I)(bb) shall apply to the gross revenue for the entity and all of the affiliates of the entity, including parents and subsidiaries, if applicable.

(bb) AFFILIATED PERSONS.—For the purpose of item (aa), persons are affiliates of each other if, directly or indirectly, either person controls or has the power to control the other person, or a third per-

[2] See References in Text note below.

son controls or has the power to control both persons.

(cc) INDICIA OF CONTROL.—For the purpose of item (aa), indicia of control include interlocking management or ownership, identity of interests among family members, shared facilities and equipment, and common use of employees.

(F) FEE REDUCTION FOR CERTAIN SMALL BUSINESSES.—

(i) DEFINITION.—In this subparagraph, the term "qualified small business entity" means a corporation, partnership, or unincorporated business that—

(I) has 500 or fewer employees;

(II) during the 3-year period prior to the most recent maintenance fee billing cycle, had an average annual global gross revenue from all sources that did not exceed $10,000,000; and

(III) holds not more than 5 pesticide registrations under this paragraph.

(ii) WAIVER.—Except as provided in clause (iii), the Administrator shall waive 25 percent of the fee under this paragraph applicable to the first registration of any qualified small business entity under this paragraph.

(iii) LIMITATION.—The Administrator shall not grant a waiver under clause (ii) to a qualified small business entity if the Administrator determines that the entity has been formed or manipulated primarily for the purpose of qualifying for the waiver.

(G) The Administrator shall exempt any public health pesticide from the payment of the fee prescribed under this paragraph if, in consultation with the Secretary of Health and Human Services, the Administrator determines, based on information supplied by the registrant, that the economic return to the registrant from sales of the pesticide does not support the registration or reregistration of the pesticide.

(H) If any fee prescribed by this paragraph with respect to the registration of a pesticide is not paid by a registrant by the time prescribed, the Administrator, by order and without hearing, may cancel the registration.

(I) The authority provided under this paragraph shall terminate on September 30, 2017..[3]

(2) Other fees

Except as provided in section 136w-8 of this title, during the period beginning on October 25, 1988, and ending on September 30, 2019, the Administrator may not levy any other fees for the registration of a pesticide under this subchapter except as provided in paragraph (1).

(j) Exemption of certain registrants

The requirements of subsections (d), (e), (f), and (i) of this section (other than subsection (i)(1) of this section) regarding data concerning an active ingredient and fees for review of such data shall not apply to any person who is the registrant of a pesticide to the extent that, under section 136a(c)(2)(D) of this title, the person would not be required to submit or cite such data to obtain an initial registration of such pesticide.

(k) Reregistration and expedited processing fund

(1) Establishment

There shall be established in the Treasury of the United States a reregistration and expedited processing fund which shall be known as the Reregistration and Expedited Processing Fund.

(2) Source and use

(A) All moneys derived from fees collected by the Administrator under subsection (i) of this section shall be deposited in the fund and shall be available to the Administrator, without fiscal year limitation, specifically to offset the costs of reregistration and expedited processing of the applications specified in paragraph (3), to enhance the information systems capabilities to improve the tracking of pesticide registration decisions, and to offset the costs of registration review under section 136a(g) of this title. Such moneys derived from fees may not be expended in any fiscal year to the extent such moneys derived from fees would exceed money appropriated for use by the Administrator and expended in such year for such costs of reregistration and expedited processing of such applications. The Administrator shall, prior to expending any such moneys derived from fees—

(i) effective October 1, 1997, adopt specific and cost accounting rules and procedures as approved by the Government Accountability Office and the Inspector General of the Environmental Protection Agency to ensure that moneys derived from fees are allocated solely to offset the costs of reregistration and expedited processing of the applications specified in paragraph (3), to enhance the information systems capabilities to improve the tracking of pesticide registration decisions, and to offset the costs of registration review under section 136a(g) of this title;

(ii) prohibit the use of such moneys derived from fees to pay for any costs other than those necessary to achieve reregistration and expedited processing of the applications specified in paragraph (3), to enhance the information systems capabilities to improve the tracking of pesticide registration decisions, and to offset the costs of registration review under section 136a(g) of this title; and

(iii) ensure that personnel and facility costs associated with the functions to be carried out under this paragraph do not exceed agency averages for comparable personnel and facility costs.

(B) The Administrator shall also—

(i) complete the review of unreviewed reregistration studies required to support the reregistration eligibility decisions scheduled for completion in accordance with subsection (*l*)(2) of this section; and

(ii) contract for such outside assistance as may be necessary for review of required studies, using a generally accepted competitive process for the selection of vendors of such assistance.

[3] So in original.

(3) Review of inert ingredients; expedited processing of similar applications

(A) The Administrator shall use for each of the fiscal years 2004 through 2006, approximately $3,300,000, and for each of fiscal years 2013 through 2017, between ⅙ and ⅛, of the maintenance fees collected in such fiscal year to obtain sufficient personnel and resources—

(i) to review and evaluate inert ingredients; and

(ii) to ensure the expedited processing and review of any application that—

(I) proposes the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that would differ in composition and labeling from any such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment;

(II) proposes an amendment to the registration of a registered pesticide that does not require scientific review of data; or

(III) proposes the initial or amended registration of an end use pesticide that, if registered as proposed, would be used for a public health pesticide.

(B) Any amounts made available under subparagraph (A) shall be used to obtain sufficient personnel and resources to carry out the activities described in such subparagraph that are in addition to the personnel and resources available to carry out such activities on October 25, 1988.

(C) So long as the Administrator has not met the time frames specified in clause (ii) of section 136a(c)(3)(B) of this title with respect to any application subject to section 136a(c)(3)(B) of this title that was received prior to August 3, 1996, the Administrator shall use the full amount of the fees specified in subparagraph (A) for the purposes specified therein. Once all applications subject to section 136a(c)(3)(B) of this title that were received prior to August 3, 1996, have been acted upon, no limitation shall be imposed by the preceding sentence of this subparagraph so long as the Administrator meets the time frames specified in clause (ii) of section 136a(c)(3)(B) of this title on 90 percent of affected applications in a fiscal year. Should the Administrator not meet such time frames in a fiscal year, the limitations imposed by the first sentence of this subparagraph shall apply until all overdue applications subject to section 136a(c)(3)(B) of this title have been acted upon.

(4) Enhancements of information technology systems for improvement in review of pesticide applications

(A) In general

For each of fiscal years 2013 through 2017, the Administrator shall use not more than $800,000 of the amounts made available to the Administrator in the Reregistration and Expedited Processing Fund for the activities described in subparagraph (B).

(B) Activities

The Administrator shall use amounts made available from the Reregistration and Expedited Processing Fund to improve the information systems capabilities for the Office of Pesticide Programs to enhance tracking of pesticide registration decisions, which shall include—

(i) the electronic tracking of—

(I) registration submissions; and

(II) the status of conditional registrations;

(ii) enhancing the database for information regarding endangered species assessments for registration review;

(iii) implementing the capability to electronically review labels submitted with registration actions; and

(iv) acquiring and implementing the capability to electronically assess and evaluate confidential statements of formula submitted with registration actions.

(5) Unused funds

Money in the fund not currently needed to carry out this section shall be—

(A) maintained on hand or on deposit;

(B) invested in obligations of the United States or guaranteed thereby; or

(C) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

(6) Accounting and performance

The Administrator shall take all steps necessary to ensure that expenditures from fees authorized by subsection (i)(1)(C)(ii)[4] of this section are used only for the purposes described in paragraphs (2), (3), and (4) and to carry out the goals established under subsection (*l*) of this section. The Reregistration and Expedited Processing Fund shall be designated as an Environmental Protection Agency component for purposes of section 3515(c) of title 31. The annual audit required under section 3521 of such title of the financial statements of activities under this subchapter under section 3515(b) of such title shall include an audit of the fees collected under subsection (i)(1)(C) of this section and disbursed, of the amount appropriated to match such fees, and of the Administrator's attainment of performance measures and goals established under subsection (*l*) of this section. Such an audit shall also include a review of the reasonableness of the overhead allocation and adequacy of disclosures of direct and indirect costs associated with carrying out the reregistration and expedited processing of the applications specified in paragraph (3), and the basis for and accuracy of all costs paid with moneys derived from such fees. The Inspector General shall conduct the annual audit and report the findings and recommendations of such audit to the Administrator and to the Committees on Agriculture of the House of Representatives

[4] See References in Text note below.

and the Senate. The cost of such audit shall be paid for out of the fees collected under subsection (i)(1)(C) of this section.

(l) Performance measures and goals

The Administrator shall establish and publish annually in the Federal Register performance measures and goals. Such measures and goals shall include—

(1) the number of products reregistered, canceled, or amended, the status of reregistration, the number and type of data requests under section 136a(c)(2)(B) of this title issued to support product reregistration by active ingredient, the progress in reducing the number of unreviewed, required reregistration studies, the aggregate status of tolerances reassessed, and the number of applications for registration submitted under subsection (k)(3) of this section that were approved or disapproved;

(2) the future schedule for reregistrations, including the projection for such schedules that will be issued under subsection (g)(2)(A) and (B) of this section in the current fiscal year and the succeeding fiscal year; and

(3) the projected year of completion of the reregistrations under this section.

(m) Judicial review

Any failure of the Administrator to take any action required by this section shall be subject to judicial review under the procedures prescribed by section 136n(b) of this title.

(n) Authorization of funds to develop public health data

(1) "Secretary" defined

For the purposes of this section, "Secretary" means the Secretary of Health and Human Services, acting through the Public Health Service.

(2) Consultation

In the case of a pesticide registered for use in public health programs for vector control or for other uses the Administrator determines to be human health protection uses, the Administrator shall, upon timely request by the registrant or any other interested person, or on the Administrator's own initiative may, consult with the Secretary prior to taking final action to suspend registration under section 136a(c)(2)(B)(iv) of this title, or cancel a registration under section 136a–1, 136d(e), or 136d(f) of this title. In consultation with the Secretary, the Administrator shall prescribe the form and content of requests under this section.

(3) Benefits to support family

The Administrator, after consulting with the Secretary, shall make a determination whether the potential benefits of continued use of the pesticide for public health or health protection purposes are of such significance as to warrant a commitment by the Secretary to conduct or to arrange for the conduct of the studies required by the Administrator to support continued registration under section 136a of this title or reregistration under this section.

(4) Additional time

If the Administrator determines that such a commitment is warranted and in the public interest, the Administrator shall notify the Secretary and shall, to the extent necessary, amend a notice issued under section 136a(c)(2)(B) of this title to specify additional reasonable time periods for submission of the data.

(5) Arrangements

The Secretary shall make such arrangements for the conduct of required studies as the Secretary finds necessary and appropriate to permit submission of data in accordance with the time periods prescribed by the Administrator. Such arrangements may include Public Health Service intramural research activities, grants, contracts, or cooperative agreements with academic, public health, or other organizations qualified by experience and training to conduct such studies.

(6) Support

The Secretary may provide for support of the required studies using funds authorized to be appropriated under this section, the Public Health Service Act [42 U.S.C. 201 et seq.], or other appropriate authorities. After a determination is made under subsection (d) of this section, the Secretary shall notify the Committees on Appropriations of the House of Representatives and the Senate of the sums required to conduct the necessary studies.

(7) Authorization of appropriations

There is authorized to be appropriated to carry out the purposes of this section $12,000,000 for fiscal year 1997, and such sums as may be necessary for succeeding fiscal years.

(June 25, 1947, ch. 125, §4, formerly §3A, as added and renumbered §4, Pub. L. 100–532, title I, §102(a), title VIII, §801(q)(2)(A), Oct. 25, 1988, 102 Stat. 2655, 2683; amended Pub. L. 101–624, title XIV, §1493, Nov. 28, 1990, 104 Stat. 3628; Pub. L. 102–237, title X, §1006(a)(4), (e), (f), Dec. 13, 1991, 105 Stat. 1895–1897; Pub. L. 104–170, title I, §103, title II, §§210(c)(2), (f)(1), 232, 237, title V, §501, Aug. 3, 1996, 110 Stat. 1490, 1496, 1498, 1508, 1509, 1536; Pub. L. 107–73, title III, [(1)–(4)], Nov. 26, 2001, 115 Stat. 686; Pub. L. 108–7, div. K, title III, [(1)–(4)], Feb. 20, 2003, 117 Stat. 513; Pub. L. 108–199, div. G, title V, §501(c), (d)(1), (e), Jan. 23, 2004, 118 Stat. 419, 422; Pub. L. 108–271, §8(b), July 7, 2004, 118 Stat. 814; Pub. L. 110–94, §4(a)–(d)(1), (e), Oct. 9, 2007, 121 Stat. 1001, 1002; Pub. L. 112–177, §2(a)(1), (2)(A), (4), Sept. 28, 2012, 126 Stat. 1327, 1329.)

REFERENCES IN TEXT

The effective date of this section, referred to in subsecs. (a), (c)(1), (2), and (e)(4)(A), is 60 days after Oct. 25, 1988. See Effective Date note below.

Section 136a(c)(1)(D) of this title, referred to in subsecs. (e)(1)(I) and (h), was redesignated section 136a(c)(1)(F) of this title by Pub. L. 102–237, title X, §1006(a)(3)(B), Dec. 13, 1991, 105 Stat. 1894.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (g)(2)(A)(1), (E)(ii), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Subsection (i)(1)(C)(ii) of this section, referred to in subsec. (k)(6), was previously a reference to subsec.

(i)(5)(C)(ii), which was repealed and a new subsec. (i)(5)(C)(ii) was added by Pub. L. 108–199, § 501(c)(2). Subsec. (i)(5)(C) was amended by Pub. L. 110–94, § 4(a), and, as so amended, related to fees but no longer contained a cl. (ii). Subsec. (i)(5) was redesignated (i)(1) by Pub. L. 112–177, § 2(a)(1)(C).

The Public Health Service Act, referred to in subsec. (n)(6), is act July 1, 1944, ch. 373, 58 Stat. 682, as amended, which is classified generally to chapter 6A (§ 201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

PRIOR PROVISIONS

A prior section 4 of act June 25, 1947, which was classified to section 136b of this title was transferred to section 11(a)–(c) of act June 25, 1947, which is classified to section 136i(a)–(c) of this title.

Another prior section 4 of act June 25, 1947, was classified to section 135b of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

AMENDMENTS

2012—Subsec. (d)(5)(B)(ii)(III). Pub. L. 112–177, § 2(a)(2)(A)(i), substituted "this section" for "subsection (i)(1)".

Subsec. (i)(1) to (4). Pub. L. 112–177, § 2(a)(1)(C), (D), redesignated pars. (5) and (6) as (1) and (2), respectively, and struck out former pars. (1) to (4) which related to initial fee for food or feed use pesticide active ingredients, final fee for food or feed use pesticide active ingredients, fees for other pesticide active ingredients, and reduction or waiver of fees for minor use and other pesticides, respectively.

Subsec. (i)(5). Pub. L. 112–177, § 2(a)(1)(D), redesignated par. (5) as (1).

Subsec. (i)(5)(C). Pub. L. 112–177, § 2(a)(1)(A)(i), substituted "aggregate amount of $27,800,000 for each of fiscal years 2013 through 2017." for "aggregate amount of $22,000,000 for each of fiscal years 2008 through 2012".

Subsec. (i)(5)(D)(i). Pub. L. 112–177, § 2(a)(1)(A)(ii)(I), substituted "shall be $115,500 for each of fiscal years 2013 through 2017;" for "shall be $71,000 for each of fiscal years 2008 through 2012;".

Subsec. (i)(5)(D)(ii). Pub. L. 112–177, § 2(a)(1)(A)(ii)(II), substituted "shall be $184,800 for each of fiscal years 2013 through 2017." for "shall be $123,000 for each of fiscal years 2008 through 2012."

Subsec. (i)(5)(E)(i)(I). Pub. L. 112–177, § 2(a)(1)(A)(iii)(I), substituted "shall be $70,600 for each of fiscal years 2013 through 2017;" for "shall be $50,000 for each of fiscal years 2008 through 2012;".

Subsec. (i)(5)(E)(i)(II). Pub. L. 112–177, § 2(a)(1)(A)(iii)(II), substituted "shall be $122,100 for each of fiscal years 2013 through 2017." for "shall be $86,000 for each of fiscal years 2008 through 2012."

Subsec. (i)(5)(F). Pub. L. 112–177, § 2(a)(1)(A)(vi), added subpar. (F). Former subpar. (F) redesignated (G).

Pub. L. 112–177, § 2(a)(1)(A)(iv), substituted "this paragraph" for "paragraph (3)" and "Human" for "Humans".

Subsec. (i)(5)(G), (H). Pub. L. 112–177, § 2(a)(1)(A)(v), redesignated subpars. (F) and (G) as (G) and (H), respectively.

Subsec. (i)(5)(I). Pub. L. 112–177, § 2(a)(1)(A)(v), (vii), redesignated subpar. (H) as (I) and substituted "2017" for "2012".

Subsec. (i)(6). Pub. L. 112–177, § 2(a)(1)(D), redesignated par. (6) as (2).

Pub. L. 112–177, § 2(a)(1)(B), substituted "2019" for "2014" and "paragraph (1)" for "paragraphs (1) through (5)".

Subsec. (i)(7). Pub. L. 112–177, § 2(a)(1)(C), struck out par. (7) which related to apportionment of certain fees among registrants of pesticides.

Subsec. (j). Pub. L. 112–177, § 2(a)(2)(A)(ii), substituted "subsection (i)(1)" for "subsection (i)(5)".

Subsec. (k)(2)(A). Pub. L. 112–177, § 2(a)(4)(A)(i), inserted ", to enhance the information systems capabilities to improve the tracking of pesticide registration decisions," after "paragraph (3)" wherever appearing.

Subsec. (k)(2)(A)(i). Pub. L. 112–177, § 2(a)(4)(A)(ii), inserted "offset" before "the costs of reregistration" and struck out "in the same portion as appropriated funds" before semicolon at end.

Subsec. (k)(3)(A). Pub. L. 112–177, § 2(a)(4)(B), in introductory provisions, substituted "2013 through 2017, between ⅙ and ⅓" for "2008 through 2012, between ⅙ and ⅓"; in cl. (i), struck out "new" before "inert"; and, in cl. (ii), substituted "any application that—" for "any application that—".

Subsec. (k)(4). Pub. L. 112–177, § 2(a)(4)(C)(ii), added par. (4). Former par. (4) redesignated (5).

Subsec. (k)(5). Pub. L. 112–177, § 2(a)(4)(C)(i), redesignated par. (4) as (5). Former par. (5) redesignated (6).

Pub. L. 112–177, § 2(a)(2)(A)(iii), substituted "subsection (i)(1)(C)(ii)" for "subsection (i)(5)(C)(ii)" and "subsection (i)(1)(C)" for "subsection (i)(5)(C)" in two places.

Subsec. (k)(6). Pub. L. 112–177, § 2(a)(4)(C)(i), (iii), redesignated par. (5) as (6) and substituted "for the purposes described in paragraphs (2), (3), and (4) and to carry out the goals established under subsection (*l*)" for "to carry out the goals established under subsection (*l*)".

2007—Subsec. (i)(5)(C). Pub. L. 110–94, § 4(a), which directed substitution of "amount of $22,000,000 for each of fiscal years 2008 through 2012" for "amount of" and all that follows through the end of clause (v), was executed by making the substitution for "amount of—

"(i) for fiscal year 2004, $26,000,000;
"(ii) for fiscal year 2005, $27,000,000;
"(iii) for fiscal year 2006, $27,000,000;
"(iv) for fiscal year 2007, $21,000,000; and
"(v) for fiscal year 2008, $15,000,000."

to reflect the probable intent of Congress. The words "amount of" appeared in the heading and twice in the text.

Subsec. (i)(5)(D)(i). Pub. L. 110–94, § 4(b)(1)(A), substituted "shall be $71,000 for each of fiscal years 2008 through 2012; and" for "shall be—

"(I) for fiscal year 2004, $84,000;
"(II) for each of fiscal years 2005 and 2006, $87,000;
"(III) for fiscal year 2007, $68,000; and
"(IV) for fiscal year 2008, $55,000; and".

Subsec. (i)(5)(D)(ii). Pub. L. 110–94, § 4(b)(1)(B), substituted "shall be $123,000 for each of fiscal years 2008 through 2012." for "shall be—

"(I) for fiscal year 2004, $145,000;
"(II) for each of fiscal years 2005 and 2006, $151,000;
"(III) for fiscal year 2007, $117,000; and
"(IV) for fiscal year 2008, $95,000."

Subsec. (i)(5)(E)(i)(I). Pub. L. 110–94, § 4(b)(2)(A), substituted "shall be $50,000 for each of fiscal years 2008 through 2012; and" for "shall be—

"(aa) for fiscal year 2004, $59,000;
"(bb) for each of fiscal years 2005 and 2006, $61,000;
"(cc) for fiscal year 2007, $48,000; and
"(dd) for fiscal year 2008, $38,500; and".

Subsec. (i)(5)(E)(i)(II). Pub. L. 110–94, § 4(b)(2)(B), substituted "shall be $86,000 for each of fiscal years 2008 through 2012." for "shall be—

"(aa) for fiscal year 2004, $102,000;
"(bb) for each of fiscal years 2005 and 2006, $106,000;
"(cc) for fiscal year 2007, $82,000; and
"(dd) for fiscal year 2008, $66,500."

Subsec. (i)(5)(H). Pub. L. 110–94, § 4(c), substituted "2012." for "2008".

Subsec. (i)(6). Pub. L. 110–94, § 4(d)(1), substituted "2014" for "2010".

Subsec. (k)(2)(A). Pub. L. 110–94, § 4(e)(1), inserted "and to offset the costs of registration review under section 136a(g) of this title" after "paragraph (3)" wherever appearing.

Subsec. (k)(3)(A). Pub. L. 110–94, § 4(e)(2), substituted "2008 through 2012" for "2007 and 2008".

2004—Subsec. (g)(2)(A). Pub. L. 108–199, § 501(c)(5)(A), added subpar. (A) and struck out former subpar. (A) which read as follows: "Within 1 year after the submis-

sion of all data concerning an active ingredient of a pesticide under subsection (f) of this section, the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration. For extraordinary circumstances, the Administrator may extend such period for not more than 1 additional year."

Subsec. (g)(2)(B). Pub. L. 108–199, § 501(c)(5)(B), inserted subpar. (B) and cl. (i) headings, designated first sentence of existing provisions as cl. (i), inserted cl. (ii) and subcl. (I) headings, designated second sentence of existing provisions as cl. (ii)(I), substituted "Subject to subclause (II), the Administrator" for "The Administrator" in subcl. (I), and added subcl. (II).

Subsec. (g)(2)(D). Pub. L. 108–199, § 501(c)(5)(C), inserted subpar. (D) and cl. (i) headings, designated existing provisions as cl. (i), and added cl. (ii).

Subsec. (i)(5)(A). Pub. L. 108–199, § 501(c)(1)(A), inserted subpar. (A) heading and substituted "for each registration" for "of—

"(i) $650 for the first registration; and

"(ii) $1,300 for each additional registration".

Subsec. (i)(5)(C). Pub. L. 108–199, § 501(c)(2), struck out cl. (i) designation before "The amount of each", inserted subpar. (C) heading, substituted "aggregate amount of—" for "aggregate amount of $21,500,000 for fiscal year 2003.", added cls. (i) to (v), and struck out former cl. (ii), which related to collection of additional fees in fiscal years 1998, 1999, and 2000.

Subsec. (i)(5)(D). Pub. L. 108–199, § 501(c)(1)(B), inserted subpar. (D) heading, substituted "shall be—" for "shall be $55,000; and" and added subcls. (I) to (IV) in cl. (i), and substituted "shall be—" for "shall be $95,000." and added subcls. (I) to (IV) in cl. (ii).

Subsec. (i)(5)(E)(i). Pub. L. 108–199, § 501(c)(1)(C), inserted subpar. (E) and cl. (i) headings, realigned margins of subcls. (I) and (II), substituted "shall be—" for "shall be $38,500; and" and inserted items (aa) to (dd) in subcl. (I), and substituted "shall be—" for "shall be $66,500." and inserted items (aa) to (dd) in subcl. (II).

Subsec. (i)(5)(E)(ii). Pub. L. 108–199, § 501(c)(3), inserted cl. (ii) heading, redesignated existing provisions as subcl. (I), inserted subcl. (I) heading, substituted "In" for "For purposes of" in subcl. (I), redesignated former subcls. (I) and (II) as items (aa) and (bb) respectively, and realigned margins, substituted "500" for "150" in item (aa), substituted "global gross revenue from pesticides that did not exceed $60,000,000." for "gross revenue from chemicals that did not exceed $40,000,000." in item (bb), and added subcl. (II).

Subsec. (i)(5)(H). Pub. L. 108–199, § 501(c)(4), substituted "2008" for "2003".

Subsec. (i)(6). Pub. L. 108–199, § 501(d)(1), substituted "Except as provided in section 136w–8 of this title, during" for "During", and substituted "2010" for "2003".

Subsec. (k)(2)(A)(i). Pub. L. 108–271 substituted "Government Accountability Office" for "General Accounting Office".

Subsec. (k)(3). Pub. L. 108–199, § 501(e)(1), substituted "Review of inert ingredients; expedited" for "Expedited" in par. heading.

Subsec. (k)(3)(A). Pub. L. 108–199, § 501(e)(2), substituted "2004 through 2006, approximately $3,300,000, and for each of fiscal years 2007 and 2008, between 1/8 and 1/7, of the maintenance fees" for "1997 through 2003, not more than 1/10 of the maintenance fees", substituted "resources" for "resources to assure the expedited processing and review of any application that", added cl. (i), inserted cl. (ii) designation and introductory provisions, and redesignated former cls. (i) to (iii) as subcls. (I) to (III), respectively, of cl. (ii).

2003—Pub. L. 108–7, which directed the amendment of "Section 136a–1 of title 7, U.S.C.", was executed by making the amendments to this section, which is section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act, to reflect the probable intent of Congress. See below.

Subsec. (i)(5)(C)(i). Pub. L. 108–7, [(1)], substituted "$21,500,000 for fiscal year 2003" for "$17,000,000 fiscal year 2002".

Subsec. (i)(5)(H). Pub. L. 108–7, [(2)], substituted "2003" for "2002".

Subsec. (i)(6). Pub. L. 108–7, [(3)], substituted "2003" for "2002".

Subsec. (k)(3)(A). Pub. L. 108–7, [(4)], substituted "2003" for "2002".

2001—Pub. L. 107–73, which directed the amendment of "Section 136a–1 of title 7, U.S.C.", was executed by making the amendments to this section, which is section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act, to reflect the probable intent of Congress. See below.

Subsec. (i)(5)(C)(i). Pub. L. 107–73, [(1)], substituted "$17,000,000" for "$14,000,000" and "fiscal year 2002" for "each fiscal year".

Subsec. (i)(5)(H). Pub. L. 107–73, [(2)], substituted "2002" for "2001".

Subsec. (i)(6). Pub. L. 107–73, [(3)], substituted "2002" for "2001".

Subsec. (k)(3)(A). Pub. L. 107–73, [(4)], substituted "2002" for "2001" and "1/10" for "1/7" in introductory provisions.

1996—Pub. L. 104–170, § 501, which directed amendment of section 4 without specifying the name of the Act being amended, was executed to this section, which is section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act, to reflect the probable intent of Congress.

Subsec. (d)(4)(B). Pub. L. 104–170, § 210(c)(2), inserted at end provisions authorizing extension of deadline for production of residue chemistry data in case of minor use and setting forth conditions to be met for such extension in cls. (i) to (iv).

Subsec. (d)(6). Pub. L. 104–170, § 210(f)(1)(A), inserted at end provisions delaying upon written request action with regard to unsupported minor uses, authorizing refusal of request where there are health or environmental concerns, authorizing publication of notice in Federal Register and monitoring of development of data, setting forth procedures where registrant is not meeting or has not met schedule for production of data, and authorizing denial, modification, or revocation of temporary extension where use may cause adverse effect on environment and requiring notice of such revocation to registrant.

Subsec. (e)(2)(B). Pub. L. 104–170, § 210(c)(2), inserted at end provisions authorizing extension of deadline for production of residue chemistry data in case of minor use and setting forth conditions to be met for such extension in cls. (i) to (iv).

Subsec. (e)(3)(A). Pub. L. 104–170, § 210(f)(1)(B), inserted at end provisions delaying upon written request action with regard to unsupported minor uses, authorizing refusal of request where there are health or environmental concerns, authorizing publication of notice in Federal Register and monitoring of development of data, setting forth procedures where registrant is not meeting or has not met schedule for production of data, and authorizing denial, modification, or revocation of temporary extension where use may cause adverse effect on environment and requiring notice of such revocation to registrant.

Subsec. (f)(2)(B). Pub. L. 104–170, § 210(c)(2), inserted at end provisions authorizing extension of deadline for production of residue chemistry data in case of minor use and setting forth conditions to be met for such extension in cls. (i) to (iv).

Subsec. (f)(3). Pub. L. 104–170, § 210(f)(1)(A), inserted at end provisions delaying upon written request action with regard to unsupported minor uses, authorizing refusal of request where there are health or environmental concerns, authorizing publication of notice in Federal Register and monitoring of development of data, setting forth procedures where registrant is not meeting or has not met schedule for production of data, and authorizing denial, modification, or revocation of temporary extension where use may cause adverse effect on environment and requiring notice of such revocation to registrant.

Subsec. (g)(2)(E). Pub. L. 104–170, § 103, added subpar. (E).

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processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such food is not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment. This section does not apply to the labeling requirements of sections 343(q) and 343(r) of this title.

(June 25, 1938, ch. 675, § 405, 52 Stat. 1049; Pub. L. 101–535, § 5(a), Nov. 8, 1990, 104 Stat. 2362.)

AMENDMENTS

1990—Pub. L. 101–535 inserted at end "This section does not apply to the labeling requirements of sections 343(q) and 343(r) of this title."

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–535 effective six months after the date of the promulgation of final regulations to implement section 343(r) of this title, or if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations (Nov. 8, 1992), with exception for persons marketing food the brand name of which contains a term defined by the Secretary under section 343(r)(2)(A)(i) of this title, see section 10(a) of Pub. L. 101–535, set out as a note under section 343 of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 101–535

Amendments by Pub. L. 101–535 not to be construed to alter authority of Secretary of Health and Human Services and Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), see section 9 of Pub. L. 101–535, set out as a note under section 343 of this title.

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see notes set out under section 321 of this title.

§ 346. Tolerances for poisonous or deleterious substances in food; regulations

Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title; but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title. While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 342(a) of this title. In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(June 25, 1938, ch. 675, § 406, 52 Stat. 1049; Pub. L. 85–929, § 3(c), Sept. 6, 1958, 72 Stat. 1785; Pub. L. 86–618, title I, § 103(a)(1), July 12, 1960, 74 Stat. 398.)

AMENDMENTS

1960—Pub. L. 86–618 repealed subsec. (b) which required Secretary to promulgate regulations for listing of coal-tar colors.

1958—Subsec. (a). Pub. L. 85–929 substituted "clause (2)(A)" for "clause (2)" in first sentence.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86–618 effective July 12, 1960, subject to the provisions of section 203 of Pub. L. 86–618, see section 202 of Pub. L. 86–618, set out as a note under section 379e of this title.

EFFECTIVE DATE OF NEMATOCIDE, PLANT REGULATOR, DEFOLIANT, AND DESICCANT AMENDMENT OF 1959

Effective date of subsec. (a) as in force prior to July 22, 1954, with respect to particular commercial use of a nematocide, plant regulator, defoliant, or desiccant in or on a raw agricultural commodity made before Jan. 1, 1958, see section 3(b) of Pub. L. 86–139, Aug. 7, 1959, 73 Stat. 288.

EFFECTIVE DATE OF 1958 AMENDMENT

For effective date of amendment by Pub. L. 85–929, see section 6(b), (c) of Pub. L. 85–929, set out as a note under section 342 of this title.

TRANSFER OF FUNCTIONS

Functions vested in Secretary of Health, Education, and Welfare [now Health and Human Services] in establishing tolerances for pesticide chemicals under this section together with authority to monitor compliance with tolerances and effectiveness of surveillance and enforcement and to provide technical assistance to States and conduct research under this chapter and section 201 et seq. of Title 42, The Public Health and Welfare, transferred to Administrator of Environmental Protection Agency by Reorg. Plan No. 3 of 1970, § 2(a)(4), eff. Dec. 2, 1970, 35 F.R. 15623, 84 Stat. 2086, set out in the Appendix to Title 5, Government Organization and Employees.

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration to Federal Security Agency, see notes set out under section 321 of this title.

§ 346a. Tolerances and exemptions for pesticide chemical residues

(a) Requirement for tolerance or exemption

(1) General rule

Except as provided in paragraph (2) or (3), any pesticide chemical residue in or on a food shall be deemed unsafe for the purpose of section 342(a)(2)(B) of this title unless—

(A) a tolerance for such pesticide chemical residue in or on such food is in effect under this section and the quantity of the residue is within the limits of the tolerance; or

(B) an exemption from the requirement of a tolerance is in effect under this section for the pesticide chemical residue.

For the purposes of this section, the term "food", when used as a noun without modifica-

tion, shall mean a raw agricultural commodity or processed food.

(2) Processed food

Notwithstanding paragraph (1)—

(A) if a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 342(a)(2)(B) of this title despite the lack of a tolerance for the pesticide chemical residue in or on the processed food if the pesticide chemical has been used in or on the raw agricultural commodity in conformity with a tolerance under this section, such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of the pesticide chemical residue in the processed food is not greater than the tolerance prescribed for the pesticide chemical residue in the raw agricultural commodity; or

(B) if an exemption for the requirement for a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 342(a)(2)(B) of this title.

(3) Residues of degradation products

If a pesticide chemical residue is present in or on a food because it is a metabolite or other degradation product of a precursor substance that itself is a pesticide chemical or pesticide chemical residue, such a residue shall not be considered to be unsafe within the meaning of section 342(a)(2)(B) of this title despite the lack of a tolerance or exemption from the need for a tolerance for such residue in or on such food if—

(A) the Administrator has not determined that the degradation product is likely to pose any potential health risk from dietary exposure that is of a different type than, or of a greater significance than, any risk posed by dietary exposure to the precursor substance;

(B) either—

(i) a tolerance is in effect under this section for residues of the precursor substance in or on the food, and the combined level of residues of the degradation product and the precursor substance in or on the food is at or below the stoichiometrically equivalent level that would be permitted by the tolerance if the residue consisted only of the precursor substance rather than the degradation product; or

(ii) an exemption from the need for a tolerance is in effect under this section for residues of the precursor substance in or on the food; and

(C) the tolerance or exemption for residues of the precursor substance does not state that it applies only to particular named substances and does not state that it does not apply to residues of the degradation product.

(4) Effect of tolerance or exemption

While a tolerance or exemption from the requirement for a tolerance is in effect under this section for a pesticide chemical residue with respect to any food, the food shall not by reason of bearing or containing any amount of such a residue be considered to be adulterated within the meaning of section 342(a)(1) of this title.

(b) Authority and standard for tolerance

(1) Authority

The Administrator may issue regulations establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food—

(A) in response to a petition filed under subsection (d) of this section; or

(B) on the Administrator's own initiative under subsection (e) of this section.

As used in this section, the term "modify" shall not mean expanding the tolerance to cover additional foods.

(2) Standard

(A) General rule

(i) Standard

The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.

(ii) Determination of safety

As used in this section, the term "safe", with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

(iii) Rule of construction

With respect to a tolerance, a pesticide chemical residue meeting the standard under clause (i) is not an eligible pesticide chemical residue for purposes of subparagraph (B).

(B) Tolerances for eligible pesticide chemical residues

(i) Definition

As used in this subparagraph, the term "eligible pesticide chemical residue" means a pesticide chemical residue as to which—

(I) the Administrator is not able to identify a level of exposure to the residue at which the residue will not cause or contribute to a known or anticipated harm to human health (referred to in this section as a "nonthreshold effect");

(II) the lifetime risk of experiencing the nonthreshold effect is appropriately

assessed by quantitative risk assessment; and

(III) with regard to any known or anticipated harm to human health for which the Administrator is able to identify a level at which the residue will not cause such harm (referred to in this section as a "threshold effect"), the Administrator determines that the level of aggregate exposure is safe.

(ii) Determination of tolerance

Notwithstanding subparagraph (A)(i), a tolerance for an eligible pesticide chemical residue may be left in effect or modified under this subparagraph if—

(I) at least one of the conditions described in clause (iii) is met; and

(II) both of the conditions described in clause (iv) are met.

(iii) Conditions regarding use

For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) Use of the pesticide chemical that produces the residue protects consumers from adverse effects on health that would pose a greater risk than the dietary risk from the residue.

(II) Use of the pesticide chemical that produces the residue is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply.

(iv) Conditions regarding risk

For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) The yearly risk associated with the nonthreshold effect from aggregate exposure to the residue does not exceed 10 times the yearly risk that would be allowed under subparagraph (A) for such effect.

(II) The tolerance is limited so as to ensure that the risk over a lifetime associated with the nonthreshold effect from aggregate exposure to the residue is not greater than twice the lifetime risk that would be allowed under subparagraph (A) for such effect.

(v) Review

Five years after the date on which the Administrator makes a determination to leave in effect or modify a tolerance under this subparagraph, and thereafter as the Administrator deems appropriate, the Administrator shall determine, after notice and opportunity for comment, whether it has been demonstrated to the Administrator that a condition described in clause (iii)(I) or clause (iii)(II) continues to exist with respect to the tolerance and that the yearly and lifetime risks from aggregate exposure to such residue continue to comply with the limits specified in clause (iv). If the Administrator determines by such date that such demonstration has not been made, the Administrator shall, not later than 180 days after the date of such determination, issue a regulation under subsection (e)(1) of this section to modify or revoke the tolerance.

(vi) Infants and children

Any tolerance under this subparagraph shall meet the requirements of subparagraph (C).

(C) Exposure of infants and children

In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator—

(i) shall assess the risk of the pesticide chemical residue based on—

(I) available information about consumption patterns among infants and children that are likely to result in disproportionately high consumption of foods containing or bearing such residue among infants and children in comparison to the general population;

(II) available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals; and

(III) available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity; and

(ii) shall—

(I) ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue; and

(II) publish a specific determination regarding the safety of the pesticide chemical residue for infants and children.

The Secretary of Health and Human Services and the Secretary of Agriculture, in consultation with the Administrator, shall conduct surveys to document dietary exposure to pesticides among infants and children. In the case of threshold effects, for purposes of clause (ii)(I) an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and postnatal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.

(D) Factors

In establishing, modifying, leaving in effect, or revoking a tolerance or exemption

for a pesticide chemical residue, the Administrator shall consider, among other relevant factors—

(i) the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue;

(ii) the nature of any toxic effect shown to be caused by the pesticide chemical or pesticide chemical residue in such studies;

(iii) available information concerning the relationship of the results of such studies to human risk;

(iv) available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers);

(v) available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity;

(vi) available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources;

(vii) available information concerning the variability of the sensitivities of major identifiable subgroups of consumers;

(viii) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects; and

(ix) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

(E) Data and information regarding anticipated and actual residue levels

(i) Authority

In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may consider available data and information on the anticipated residue levels of the pesticide chemical in or on food and the actual residue levels of the pesticide chemical that have been measured in food, including residue data collected by the Food and Drug Administration.

(ii) Requirement

If the Administrator relies on anticipated or actual residue levels in establishing, modifying, or leaving in effect a tolerance, the Administrator shall pursuant to subsection (f)(1) of this section require that data be provided five years after the date on which the tolerance is established, modified, or left in effect, and thereafter as the Administrator deems appropriate, demonstrating that such residue levels are not above the levels so relied on. If such data are not so provided, or if the data do not demonstrate that the residue levels are not above the levels so relied on, the Administrator shall, not later than 180 days after the date on which the data were required to be provided, issue a regulation under subsection (e)(1) of this section, or an order under subsection (f)(2) of this section, as appropriate, to modify or revoke the tolerance.

(F) Percent of food actually treated

In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may, when assessing chronic dietary risk, consider available data and information on the percent of food actually treated with the pesticide chemical (including aggregate pesticide use data collected by the Department of Agriculture) only if the Administrator—

(i) finds that the data are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide chemical residue;

(ii) finds that the exposure estimate does not understate exposure for any significant subpopulation group;

(iii) finds that, if data are available on pesticide use and consumption of food in a particular area, the population in such area is not dietarily exposed to residues above those estimated by the Administrator; and

(iv) provides for the periodic reevaluation of the estimate of anticipated dietary exposure.

(3) Detection methods

(A) General rule

A tolerance for a pesticide chemical residue in or on a food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary, that there is a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food.

(B) Detection limit

A tolerance for a pesticide chemical residue in or on a food shall not be established at or modified to a level lower than the limit of detection of the method for detecting and measuring the pesticide chemical residue specified by the Administrator under subparagraph (A).

(4) International standards

In establishing a tolerance for a pesticide chemical residue in or on a food, the Administrator shall determine whether a maximum residue level for the pesticide chemical has been established by the Codex Alimentarius Commission. If a Codex maximum residue level has been established for the pesticide chemical and the Administrator does not propose to adopt the Codex level, the Administrator shall publish for public comment a notice explaining the reasons for departing from the Codex level.

(c) Authority and standard for exemptions

(1) Authority

The Administrator may issue a regulation establishing, modifying, or revoking an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food—

(A) in response to a petition filed under subsection (d) of this section; or

(B) on the Administrator's initiative under subsection (e) of this section.

(2) Standard

(A) General rule

(i) Standard

The Administrator may establish or leave in effect an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the exemption is safe. The Administrator shall modify or revoke an exemption if the Administrator determines it is not safe.

(ii) Determination of safety

The term "safe", with respect to an exemption for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

(B) Factors

In making a determination under this paragraph, the Administrator shall take into account, among other relevant considerations, the considerations set forth in subparagraphs (C) and (D) of subsection (b)(2) of this section.

(3) Limitation

An exemption from the requirement for a tolerance for a pesticide chemical residue in or on food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary—

(A) that there is a practical method for detecting and measuring the levels of such pesticide chemical residue in or on food; or

(B) that there is no need for such a method, and states the reasons for such determination in issuing the regulation establishing or modifying the exemption.

(d) Petition for tolerance or exemption

(1) Petitions and petitioners

Any person may file with the Administrator a petition proposing the issuance of a regulation—

(A) establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food; or

(B) establishing, modifying, or revoking an exemption from the requirement of a tolerance for such a residue.

(2) Petition contents

(A) Establishment

A petition under paragraph (1) to establish a tolerance or exemption for a pesticide chemical residue shall be supported by such data and information as are specified in regulations issued by the Administrator, including—

(i)(I) an informative summary of the petition and of the data, information, and arguments submitted or cited in support of the petition; and

(II) a statement that the petitioner agrees that such summary or any information it contains may be published as a part of the notice of filing of the petition to be published under this subsection and as part of a proposed or final regulation issued under this section;

(ii) the name, chemical identity, and composition of the pesticide chemical residue and of the pesticide chemical that produces the residue;

(iii) data showing the recommended amount, frequency, method, and time of application of that pesticide chemical;

(iv) full reports of tests and investigations made with respect to the safety of the pesticide chemical, including full information as to the methods and controls used in conducting those tests and investigations;

(v) full reports of tests and investigations made with respect to the nature and amount of the pesticide chemical residue that is likely to remain in or on the food, including a description of the analytical methods used;

(vi) a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food, or for exemptions, a statement why such a method is not needed;

(vii) a proposed tolerance for the pesticide chemical residue, if a tolerance is proposed;

(viii) if the petition relates to a tolerance for a processed food, reports of investigations conducted using the processing method(s) used to produce that food;

(ix) such information as the Administrator may require to make the determination under subsection (b)(2)(C) of this section;

(x) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects;

(xi) information regarding exposure to the pesticide chemical residue due to any tolerance or exemption already granted for such residue;

(xii) practical methods for removing any amount of the residue that would exceed any proposed tolerance; and

(xiii) such other data and information as the Administrator requires by regulation to support the petition.

If information or data required by this subparagraph is available to the Administrator, the person submitting the petition may cite the availability of the information or data in lieu of submitting it. The Administrator

may require a petition to be accompanied by samples of the pesticide chemical with respect to which the petition is filed.

(B) Modification or revocation

The Administrator may by regulation establish the requirements for information and data to support a petition to modify or revoke a tolerance or to modify or revoke an exemption from the requirement for a tolerance.

(3) Notice

A notice of the filing of a petition that the Administrator determines has met the requirements of paragraph (2) shall be published by the Administrator within 30 days after such determination. The notice shall announce the availability of a description of the analytical methods available to the Administrator for the detection and measurement of the pesticide chemical residue with respect to which the petition is filed or shall set forth the petitioner's statement of why such a method is not needed. The notice shall include the summary required by paragraph (2)(A)(i)(I).

(4) Actions by the Administrator

(A) In general

The Administrator shall, after giving due consideration to a petition filed under paragraph (1) and any other information available to the Administrator—

(i) issue a final regulation (which may vary from that sought by the petition) establishing, modifying, or revoking a tolerance for the pesticide chemical residue or an exemption of the pesticide chemical residue from the requirement of a tolerance (which final regulation shall be issued without further notice and without further period for public comment);

(ii) issue a proposed regulation under subsection (e) of this section, and thereafter issue a final regulation under such subsection; or

(iii) issue an order denying the petition.

(B) Priorities

The Administrator shall give priority to petitions for the establishment or modification of a tolerance or exemption for a pesticide chemical residue that appears to pose a significantly lower risk to human health from dietary exposure than pesticide chemical residues that have tolerances in effect for the same or similar uses.

(C) Expedited review of certain petitions

(i) Date certain for review

If a person files a complete petition with the Administrator proposing the issuance of a regulation establishing a tolerance or exemption for a pesticide chemical residue that presents a lower risk to human health than a pesticide chemical residue for which a tolerance has been left in effect or modified under subsection (b)(2)(B) of this section, the Administrator shall complete action on such petition under this paragraph within 1 year.

(ii) Required determinations

If the Administrator issues a final regulation establishing a tolerance or exemption for a safer pesticide chemical residue under clause (i), the Administrator shall, not later than 180 days after the date on which the regulation is issued, determine whether a condition described in subclause (I) or (II) of subsection (b)(2)(B)(iii) of this section continues to exist with respect to a tolerance that has been left in effect or modified under subsection (b)(2)(B) of this section. If such condition does not continue to exist, the Administrator shall, not later than 180 days after the date on which the determination under the preceding sentence is made, issue a regulation under subsection (e)(1) of this section to modify or revoke the tolerance.

(e) Action on Administrator's own initiative

(1) General rule

The Administrator may issue a regulation—

(A) establishing, modifying, suspending under subsection (*l*)(3) of this section, or revoking a tolerance for a pesticide chemical or a pesticide chemical residue;

(B) establishing, modifying, suspending under subsection (*l*)(3) of this section, or revoking an exemption of a pesticide chemical residue from the requirement of a tolerance; or

(C) establishing general procedures and requirements to implement this section.

(2) Notice

Before issuing a final regulation under paragraph (1), the Administrator shall issue a notice of proposed rulemaking and provide a period of not less than 60 days for public comment on the proposed regulation, except that a shorter period for comment may be provided if the Administrator for good cause finds that it would be in the public interest to do so and states the reasons for the finding in the notice of proposed rulemaking.

(f) Special data requirements

(1) Requiring submission of additional data

If the Administrator determines that additional data or information are reasonably required to support the continuation of a tolerance or exemption that is in effect under this section for a pesticide chemical residue on a food, the Administrator shall—

(A) issue a notice requiring the person holding the pesticide registrations associated with such tolerance or exemption to submit the data or information under section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136a(c)(2)(B)];

(B) issue a rule requiring that testing be conducted on a substance or mixture under section 4 of the Toxic Substances Control Act [15 U.S.C. 2603]; or

(C) publish in the Federal Register, after first providing notice and an opportunity for comment of not less than 60 days' duration, an order—

(i) requiring the submission to the Administrator by one or more interested persons of a notice identifying the person or persons who will submit the required data and information;

(ii) describing the type of data and information required to be submitted to the Administrator and stating why the data and information could not be obtained under the authority of section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136a(c)(2)(B)] or section 4 of the Toxic Substances Control Act [15 U.S.C. 2603];

(iii) describing the reports of the Administrator required to be prepared during and after the collection of the data and information;

(iv) requiring the submission to the Administrator of the data, information, and reports referred to in clauses (ii) and (iii); and

(v) establishing dates by which the submissions described in clauses (i) and (iv) must be made.

The Administrator may under subparagraph (C) revise any such order to correct an error. The Administrator may under this paragraph require data or information pertaining to whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects.

(2) Noncompliance

If a submission required by a notice issued in accordance with paragraph (1)(A), a rule issued under paragraph (1)(B), or an order issued under paragraph (1)(C) is not made by the time specified in such notice, rule, or order, the Administrator may by order published in the Federal Register modify or revoke the tolerance or exemption in question. In any review of such an order under subsection (g)(2) of this section, the only material issue shall be whether a submission required under paragraph (1) was not made by the time specified.

(g) Effective date, objections, hearings, and administrative review

(1) Effective date

A regulation or order issued under subsection (d)(4), (e)(1), or (f)(2) of this section shall take effect upon publication unless the regulation or order specifies otherwise. The Administrator may stay the effectiveness of the regulation or order if, after issuance of such regulation or order, objections are filed with respect to such regulation or order pursuant to paragraph (2).

(2) Further proceedings

(A) Objections

Within 60 days after a regulation or order is issued under subsection (d)(4), (e)(1)(A), (e)(1)(B), (f)(2), (n)(3), or (n)(5)(C) of this section, any person may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation or order deemed objectionable and stating reasonable grounds therefor. If the regulation or order was issued in response to a petition under subsection (d)(1) of this section, a copy of each objection filed by a person other than the petitioner shall be served by the Administrator on the petitioner.

(B) Hearing

An objection may include a request for a public evidentiary hearing upon the objection. The Administrator shall, upon the initiative of the Administrator or upon the request of an interested person and after due notice, hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections. The presiding officer in such a hearing may authorize a party to obtain discovery from other persons and may upon a showing of good cause made by a party issue a subpoena to compel testimony or production of documents from any person. The presiding officer shall be governed by the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, such a subpoena may be enforced by a Federal district court.

(C) Final decision

As soon as practicable after receiving the arguments of the parties, the Administrator shall issue an order stating the action taken upon each such objection and setting forth any revision to the regulation or prior order that the Administrator has found to be warranted. If a hearing was held under subparagraph (B), such order and any revision to the regulation or prior order shall, with respect to questions of fact at issue in the hearing, be based only on substantial evidence of record at such hearing, and shall set forth in detail the findings of facts and the conclusions of law or policy upon which the order or regulation is based.

(h) Judicial review

(1) Petition

In a case of actual controversy as to the validity of any regulation issued under subsection (e)(1)(C) of this section, or any order issued under subsection (f)(1)(C) or (g)(2)(C) of this section, or any regulation that is the subject of such an order, any person who will be adversely affected by such order or regulation may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein that person resides or has its principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after publication of such order or regulation, a petition praying that the order or regulation be set aside in whole or in part.

(2) Record and jurisdiction

A copy of the petition under paragraph (1) shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the order or regulation, as provided in section 2112 of title

28. Upon the filing of such a petition, the court shall have exclusive jurisdiction to affirm or set aside the order or regulation complained of in whole or in part. As to orders issued following a public evidentiary hearing, the findings of the Administrator with respect to questions of fact shall be sustained only if supported by substantial evidence when considered on the record as a whole.

(3) Additional evidence

If a party applies to the court for leave to adduce additional evidence and shows to the satisfaction of the court that the additional evidence is material and that there were reasonable grounds for the failure to adduce the evidence in the proceeding before the Administrator, the court may order that the additional evidence (and evidence in rebuttal thereof) shall be taken before the Administrator in the manner and upon the terms and conditions the court deems proper. The Administrator may modify prior findings as to the facts by reason of the additional evidence so taken and may modify the order or regulation accordingly. The Administrator shall file with the court any such modified finding, order, or regulation.

(4) Final judgment; Supreme Court review

The judgment of the court affirming or setting aside, in whole or in part, any regulation or any order and any regulation which is the subject of such an order shall be final, subject to review by the Supreme Court of the United States as provided in section 1254 of title 28. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of a regulation or order.

(5) Application

Any issue as to which review is or was obtainable under this subsection shall not be the subject of judicial review under any other provision of law.

(i) Confidentiality and use of data

(1) General rule

Data and information that are or have been submitted to the Administrator under this section or section 348 of this title in support of a tolerance or an exemption from a tolerance shall be entitled to confidential treatment for reasons of business confidentiality and to exclusive use and data compensation to the same extent provided by sections 3 and 10 of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136a, 136h].

(2) Exceptions

(A) In general

Data and information that are entitled to confidential treatment under paragraph (1) may be disclosed, under such security requirements as the Administrator may provide by regulation, to—

(i) employees of the United States authorized by the Administrator to examine such data and information in the carrying out of their official duties under this chapter or other Federal statutes intended to protect the public health; or

(ii) contractors with the United States authorized by the Administrator to examine such data and information in the carrying out of contracts under this chapter or such statutes.

(B) Congress

This subsection does not authorize the withholding of data or information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(3) Summaries

Notwithstanding any provision of this subsection or other law, the Administrator may publish the informative summary required by subsection (d)(2)(A)(i) of this section and may, in issuing a proposed or final regulation or order under this section, publish an informative summary of the data relating to the regulation or order.

(j) Status of previously issued regulations

(1) Regulations under section 346

Regulations affecting pesticide chemical residues in or on raw agricultural commodities promulgated, in accordance with section 371(e) of this title, under the authority of section 346(a)[1] of this title upon the basis of public hearings instituted before January 1, 1953, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsections (d) and (e) of this section, and shall be subject to review under subsection (q) of this section.

(2) Regulations under section 348

Regulations that established tolerances for substances that are pesticide chemical residues in or on processed food, or that otherwise stated the conditions under which such pesticide chemicals could be safely used, and that were issued under section 348 of this title on or before August 3, 1996, shall be deemed to be regulations issued under this section and shall be subject to modification or revocation under subsection (d) or (e) of this section, and shall be subject to review under subsection (q) of this section.

(3) Regulations under section 346a

Regulations that established tolerances or exemptions under this section that were issued on or before August 3, 1996, shall remain in effect unless modified or revoked under subsection (d) or (e) of this section, and shall be subject to review under subsection (q) of this section.

(4) Certain substances

With respect to a substance that is not included in the definition of the term "pesticide chemical" under section 321(q)(1) of this title but was so included on the day before October 30, 1998, the following applies as of October 30, 1998:

(A) Notwithstanding paragraph (2), any regulation applying to the use of the sub-

[1] See References in Text note below.

stance that was in effect on the day before October 30, 1998, 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 348 of this title.

(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 August 3, 1996) is deemed to have been issued under section 348 of this title.

(k) Transitional provision

If, on the day before August 3, 1996, a substance that is a pesticide chemical was, with respect to a particular pesticidal use of the substance and any resulting pesticide chemical residue in or on a particular food—

(1) regarded by the Administrator or the Secretary as generally recognized as safe for use within the meaning of the provisions of subsection (a) of this section or section 321(s) of this title as then in effect; or

(2) regarded by the Secretary as a substance described by section 321(s)(4) of this title;

such a pesticide chemical residue shall be regarded as exempt from the requirement for a tolerance, as of August 3, 1996. The Administrator shall by regulation indicate which substances are described by this subsection. Any exemption under this subsection may be modified or revoked as if it had been issued under subsection (c) of this section.

(l) Harmonization with action under other laws

(1) Coordination with FIFRA

To the extent practicable and consistent with the review deadlines in subsection (q) of this section, in issuing a final rule under this subsection that suspends or revokes a tolerance or exemption for a pesticide chemical residue in or on food, the Administrator shall coordinate such action with any related necessary action under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.].

(2) Revocation of tolerance or exemption following cancellation of associated registrations

If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, cancels the registration of each pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, or requires that the registration of each such pesticide be modified to prohibit its use in connection with the production, storage, or transportation of such food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall revoke any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) of this section shall apply to actions taken under this paragraph. A revocation under this paragraph shall become effective not later than 180 days after—

(A) the date by which each such cancellation of a registration has become effective; or

(B) the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation, whichever is later.

(3) Suspension of tolerance or exemption following suspension of associated registrations

(A) Suspension

If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, suspends the use of each registered pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall suspend any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) of this section shall apply to actions taken under this paragraph. A suspension under this paragraph shall become effective not later than 60 days after the date by which each such suspension of use has become effective.

(B) Effect of suspension

The suspension of a tolerance or exemption under subparagraph (A) shall be effective as long as the use of each associated registration of a pesticide is suspended under the Federal Insecticide, Fungicide, and Rodenticide Act. While a suspension of a tolerance or exemption is effective the tolerance or exemption shall not be considered to be in effect. If the suspension of use of the pesticide under that Act is terminated, leaving the registration of the pesticide for such use in effect under that Act, the Administrator shall rescind any associated suspension of tolerance or exemption.

(4) Tolerances for unavoidable residues

In connection with action taken under paragraph (2) or (3), or with respect to pesticides whose registrations were suspended or canceled prior to August 3, 1996, under the Federal Insecticide, Fungicide, and Rodenticide Act, if the Administrator determines that a residue of the canceled or suspended pesticide chemical will unavoidably persist in the environment and thereby be present in or on a food, the Administrator may establish a tolerance for the pesticide chemical residue. In establishing such a tolerance, the Administrator shall take into account both the factors set forth in subsection (b)(2) of this section and the unavoidability of the residue. Subsection (e) of this section shall apply to the establishment of such tolerance. The Administrator shall review any such tolerance periodically and modify it as necessary so that it allows no greater level of the pesticide chemical residue than is unavoidable.

(5) Pesticide residues resulting from lawful application of pesticide

Notwithstanding any other provision of this chapter, if a tolerance or exemption for a pesticide chemical residue in or on a food has been revoked, suspended, or modified under

this section, an article of that food shall not be deemed unsafe solely because of the presence of such pesticide chemical residue in or on such food if it is shown to the satisfaction of the Secretary that—

(A) the residue is present as the result of an application or use of a pesticide at a time and in a manner that was lawful under the Federal Insecticide, Fungicide, and Rodenticide Act; and

(B) the residue does not exceed a level that was authorized at the time of that application or use to be present on the food under a tolerance, exemption, food additive regulation, or other sanction then in effect under this chapter;

unless, in the case of any tolerance or exemption revoked, suspended, or modified under this subsection or subsection (d) or (e) of this section, the Administrator has issued a determination that consumption of the legally treated food during the period of its likely availability in commerce will pose an unreasonable dietary risk.

(6) Tolerance for use of pesticides under an emergency exemption

If the Administrator grants an exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136p) for a pesticide chemical, the Administrator shall establish a tolerance or exemption from the requirement for a tolerance for the pesticide chemical residue. Such a tolerance or exemption from a tolerance shall have an expiration date. The Administrator may establish such a tolerance or exemption without providing notice or a period for comment on the tolerance or exemption. The Administrator shall promulgate regulations within 365 days after August 3, 1996, governing the establishment of tolerances and exemptions under this paragraph. Such regulations shall be consistent with the safety standard under subsections (b)(2) and (c)(2) of this section and with section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act.

(m) Fees

(1) Amount

The Administrator shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Administrator, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Administrator's functions under this section. Under the regulations, the performance of the Administrator's services or other functions under this section, including—

(A) the acceptance for filing of a petition submitted under subsection (d) of this section;

(B) establishing, modifying, leaving in effect, or revoking a tolerance or establishing, modifying, leaving in effect, or revoking an exemption from the requirement for a tolerance under this section;

(C) the acceptance for filing of objections under subsection (g) of this section; or

(D) the certification and filing in court of a transcript of the proceedings and the record under subsection (h) of this section;

may be conditioned upon the payment of such fees. The regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Administrator such a waiver or refund is equitable and not contrary to the purposes of this subsection.

(2) Deposit

All fees collected under paragraph (1) shall be deposited in the Reregistration and Expedited Processing Fund created by section 4(k) of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136a–1(k)]. Such fees shall be available to the Administrator, without fiscal year limitation, for the performance of the Administrator's services or functions as specified in paragraph (1).

(3) Prohibition

During the period beginning on October 1, 2007, and ending on September 30, 2017, the Administrator shall not collect any tolerance fees under paragraph (1).

(n) National uniformity of tolerances

(1) "Qualifying pesticide chemical residue" defined

For purposes of this subsection, the term "qualifying pesticide chemical residue" means a pesticide chemical residue resulting from the use, in production, processing, or storage of a food, of a pesticide chemical that is an active ingredient and that—

(A) was first approved for such use in a registration of a pesticide issued under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136a(c)(5)] on or after April 25, 1985, on the basis of data determined by the Administrator to meet all applicable requirements for data prescribed by regulations in effect under that Act [7 U.S.C. 136 et seq.] on April 25, 1985; or

(B) was approved for such use in a reregistration eligibility determination issued under section 4(g) of that Act [7 U.S.C. 136a–1(g)] on or after August 3, 1996.

(2) "Qualifying Federal determination" defined

For purposes of this subsection, the term "qualifying Federal determination" means a tolerance or exemption from the requirement for a tolerance for a qualifying pesticide chemical residue that—

(A) is issued under this section after August 3, 1996, and determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or (c)(2) (in the case of an exemption) of this section; or

(B)(i) pursuant to subsection (j) of this section is remaining in effect or is deemed to have been issued under this section, or is regarded under subsection (k) of this section as exempt from the requirement for a tolerance; and

(ii) is determined by the Administrator to meet the standard under subsection (b)(2)(A) (in the case of a tolerance) or (c)(2) (in the case of an exemption) of this section.

(3) Limitation

The Administrator may make the determination described in paragraph (2)(B)(ii) only

by issuing a rule in accordance with the procedure set forth in subsection (d) or (e) of this section and only if the Administrator issues a proposed rule and allows a period of not less than 30 days for comment on the proposed rule. Any such rule shall be reviewable in accordance with subsections (g) and (h) of this section.

(4) State authority

Except as provided in paragraphs (5), (6), and (8) no State or political subdivision may establish or enforce any regulatory limit on a qualifying pesticide chemical residue in or on any food if a qualifying Federal determination applies to the presence of such pesticide chemical residue in or on such food, unless such State regulatory limit is identical to such qualifying Federal determination. A State or political subdivision shall be deemed to establish or enforce a regulatory limit on a pesticide chemical residue in or on a food if it purports to prohibit or penalize the production, processing, shipping, or other handling of a food because it contains a pesticide residue (in excess of a prescribed limit).

(5) Petition procedure

(A) In general

Any State may petition the Administrator for authorization to establish in such State a regulatory limit on a qualifying pesticide chemical residue in or on any food that is not identical to the qualifying Federal determination applicable to such qualifying pesticide chemical residue.

(B) Petition requirements

Any petition under subparagraph (A) shall—

(i) satisfy any requirements prescribed, by rule, by the Administrator; and

(ii) be supported by scientific data about the pesticide chemical residue that is the subject of the petition or about chemically related pesticide chemical residues, data on the consumption within such State of food bearing the pesticide chemical residue, and data on exposure of humans within such State to the pesticide chemical residue.

(C) Authorization

The Administrator may, by order, grant the authorization described in subparagraph (A) if the Administrator determines that the proposed State regulatory limit—

(i) is justified by compelling local conditions; and

(ii) would not cause any food to be a violation of Federal law.

(D) Treatment

In lieu of any action authorized under subparagraph (C), the Administrator may treat a petition under this paragraph as a petition under subsection (d) of this section to modify or revoke a tolerance or an exemption. If the Administrator determines to treat a petition under this paragraph as a petition under subsection (d) of this section, the Administrator shall thereafter act on the petition pursuant to subsection (d) of this section.

(E) Review

Any order of the Administrator granting or denying the authorization described in subparagraph (A) shall be subject to review in the manner described in subsections (g) and (h) of this section.

(6) Urgent petition procedure

Any State petition to the Administrator pursuant to paragraph (5) that demonstrates that consumption of a food containing such pesticide residue level during the period of the food's likely availability in the State will pose a significant public health threat from acute exposure shall be considered an urgent petition. If an order by the Administrator to grant or deny the requested authorization in an urgent petition is not made within 30 days of receipt of the petition, the petitioning State may establish and enforce a temporary regulatory limit on a qualifying pesticide chemical residue in or on the food. The temporary regulatory limit shall be validated or terminated by the Administrator's final order on the petition.

(7) Residues from lawful application

No State or political subdivision may enforce any regulatory limit on the level of a pesticide chemical residue that may appear in or on any food if, at the time of the application of the pesticide that resulted in such residue, the sale of such food with such residue level was lawful under this section and under the law of such State, unless the State demonstrates that consumption of the food containing such pesticide residue level during the period of the food's likely availability in the State will pose an unreasonable dietary risk to the health of persons within such State.

(8) Savings

Nothing in this chapter preempts the authority of any State or political subdivision to require that a food containing a pesticide chemical residue bear or be the subject of a warning or other statement relating to the presence of the pesticide chemical residue in or on such food.

(o) Consumer right to know

Not later than 2 years after August 3, 1996, and annually thereafter, the Administrator shall, in consultation with the Secretary of Agriculture and the Secretary of Health and Human Services, publish in a format understandable to a lay person, and distribute to large retail grocers for public display (in a manner determined by the grocer), the following information, at a minimum:

(1) A discussion of the risks and benefits of pesticide chemical residues in or on food purchased by consumers.

(2) A listing of actions taken under subparagraph (B) of subsection (b)(2) of this section that may result in pesticide chemical residues in or on food that present a yearly or lifetime risk above the risk allowed under subparagraph (A) of such subsection, and the food on which the pesticide chemicals producing the residues are used.

(3) Recommendations to consumers for reducing dietary exposure to pesticide chemical residues in a manner consistent with maintaining a healthy diet, including a list of food that may reasonably substitute for food listed under paragraph (2).

Nothing in this subsection shall prevent retail grocers from providing additional information.

(p) Estrogenic substances screening program

(1) Development

Not later than 2 years after August 3, 1996, the Administrator shall in consultation with the Secretary of Health and Human Services develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate.

(2) Implementation

Not later than 3 years after August 3, 1996, after obtaining public comment and review of the screening program described in paragraph (1) by the scientific advisory panel established under section 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136w(d)] or the science advisory board established by section 4365[2] of title 42, the Administrator shall implement the program.

(3) Substances

In carrying out the screening program described in paragraph (1), the Administrator—

(A) shall provide for the testing of all pesticide chemicals; and

(B) may provide for the testing of any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substantial population may be exposed to such substance.

(4) Exemption

Notwithstanding paragraph (3), the Administrator may, by order, exempt from the requirements of this section a biologic substance or other substance if the Administrator determines that the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen.

(5) Collection of information

(A) In general

The Administrator shall issue an order to a registrant of a substance for which testing is required under this subsection, or to a person who manufactures or imports a substance for which testing is required under this subsection, to conduct testing in accordance with the screening program described in paragraph (1), and submit information obtained from the testing to the Administrator, within a reasonable time period that the Administrator determines is sufficient for the generation of the information.

[2] See References in Text note below.

(B) Procedures

To the extent practicable the Administrator shall minimize duplicative testing of the same substance for the same endocrine effect, develop, as appropriate, procedures for fair and equitable sharing of test costs, and develop, as necessary, procedures for handling of confidential business information.

(C) Failure of registrants to submit information

(i) Suspension

If a registrant of a substance referred to in paragraph (3)(A) fails to comply with an order under subparagraph (A) of this paragraph, the Administrator shall issue a notice of intent to suspend the sale or distribution of the substance by the registrant. Any suspension proposed under this paragraph shall become final at the end of the 30-day period beginning on the date that the registrant receives the notice of intent to suspend, unless during that period a person adversely affected by the notice requests a hearing or the Administrator determines that the registrant has complied fully with this paragraph.

(ii) Hearing

If a person requests a hearing under clause (i), the hearing shall be conducted in accordance with section 554 of title 5. The only matter for resolution at the hearing shall be whether the registrant has failed to comply with an order under subparagraph (A) of this paragraph. A decision by the Administrator after completion of a hearing shall be considered to be a final agency action.

(iii) Termination of suspensions

The Administrator shall terminate a suspension under this subparagraph issued with respect to a registrant if the Administrator determines that the registrant has complied fully with this paragraph.

(D) Noncompliance by other persons

Any person (other than a registrant) who fails to comply with an order under subparagraph (A) shall be liable for the same penalties and sanctions as are provided under section 16 of the Toxic Substances Control Act [15 U.S.C. 2615] in the case of a violation referred to in that section. Such penalties and sanctions shall be assessed and imposed in the same manner as provided in such section 16.

(6) Agency action

In the case of any substance that is found, as a result of testing and evaluation under this section, to have an endocrine effect on humans, the Administrator shall, as appropriate, take action under such statutory authority as is available to the Administrator, including consideration under other sections of this chapter, as is necessary to ensure the protection of public health.

(7) Report to Congress

Not later than 4 years after August 3, 1996, the Administrator shall prepare and submit to Congress a report containing—

(A) the findings of the Administrator resulting from the screening program described in paragraph (1);

(B) recommendations for further testing needed to evaluate the impact on human health of the substances tested under the screening program; and

(C) recommendations for any further actions (including any action described in paragraph (6)) that the Administrator determines are appropriate based on the findings.

(q) Schedule for review

(1) In general

The Administrator shall review tolerances and exemptions for pesticide chemical residues in effect on the day before August 3, 1996, as expeditiously as practicable, assuring that—

(A) 33 percent of such tolerances and exemptions are reviewed within 3 years of August 3, 1996;

(B) 66 percent of such tolerances and exemptions are reviewed within 6 years of August 3, 1996; and

(C) 100 percent of such tolerances and exemptions are reviewed within 10 years of August 3, 1996.

In conducting a review of a tolerance or exemption, the Administrator shall determine whether the tolerance or exemption meets the requirements of subsections[3] (b)(2) or (c)(2) of this section and shall, by the deadline for the review of the tolerance or exemption, issue a regulation under subsection (d)(4) or (e)(1) of this section to modify or revoke the tolerance or exemption if the tolerance or exemption does not meet such requirements.

(2) Priorities

In determining priorities for reviewing tolerances and exemptions under paragraph (1), the Administrator shall give priority to the review of the tolerances or exemptions that appear to pose the greatest risk to public health.

(3) Publication of schedule

Not later than 12 months after August 3, 1996, the Administrator shall publish a schedule for review of tolerances and exemptions established prior to August 3, 1996. The determination of priorities for the review of tolerances and exemptions pursuant to this subsection is not a rulemaking and shall not be subject to judicial review, except that failure to take final action pursuant to the schedule established by this paragraph shall be subject to judicial review.

(r) Temporary tolerance or exemption

The Administrator may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.] or upon the Administrator's own initiative, establish a temporary tolerance or exemption for the pesticide chemical residue for the uses covered by the permit. Subsections (b)(2), (c)(2), (d), and (e) of this section shall apply to actions taken under this subsection.

(s) Savings clause

Nothing in this section shall be construed to amend or modify the provisions of the Toxic Substances Control Act [15 U.S.C. 2601 et seq.] or the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.].

(June 25, 1938, ch. 675, § 408, as added July 22, 1954, ch. 559, § 3, 68 Stat. 511; amended Pub. L. 85–791, § 20, Aug. 28, 1958, 72 Stat. 947; Pub. L. 91–515, title VI, § 601(d)(1), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–157, title III, § 303(a), Nov. 18, 1971, 85 Stat. 464; Pub. L. 92–516, § 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 98–620, title IV, § 402(25)(A), Nov. 8, 1984, 98 Stat. 3359; Pub. L. 102–300, § 6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 102–571, title I, § 107(7), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103–80, § 3(k), Aug. 13, 1993, 107 Stat. 776; Pub. L. 104–170, title IV, § 405, Aug. 3, 1996, 110 Stat. 1514; Pub. L. 105–324, § 2(b), Oct. 30, 1998, 112 Stat. 3036; Pub. L. 110–94, § 4(d)(2), Oct. 9, 2007, 121 Stat. 1002; Pub. L. 112–177, § 2(a)(3), Sept. 28, 2012, 126 Stat. 1329.)

REFERENCES IN TEXT

The Federal Rules of Civil Procedure, referred to in subsec. (g)(2)(B), are set out in the Appendix to Title 28, Judiciary and Judicial Procedure.

Section 346 of this title, referred to in subsec. (j)(1), originally consisted of subsecs. (a) and (b). Subsec. (a) was redesignated as the entire section 346 and subsec. (b) was repealed by Pub. L. 86–618, title I, § 103(a)(1), 74 Stat. 398.

The Federal Insecticide, Fungicide, and Rodenticide Act, referred to in subsecs. (l), (n)(1)(A), (r), and (s), is act June 25, 1947, ch. 125, as amended generally by Pub. L. 92–516, Oct. 21, 1972, 86 Stat. 973, which is classified generally to subchapter II (§ 136 et seq.) of chapter 6 of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 136 of Title 7 and Tables.

Section 4365 of title 42, referred to in subsec. (p)(2), was in the original "section 8 of the Environmental Research, Development, and Demonstration Act of 1978", and was translated as meaning section 8 of the Environmental Research, Development, and Demonstration Authorization Act of 1978, to reflect the probable intent of Congress.

The Toxic Substances Control Act, referred to in subsec. (s), is Pub. L. 94–469, Oct. 11, 1976, 90 Stat. 2003, as amended, which is classified generally to chapter 53 (§ 2601 et seq.) of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see Short Title note set out under section 2601 of Title 15 and Tables.

CODIFICATION

August 3, 1996, referred to in subsecs. (k), (n)(1)(B), (2)(A), and (p)(1), (2), (7), was in the original references to the date of enactment of this subsection and the date of enactment of this section, which was translated as meaning the date of enactment of Pub. L. 104–170, which amended this section generally, to reflect the probable intent of Congress.

AMENDMENTS

2012—Subsec. (m)(3). Pub. L. 112–177 substituted "September 30, 2017" for "September 30, 2012".

2007—Subsec. (m)(3). Pub. L. 110–94 added par. (3).

1998—Subsec. (j)(4). Pub. L. 105–324 added par. (4).

[3] So in original. Probably should be "subsection".

1996—Pub. L. 104–170 amended section generally, substituting, in subsec. (a), provisions relating to requirement for tolerance or exemption for provisions relating to conditions for safety; in subsec. (b), provisions relating to authority and standard for tolerance for provisions relating to establishment of tolerances; in subsec. (c), provisions relating to authority and standard for exemptions for provisions relating to exemptions; in subsec. (d), provisions relating to petition for tolerance or exemption for provisions relating to regulations pursuant to petition, publication of notice, time for issuance, referral to advisory committees, effective date, and hearings; in subsec. (e), provisions relating to action on Administrator's own initiative for provisions relating to regulations pursuant to Administrator's proposals; in subsec. (f), provisions relating to special data requirements for provisions relating to data submitted as confidential; in subsec. (g), provisions relating to effective date, objections, hearings, and administrative review for provisions relating to advisory committees and their appointment, composition, compensation, and clerical assistance; in subsec. (h), provisions relating to judicial review for provisions relating to right of consultation; in subsec. (i), provisions relating to confidentiality and use of data for provisions relating to judicial review; in subsec. (j), provisions relating to status of previously issued regulations for provisions relating to temporary tolerances; in subsec. (k), provisions relating to transitions for provisions relating to regulations based on public hearings before January 1, 1953; in subsec. (*l*), provisions relating to harmonization with action under other laws for provisions relating to pesticides under Federal Insecticide, Fungicide, and Rodenticide Act, functions of Administrator of Environmental Protection Agency, certifications, hearings, time limitations, opinions, and regulations; in subsec. (m), provisions relating to fees for provisions relating to amendment of regulations; in subsec. (n), provisions relating to national uniformity of tolerances for provisions relating to guaranties; in subsec. (*o*), provisions relating to consumer right to know for provisions relating to payment of fees, services or functions conditioned on payment, and waiver or refund of fees; and adding subsecs. (p) to (s).

1993—Pub. L. 103–80, §3(k)(6), substituted "Administrator" for "Secretary" wherever appearing except when followed by "of Agriculture".

Subsec. (a)(1). Pub. L. 103–80, §3(k)(1), substituted "Administrator of the Environmental Protection Agency (hereinafter in this section referred to as the 'Administrator')" for "Secretary of Health and Human Services".

Subsec. (d)(5). Pub. L. 103–80, §3(k)(2), substituted "section 556(c) of title 5" for "section 7(c) of the Administrative Procedure Act (5 U.S.C., sec. 1006(c))".

Subsec. (*l*). Pub. L. 103–80, §3(k)(3), substituted "In the event" for "It the event" before "a hearing is requested".

Subsec. (n). Pub. L. 103–80, §3(k)(4), made technical amendment to reference to section 333(c) of this title to reflect amendment of corresponding provision of original act.

Subsec. (*o*). Pub. L. 103–80, §3(k)(5), which directed the substitution of "Administrator" for "Secretary of Health and Human Services" wherever appearing in the original text, was executed by making the substitution in the first sentence before "shall by regulation require", the only place "Secretary of Health and Human Services" appeared in the original text.

1992—Subsecs. (a), (d), (h), (i), (*l*), (m), (*o*). Pub. L. 102–300 substituted "Health and Human Services" for "Health, Education, and Welfare" wherever appearing in the original statutory text.

Subsec. (g). Pub. L. 102–571 substituted "379e" for "376".

1984—Subsec. (i)(5). Pub. L. 98–620 struck out provision that required the court to advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

1972—Subsecs. (d)(1), (e), (*l*). Pub. L. 92–516 substituted references to pesticide for references to economic poison wherever appearing therein.

1971—Subsec. (g). Pub. L. 92–157 struck out ", which the Secretary shall by rules and regulations prescribe," after "as compensation for their services a reasonable per diem" prior to amendment in 1970, by Pub. L. 91–515, which overlooked such language when amending subsec. (g) as provided in 1970 Amendment note.

1970—Subsec. (g). Pub. L. 91–515 substituted provisions authorizing members of an advisory committee to receive compensation and travel expenses in accordance with section 376(b)(5)(D) of this title, for provisions authorizing such members to receive as compensation a reasonable per diem for time actually spent on committee work, and necessary traveling and subsistence expenses while serving away from their places of residence.

1958—Subsec. (i)(2). Pub. L. 85–791, §20(a), in first sentence, substituted "transmitted by the clerk of the court to the Secretary, or" for "served upon the Secretary, or upon", substituted "file in the court the record of the proceedings" for "certify and file in the court a transcript of the proceedings and the record", and inserted "as provided in section 2112 of title 28", and which, in second sentence, substituted "the filing of such petition" for "such filing".

Subsec. (i)(3). Pub. L. 85–791, §20(b), in first sentence, substituted "transmitted by the clerk of the court to the Secretary of Agriculture, or" for "served upon the Secretary of Agriculture, or upon", substituted "file in the court the record of the proceedings" for "certify and file in the court a transcript of the proceedings and the record", and inserted "as provided in section 2112 of title 28", and, in second sentence, substituted "the filing of such petition" for "such filing".

EFFECTIVE DATE OF 2012 AMENDMENT

Amendment by Pub. L. 112–177 effective Oct. 1, 2012, see section 2(c) of Pub. L. 112–177, set out as a note under section 136a–1 of Title 7, Agriculture.

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 110–94 effective Oct. 1, 2007, see section 6 of Pub. L. 110–94, set out as a note under section 136a of Title 7, Agriculture.

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98–620 not applicable to cases pending on Nov. 8, 1984, see section 403 of Pub. L. 98–620, set out as an Effective Date note under section 1657 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by Pub. L. 92–516 effective at close of Oct. 21, 1972, except if regulations are necessary for implementation of any provision that becomes effective on Oct. 21, 1972, and continuation in effect of subchapter I of chapter 6 of Title 7, Agriculture, and regulations thereunder, relating to control of economic poisons, as in existence prior to Oct. 21, 1972, until superseded by provisions of Pub. L. 92–516 and regulations thereunder, see section 4 of Pub. L. 92–516, set out as an Effective Date note under section 136 of Title 7.

TOLERANCE FEES

Pub. L. 108–199, div. G, title V, §501(d)(2), Jan. 23, 2004, 118 Stat. 422, provided that: "Notwithstanding section 408(m)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(m)(1)), during the period beginning on October 1, 2003, and ending on September 30, 2008, the Administrator of the Environmental Protection Agency shall not collect any tolerance fees under that section."

DATA COLLECTION ACTIVITIES TO ASSURE HEALTH OF INFANTS AND CHILDREN

Pub. L. 104–170, title III, §301, Aug. 3, 1996, 110 Stat. 1511, provided that:

"(a) IN GENERAL.—The Secretary of Agriculture, in consultation with the Administrator of the Environ-

mental Protection Agency and the Secretary of Health and Human Services, shall coordinate the development and implementation of survey procedures to ensure that adequate data on food consumption patterns of infants and children are collected.

"(b) PROCEDURES.—To the extent practicable, the procedures referred to in subsection (a) shall include the collection of data on food consumption patterns of a statistically valid sample of infants and children.

"(c) RESIDUE DATA COLLECTION.—The Secretary of Agriculture shall ensure that the residue data collection activities conducted by the Department of Agriculture in cooperation with the Environmental Protection Agency and the Department of Health and Human Services, provide for the improved data collection of pesticide residues, including guidelines for the use of comparable analytical and standardized reporting methods, and the increased sampling of foods most likely consumed by infants and children."

§ 346b. Authorization of appropriations

There are authorized to be appropriated, out of any moneys in the Treasury not otherwise appropriated, such sums as may be necessary for the purpose and administration of sections 321(q), (r), 342(a)(2), and 346a of this title.

(July 22, 1954, ch. 559, § 4, 68 Stat. 517.)

CODIFICATION

Section was not enacted as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

§ 347. Intrastate sales of colored oleomargarine

(a) Law governing

Colored oleomargarine or colored margarine which is sold in the same State or Territory in which it is produced shall be subject in the same manner and to the same extent to the provisions of this chapter as if it had been introduced in interstate commerce.

(b) Labeling and packaging requirements

No person shall sell, or offer for sale, colored oleomargarine or colored margarine unless—

(1) such oleomargarine or margarine is packaged,

(2) the net weight of the contents of any package sold in a retail establishment is one pound or less,

(3) there appears on the label of the package (A) the word "oleomargarine" or "margarine" in type or lettering at least as large as any other type or lettering on such label, and (B) a full and accurate statement of all the ingredients contained in such oleomargarine or margarine, and

(4) each part of the contents of the package is contained in a wrapper which bears the word "oleomargarine" or "margarine" in type or lettering not smaller than 20-point type.

The requirements of this subsection shall be in addition to and not in lieu of any of the other requirements of this chapter.

(c) Sales in public eating places

No person shall possess in a form ready for serving colored oleomargarine or colored margarine at a public eating place unless a notice that oleomargarine or margarine is served is displayed prominently and conspicuously in such place and in such manner as to render it likely to be read and understood by the ordinary individual being served in such eating place or is printed or is otherwise set forth on the menu in type or lettering not smaller than that normally used to designate the serving of other food items. No person shall serve colored oleomargarine or colored margarine at a public eating place, whether or not any charge is made therefor, unless (1) each separate serving bears or is accompanied by labeling identifying it as oleomargarine or margarine, or (2) each separate serving thereof is triangular in shape.

(d) Exemption from labeling requirements

Colored oleomargarine or colored margarine when served with meals at a public eating place shall at the time of such service be exempt from the labeling requirements of section 343 of this title (except paragraphs (a) and (f)) if it complies with the requirements of subsection (b) of this section.

(e) Color content of oleomargarine

For the purpose of this section colored oleomargarine or colored margarine is oleomargarine or margarine having a tint or shade containing more than one and six-tenths degrees of yellow, or of yellow and red collectively, but with an excess of yellow over red, measured in terms of Lovibond tintometer scale or its equivalent.

(June 25, 1938, ch. 675, § 407, as added Mar. 16, 1950, ch. 61, § 3(c), 64 Stat. 20.)

EFFECTIVE DATE

Act Mar. 16, 1950, ch. 61, § 7, 64 Stat. 22, provided that: "This Act [enacting this section and sections 347a and 347b of this title and amending sections 331 and 342 of this title and sections 45 and 55 of Title 15, Commerce and Trade] shall become effective on July 1, 1950."

TRANSFER OF APPROPRIATIONS

Act Mar. 16, 1950, ch. 61, § 5, 64 Stat. 22, provided that: "So much of the unexpended balances of appropriations, allocations, or other funds (including funds available for the fiscal year ending June 30, 1950) for the use of the Bureau of Internal Revenue of the Treasury Department in the exercise of functions under the Oleomargarine Tax Act (26 U.S.C., § 2300, subchapter A) [now section 4591 et seq. of Title 26, Internal Revenue Code], as the Director of the Bureau of the Budget [now Director of the Office of Management and Budget] may determine, shall be transferred to the Federal Security Agency (Food and Drug Administration) [now the Department of Health and Human Services] for use in the enforcement of this Act [see Effective Date note above]."

§ 347a. Congressional declaration of policy regarding oleomargarine sales

The Congress finds and declares that the sale, or the serving in public eating places, of colored oleomargarine or colored margarine without clear identification as such or which is otherwise adulterated or misbranded within the meaning of this chapter depresses the market in interstate commerce for butter and for oleomargarine or margarine clearly identified and neither adulterated nor misbranded, and constitutes a burden on interstate commerce in such articles. Such burden exists, irrespective of whether such oleomargarine or margarine originates from an interstate source or from the State in which it is sold.

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tion of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(June 25, 1938, ch. 675, § 406, 52 Stat. 1049; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Sept. 6, 1958, Pub. L. 85-929, § 3(c), 72 Stat. 1785; July 12, 1960, Pub. L. 86-618, title I, § 103(a)(1), 74 Stat. 398.)

AMENDMENTS

1960—Pub. L. 86-618 repealed former subsec. (b), which required the Secretary to promulgate regulations for the listing of coal-tar colors.

1958—Subsec. (a). Pub. L. 85-929 substituted "clause (2)(A)" for "clause (2)" in first sentence.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86-618 effective, subject to the provisions of section 203 of Pub. L. 86-618, on July 12, 1960, see section 202 of Pub. L. 86-618, set out as an Effective Date of 1960 Amendment note under section 376 of this title.

EFFECTIVE DATE OF NEMATOCIDE, PLANT REGULATOR, DEFOLIANT, AND DESICCANT AMENDMENT OF 1959

Effective date of subsec. (a) as in force prior to July 22, 1954, with respect to particular commercial use of a nematocide, plant regulator, defoliant, or desiccant in or on a raw agricultural commodity made before Jan. 1, 1958, see section 3(b) of Pub. L. 86-139, Aug. 7, 1959, 73 Stat. 288.

EFFECTIVE DATE OF 1958 AMENDMENT

Effective date of 1958 amendment of subsec. (a), see section 6(b), (c) of Pub. L. 85-929, set out as an Effective Date of 1958 Amendment note under section 342 of this title.

TRANSFER OF FUNCTIONS

All functions vested in the Secretary of Health, Education, and Welfare in establishing tolerances for pesticide chemicals under this section together with the authority to monitor compliance with the tolerances and the effectiveness of surveillance and enforcement and to provide technical assistance to the States and conduct research under this chapter and section 201 et seq. of Title 42, The Public Health and Welfare, were transferred to the Administrator of the Environmental Protection Agency by Reorg. Plan No. 3 of 1970, § 2(a)(4), eff. Dec. 2, 1970, 35 F.R. 15623, 84 Stat. 2086, set out in the Appendix to Title 5, Government Organization and Employees.

For transfer of functions of the Federal Security Administrator to the Secretary of Health, Education, and Welfare [now Health and Human Services], and of the Food and Drug Administration to the Federal Security Agency, see Transfer of Functions note set out under section 41 of this title.

CROSS REFERENCES

Pesticide chemical regulations, see section 346a of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 342, 346a, 371 of this title.

§ 346a. Tolerances for pesticide chemicals in or on raw agricultural commodities

(a) Conditions of safety

Any poisonous or deleterious pesticide chemical, or any pesticide chemical which is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, added to a raw agricultural commodity, shall be deemed unsafe for the purposes of the application of clause (2) of section 342(a) of this title unless—

(1) a tolerance for such pesticide chemical in or on the raw agricultural commodity has been prescribed by the Administrator of the Environmental Protection Agency under this section and the quantity of such pesticide chemical in or on the raw agricultural commodity is within the limits of the tolerance so prescribed; or

(2) with respect to use in or on such raw agricultural commodity, the pesticide chemical has been exempted from the requirement of a tolerance by the Administrator under this section.

While a tolerance or exemption from tolerance is in effect for a pesticide chemical with respect to any raw agricultural commodity, such raw agricultural commodity shall not, by reason of bearing or containing any added amount of such pesticide chemical, be considered to be adulterated within the meaning of clause (1) of section 342(a) of this title.

(b) Establishment of tolerances

The Administrator shall promulgate regulations establishing tolerances with respect to the use in or on raw agricultural commodities of poisonous or deleterious pesticide chemicals and of pesticide chemicals which are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, to the extent necessary to protect the public health. In establishing any such regulation, the Administrator shall give appropriate consideration, among other relevant factors, (1) to the necessity for the production of an adequate, wholesome, and economical food supply; (2) to the other ways in which the consumer may be affected by the same pesticide chemical or by other related substances that are poisonous or deleterious; and (3) to the opinion submitted with a certification of usefulness under subsection (*l*) of this section. Such regulations shall be promulgated in the manner prescribed in subsection (d) or (e) of this section. In carrying out the provisions of this section relating to the establishment of tolerances, the Administrator may establish the tolerance applicable with respect to the use of any pesticide chemical in or on any raw agricultural commodity at zero level if the scientific data before the Administrator does not justify the establishment of a greater tolerance.

(c) Exemptions

The Administrator shall promulgate regulations exempting any pesticide chemical from the necessity of a tolerance with respect to use in or on any or all raw agricultural commodities when such a tolerance is not necessary to protect the public health. Such regulations shall be promulgated in the manner prescribed in subsection (d) or (e) of this section.

(d) Regulations pursuant to petition; publication of notice; time for issuance; referral to advisory committees; effective date; hearings

(1) Any person who has registered, or who has submitted an application for the registration of, a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.] may file with the Administrator a petition proposing the issuance of a regulation establishing a tolerance for a pesticide chemical which constitutes, or is an ingredient of, such pesticide, or exempting the pesticide chemical from the requirement of a tolerance. The petition shall contain data showing—

(A) the name, chemical identity, and composition of the pesticide chemical;

(B) the amount, frequency, and time of application of the pesticide chemical;

(C) full reports of investigations made with respect to the safety of the pesticide chemical;

(D) the results of tests on the amount of residue remaining, including a description of the analytical methods used;

(E) practicable methods for removing residue which exceeds any proposed tolerance;

(F) proposed tolerances for the pesticide chemical if tolerances are proposed; and

(G) reasonable grounds in support of the petition.

Samples of the pesticide chemical shall be furnished to the Administrator upon request. Notice of the filing of such petition shall be published in general terms by the Administrator within thirty days after filing. Such notice shall include the analytical methods available for the determination of the residue of the pesticide chemical for which a tolerance or exemption is proposed.

(2) Within ninety days after a certification of usefulness under subsection (*l*) of this section with respect to the pesticide chemical named in the petition, the Administrator shall, after giving due consideration to the data submitted in the petition or otherwise before him, by order make public a regulation—

(A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful, or

(B) exempting the pesticide chemical from the necessity of a tolerance for such purposes,

unless within such ninety-day period the person filing the petition requests that the petition be referred to an advisory committee or the Administrator within such period otherwise deems such referral necessary, in either of which events the provisions of paragraph (3) of this subsection shall apply in lieu hereof.

(3) In the event that the person filing the petition requests, within ninety days after a certification of usefulness under subsection (*l*) of this section with respect to the pesticide chemical named in the petition, that the petition be referred to an advisory committee, or in the event the Administrator within such period otherwise deems such referral necessary, the Administrator shall forthwith submit the petition and other data before him to an advisory committee to be appointed in accordance with subsection (g) of this section. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Administrator and other data before it, certify to the Administrator a report and recommendations on the proposal in the petition to the Administrator, together with all underlying data and a statement of the reasons or basis for the recommendations. The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Administrator shall, after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, by order make public a regulation—

(A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful; or

(B) exempting the pesticide chemical from the necessity of a tolerance for such purposes.

(4) The regulations published under paragraph (2) or (3) of this subsection will be effective upon publication.

(5) Within thirty days after publication, any person adversely affected by a regulation published pursuant to paragraph (2) or (3) of this subsection, or pursuant to subsection (e) of this section, may file objections thereto with the Administrator, specifying with particularity the provisions of the regulation deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. A copy of the objections filed by a person other than the petitioner shall be served on the petitioner, if the regulation was issued pursuant to a petition. The petitioner shall have two weeks to make a written reply to the objections. The Administrator shall thereupon, after due notice, hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. Any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee shall be made a part of the record of the hearing, if relevant and material, subject to the provisions of section 556(d) of title 5. The National Academy of Sciences shall designate a member of the advisory committee to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Administrator, the petitioner, or the officer conducting the hearing: *Provided*, That this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearing, the Administrator shall act upon such objections and by order make public a regulation. Such regulation shall be based only on substantial evidence of record at such hearing, including any report, recommendations, underlying data, and reasons certified to the Administrator by an advisory committee, and shall set forth detailed findings of fact upon which the regulation is based. No such

order shall take effect prior to the ninetieth day after its publication, unless the Administrator finds that emergency conditions exist necessitating an earlier effective date, in which event the Administrator shall specify in the order his findings as to such conditions.

(e) Regulations pursuant to Administrator's proposals

The Administrator may at any time, upon his own initiative or upon the request of any interested person, propose the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting it from the necessity of a tolerance. Thirty days after publication of such a proposal, the Administrator may by order publish a regulation based upon the proposal which shall become effective upon publication unless within such thirty-day period a person who has registered, or who has submitted an application for the registration of, a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.] containing the pesticide chemical named in the proposal, requests that the proposal be referred to an advisory committee. In the event of such a request, the Administrator shall forthwith submit the proposal and other relevant data before him to an advisory committee to be appointed in accordance with subsection (g) of this section. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Administrator and other data before it, certify to the Administrator a report and recommendations on the proposal together with all underlying data and a statement of the reasons or basis for the recommendations. The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Administrator may, after giving due consideration to all data before him, including such report, recommendations, underlying data and statement, by order publish a regulation establishing a tolerance for the pesticide chemical named in the proposal or exempting it from the necessity of a tolerance which shall become effective upon publication. Regulations issued under this subsection shall upon publication be subject to paragraph (5) of subsection (d) of this section.

(f) Data submitted as confidential

All data submitted to the Administrator or to an advisory committee in support of a petition under this section shall be considered confidential by the Administrator and by such advisory committee until publication of a regulation under paragraph (2) or (3) of subsection (d) of this section. Until such publication, such data shall not be revealed to any person other than those authorized by the Administrator or by an advisory committee in the carrying out of their official duties under this section.

(g) Advisory committees; appointment; composition; compensation; clerical assistance

Whenever the referral of a petition or proposal to an advisory committee is requested under this section, or the Administrator otherwise deems such referral necessary the Administrator shall forthwith appoint a committee of competent experts to review the petition or proposal and to make a report and recommendations thereon. Each such advisory committee shall be composed of experts, qualified in the subject matter of the petition and of adequately diversified professional background selected by the National Academy of Sciences and shall include one or more representatives from land-grant colleges. The size of the committee shall be determined by the Administrator. Members of an advisory committee shall receive compensation and travel expenses in accordance with section 376(b)(5)(D) of this title. The members shall not be subject to any other provision of law regarding the appointment and compensation of employees of the United States. The Administrator shall furnish the Committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee.

(h) Right of consultation

A person who has filed a petition or who has requested the referral of a proposal to an advisory committee in accordance with the provisions of this section, as well as representatives of the Environmental Protection Agency, shall have the right to consult with any advisory committee provided for in subsection (g) of this section in connection with the petition or proposal.

(i) Judicial review

(1) In a case of actual controversy as to the validity of any order under subsections (d)(5), (e), or (*l*) of this section any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

(2) In the case of a petition with respect to an order under subsection (d)(5) or (e) of this section, a copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by him for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28. Upon the filing of such petition, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Administrator with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole, including any report and recommendation of an advisory committee.

(3) In the case of a petition with respect to an order under subsection (*l*) of this section, a copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator, or any officer designated by him for that purpose, and thereupon the Administrator

shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28. Upon the filing of such petition, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Administrator with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole.

(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Administrator and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Administrator may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order. The courts shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

(j) Temporary tolerances

The Administrator may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.] or upon his own initiative, establish a temporary tolerance for the pesticide chemical for the uses covered by the permit whenever in his judgment such action is deemed necessary to protect the public health, or may temporarily exempt such pesticide chemical from a tolerance. In establishing such a tolerance, the Administrator shall give due regard to the necessity for experimental work in developing an adequate, wholesome, and economical food supply and to the limited hazard to the public health involved in such work when conducted in accordance with applicable regulations under the Federal Insecticide, Fungicide, and Rodenticide Act.

(k) Regulations based on public hearings before January 1, 1953

Regulations affecting pesticide chemicals in or on raw agricultural commodities which are promulgated under the authority of section 346(a) of this title upon the basis of public hearings instituted before January 1, 1953, in accordance with section 371(a) of this title, shall be deemed to be regulations under this section and shall be subject to amendment or repeal as provided in subsection (m) of this section.

(l) Pesticides under Federal Insecticide, Fungicide, and Rodenticide Act; functions of Administrator of the Environmental Protection Agency; certifications; hearing; time limitation; opinion; regulations

The Administrator, upon request of any person who has registered, or who has submitted an application for the registration of, a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.], and whose request is accompanied by a copy of a petition filed by such person under subsection (d)(1) of this section with respect to a pesticide chemical which constitutes, or is an ingredient of, such pesticide, shall, within thirty days or within sixty days if upon notice prior to the termination of such thirty days the Administrator deems it necessary to postpone action for such period, on the basis of data before him, either—

(1) certify that such pesticide chemical is useful for the purpose for which a tolerance or exemption is sought; or

(2) notify the person requesting the certification of his proposal to certify that the pesticide chemical does not appear to be useful for the purpose for which a tolerance or exemption is sought, or appears to be useful for only some of the purposes for which a tolerance or exemption is sought.

In the event that the Administrator takes the action described in clause (2) of the preceding sentence, the person requesting the certification, within one week after receiving the proposed certification, may either (A) request the Administrator to certify on the basis of the proposed certification; (B) request a hearing on the proposed certification or the parts thereof objected to; or (C) request both such certification and such hearing. If no such action is taken, the Administrator may by order make the certification as proposed. In the event that the action described in clause (A) or (C) is taken, the Administrator shall by order make the certification as proposed with respect to such parts thereof as are requested. It [1] the event a hearing is requested, the Administrator shall provide opportunity for a prompt hearing. The certification of the Administrator as the result of such hearing shall be made by order and shall be based only on substantial evidence of record at the hearing and shall set forth detailed findings of fact. In no event shall the time elapsing between the making of a request for a certification under this subsection and final certification by the Administrator exceed one hundred and sixty days. The Administrator shall submit with any certification of usefulness under this subsection an opinion, based on the data before him, whether the tolerance or exemption proposed by the petitioner reasonably reflects the amount of residue likely to result when the pesticide chemical is used in the manner proposed for the purpose for which the certification is made. The Administrator, after due notice and opportunity for public hearing, is authorized to promulgate rules and

[1] So in original. Probably should be "In".

regulations for carrying out the provisions of this subsection.

(m) Amendment of regulations

The Administrator shall prescribe by regulations the procedure by which regulations under this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of regulations establishing tolerances, including the appointment of advisory committees and the procedure for referring petitions to such committees.

(n) Guaranties

The provisions of section 333(c) of this title with respect to the furnishing of guaranties shall be applicable to raw agricultural commodities covered by this section.

(o) Payment of fees; services or functions as conditioned on; waiver or refund of fees

The Administrator shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Administrator, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Administrator's functions under this section. Under such regulations, the performance of the Administrator's services or other functions pursuant to this section, including any one or more of the following, may be conditioned upon the payment of such fees: (1) The acceptance of filing of a petition submitted under subsection (d) of this section; (2) the promulgation of a regulation establishing a tolerance, or an exemption from the necessity of a tolerance, under this section, or the amendment or repeal of such a regulation; (3) the referral of a petition or proposal under this section to an advisory committee; (4) the acceptance for filing of objections under subsection (d)(5) of this section; or (5) the certification and filing in court of a transcript of the proceedings and the record under subsection (i)(2) of this section. Such regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Administrator such waiver or refund is equitable and not contrary to the purposes of this subsection.

(June 25, 1938, ch. 675, § 408, as added July 22, 1954, ch. 559, § 3, 68 Stat. 511, and amended Aug. 28, 1958, Pub. L. 85-791, § 20, 72 Stat. 947; Oct. 30, 1970, Pub. L. 91-515, title VI, § 601(d)(1), 84 Stat. 1311; 1970 Reorg. Plan No. 3, § 2(a)(4), (8)(ii), eff. Dec. 2, 1970, 35 F.R. 15623, 84 Stat. 2086; Nov. 18, 1971, Pub. L. 92-157, title III, § 303(a), 85 Stat. 464; Oct. 21, 1972, Pub. L. 92-516, § 3(3), 86 Stat. 998.)

REFERENCES IN TEXT

The Federal Insecticide, Fungicide, and Rodenticide Act, referred to in subsecs. (d)(1), (e), (j), and (l), is act June 25, 1947, ch. 125, as amended generally by Pub. L. 92-516, Oct. 21, 1972, 86 Stat. 973, which is classified generally to subchapter II (§ 136 et seq.) of chapter 6 of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 136 of Title 7 and Tables.

CODIFICATION

In subsec. (d)(5), "section 556(d) of title 5" was substituted for "section 7(c) of the Administrative Procedure Act (5 U.S.C. sec. 1006(c))" on authority of Pub. L. 89-554, § 7(b), Sept. 6, 1966, 80 Stat. 631, the first section of which enacted Title 5, Government Organization and Employees.

AMENDMENTS

1972—Subsecs. (d)(1), (e), (l). Pub. L. 92-516 substituted references to pesticide for references to economic poison wherever appearing therein.

1971—Subsec. (g). Pub. L. 92-157 struck out ", which the Secretary shall by rules and regulations prescribe," appearing following "as compensation for their services a reasonable per diem" prior to amendment in 1970, by Pub. L. 91-515, which overlooked such language when amending subsec. (g) as provided in 1970 Amendment note.

1970—Subsec. (g). Pub. L. 91-515 substituted provisions authorizing members of an advisory committee to receive compensation and travel expenses in accordance with section 376(b)(5)(D) of this title, for provisions authorizing such members to receive as compensation a reasonable per diem for time actually spent on committee work, and necessary traveling and subsistence expenses while serving away from their places of residence.

1958—Subsec. (i)(2). Pub. L. 85-791, § 20(a), in first sentence, substituted "transmitted by the clerk of the court to the Secretary, or" for "served upon the Secretary, or upon", substituted "file in the court the record of the proceedings" for "certify and file in the court a transcript of the proceedings and the record", and inserted "as provided in section 2112 of title 28", and which, in second sentence, substituted "the filing of such petition" for "such filing".

Subsec. (i)(3). Pub. L. 85-791, § 20(b), in first sentence, substituted "transmitted by the clerk of the court to the Secretary of Agriculture, or" for "served upon the Secretary of Agriculture, or upon", substituted "file in the court the record of the proceedings" for "certify and file in the court a transcript of the proceedings and the record", and inserted "as provided in section 2112 of title 28", and, in second sentence, substituted "the filing of such petition" for "such filing".

EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by Pub. L. 92-516 effective at the close of Oct. 21, 1972, except if regulations are necessary for the implementation of any provision that becomes effective on Oct. 21, 1972, and continuation in effect of subchapter I of chapter 6 of Title 7, Agriculture, and regulations thereunder, relating to the control of economic poisons, as in existence prior to Oct. 21, 1972, until superseded by provisions of Pub. L. 92-516 and regulations thereunder, see section 4 of Pub. L. 92-516, set out as an Effective Date note under section 136 of Title 7.

TRANSFER OF FUNCTIONS

"Administrator of the Environmental Protection Agency" was substituted, in subsecs. (a) to (j), (l), (m), and (o), for "Secretary of Health, Education, and Welfare" and in subsecs. (b), (d), (i), and (l), for "Secretary of Agriculture" pursuant to Reorg. Plan No. 3 of 1970, set out in the Appendix to Title 5, Government Organization and Employees, which transferred to the Administrator of the Environmental Protection Agency all functions vested in the Secretary of Health, Education, and Welfare in establishing tolerances for pesticide chemicals under this section together with the authority to monitor compliance with the tolerances and the effectiveness of surveillance and enforcement and to provide technical assistance to the States and conduct research under this chapter and section 201 et seq. of Title 42, The Public Health and Welfare, and which also transferred to the Administrator of the Environmental Protection Agency the functions of Agriculture Department and the Secretary of Agriculture under subsec. (l) of this section.

justify the factual determination urged.

(3) Resolution of the factual issue(s) in the manner sought by the person requesting the hearing would be adequate to justify the action requested. An evidentiary hearing will not be granted on factual issues that are not determinative with respect to the action requested. For example, a hearing will not be granted if the Administrator concludes that the action would be the same even if the factual issue were resolved in the manner sought.

(c) Where appropriate, the Administrator will make rulings on any issues raised by an objection which are necessary for resolution prior to determining whether a request for an evidentiary hearing should be granted.

§ 178.35 Modification or revocation of regulation or prior order.

(a) If the Administrator determines upon review of an objection or request for hearing that the regulation or prior order in question should be modified or revoked, the Administrator will publish an order setting forth any revision to the regulation or prior order that the Administrator has found to be warranted.

(b) The Administrator will provide an opportunity for objections and requests for hearing on such order to the extent required by law. Such objections to the modification or revocation of the regulation, and requests for a hearing on such objections, may be submitted under §§ 178.20 through 178.27.

(c) Objections and requests for hearing that are not affected by the modification or revocation will remain on file and be acted upon in accordance with this part.

[55 FR 50291, Dec. 5, 1990, as amended at 70 FR 33359, June 8, 2005]

§ 178.37 Order responding to objections on which a hearing was not requested or was denied.

(a) The Administrator will publish in the FEDERAL REGISTER an order under FFDCA section 408(g)(2)(B) or section 408(g)(2)(C) setting forth the Administrator's determination on each denial of a request for a hearing, and on each objection submitted under § 178.20 on which:

(1) A hearing was not requested.

(2) A hearing was requested, but denied.

(b) Each order published under paragraph (a) of this section must state the reasons for the Administrator's determination. If the order denies a request for a hearing on the objection, the order also must state the reason for that denial (e.g., why the request for a hearing did not conform to § 178.27, or why the request was denied under § 178.32).

(c) Each order published under paragraph (a) of this section must state its effective date.

[55 FR 50291, Dec. 5, 1990, as amended at 70 FR 33359, June 8, 2005]

Subpart C [Reserved]

Subpart D—Judicial Review

§ 178.65 Judicial review.

An order issued under § 178.37 is final agency action reviewable in the courts as provided by FFDCA section 408(h), as of the date of publication of the order in the FEDERAL REGISTER. The failure to file a petition for judicial review within the period ending on the 60th day after the date of the publication of the order constitutes a waiver under FFDCA section 408(h) of the right to judicial review of the order and of any regulation promulgated by the order.

[70 FR 33359, June 8, 2005]

§ 178.70 Administrative record.

(a) For purposes of judicial review, the record of an administrative proceeding that culminates in an order under § 178.37 consists of:

(1) The objection ruled on (and any request for hearing that was included with the objection).

(2) Any order issued under § 180.7(g) of this chapter to which the objection related, and:

(i) Any regulation or petition denial that was the subject of that order.

(ii) The petition to which such order responded.

(iii) Any amendment or supplement of the petition.

(iv) The data and information submitted in support of the petition.

deems adequate to permit tests of analytical methods used to determine residues of the pesticide chemical and of methods proposed by the petitioner for removing any residues of the chemical that exceed the tolerance proposed.

(h) The Administrator shall determine, in accordance with the Act, whether to issue an order that establishes, modifies, or revokes a tolerance regulation (whether or not in accord with the action proposed by the petitioner), whether to publish a proposed tolerance regulation and request public comment thereon under §180.29, or whether to deny the petition. The Administrator shall publish in the FEDERAL REGISTER such order or proposed regulation. After receiving comments on any proposed regulation, the Administrator may issue an order that establishes, modifies, or revokes a tolerance regulation. An order published under this section shall describe briefly how to submit objections and requests for a hearing under part 178 of this chapter. A regulation issued under this section shall be effective on the date of publication in the FEDERAL REGISTER unless otherwise provided in the regulation.

[70 FR 33360, June 8, 2005, as amended at 73 FR 75600, Dec. 12, 2008]

§ 180.8 Withdrawal of petitions without prejudice.

In some cases the Administrator will notify the petitioner that the petition, while technically complete, is inadequate to justify the establishment of a tolerance or the tolerance requested by petitioner. This may be due to the fact that the data are not sufficiently clear or complete. In such cases, the petitioner may withdraw the petition pending its clarification or the obtaining of additional data. This withdrawal may be without prejudice to a future filing. A deposit for fees as specified in §180.33 shall accompany the resubmission of the petition.

[70 FR 33361, June 8, 2005]

§ 180.9 Substantive amendments to petitions.

After a petition has been filed, the petitioner may submit additional information or data in support thereof, but in such cases the petition will be given a new filing date.

[70 FR 33361, June 8, 2005]

§ 180.29 Establishment, modification, and revocation of tolerance on initiative of Administrator.

(a) Upon the Administrator's own initiative, the Administrator may propose, under FFDCA section 408(e), the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting it from the necessity of a tolerance, or a regulation modifying or revoking an existing tolerance or exemption.

(b) The Administrator shall provide a period of not less than 60 days for persons to comment on the proposed regulation, except that a shorter period for comment may be provided if the Administrator for good cause finds that it would be in the public interest to do so and states the reasons for the finding in the notice of proposed rulemaking.

(c) After reviewing any timely comments received, the Administrator may by order establish, modify, or revoke a tolerance regulation, which order and regulation shall be published in the FEDERAL REGISTER. An order published under this section shall state that persons may submit objections and requests for a hearing in the manner described in part 178 of this chapter.

(d) Any final regulation issued under this section shall be effective on the date of publication in the FEDERAL REGISTER unless otherwise provided in the regulation.

[70 FR 33361, June 8, 2005]

§ 180.30 Judicial review.

(a) Under FFDCA section 408(h), judicial review is available in the United States Courts of Appeal as to the following actions:

(1) Regulations establishing general procedures and requirements under FFDCA section 408(e)(1)(C).

(2) Orders issued under FFDCA section 408(f)(1)(C) requiring the submission of data.

(3) Orders issued under FFDCA section 408(g)(2)(C) ruling on objections to establishment, modification, or revocation of a tolerance or exemption under

FFDCA section 408(d)(4), or any regulation that is the subject of such an order. The underlying action here is Agency disposition of a petition seeking the establishment, modification, or revocation of a tolerance or exemption.

(4) Orders issued under FFDCA section 408(g)(2)(C) ruling on objections to the denial of a petition under FFDCA section 408(d)(4).

(5) Orders issued under FFDCA section 408(g)(2)(C) ruling on objections to the establishment, modification, suspension, or revocation of a tolerance or exemption under FFDCA section 408(e)(1)(A) or (e)(1)(B). The underlying action here is the establishment, modification, suspension, or revocation of a tolerance or exemption upon the initiative of EPA including EPA actions pursuant to FFDCA sections 408(b)(2)(B)(v), 408(b)(2)(E)(ii), 408(d)(4)(C)(ii), 408(l)(4), and 408(q)(1).

(6) Orders issued under FFDCA section 408(g)(2)(C) ruling on objections to the revocation or modification of a tolerance or exemption under FFDCA section 408(f)(2) for noncompliance with requirements for the submission of data.

(7) Orders issued under FFDCA section 408(g)(2)(C) ruling on objections to rules issued under FFDCA sections 408(n)(3) and 408(d) or (e) regarding determinations pertaining to State authority to establish regulatory limits on pesticide chemical residues.

(8) Orders issued under FFDCA section 408(g)(2)(C) ruling on objections to orders issued under FFDCA section 408(n)(5)(C) authorizing States to establish regulatory limits not identical to certain tolerances or exemptions.

(b) Any issue as to which review is or was obtainable under paragraph (a) of this section shall not be the subject of judicial review under any other provision of law. In part, this means that, for the Agency actions subject to the objection procedure in FFDCA section 408(g)(2), judicial review is not available unless an adversely affected party exhausts these objection procedures, and any petition procedures preliminary thereto.

[70 FR 33362, June 8, 2005]

§ 180.31 Temporary tolerances.

(a) A temporary tolerance (or exemption from a tolerance) established under the authority of FFDCA section 408(r) shall be deemed to be a tolerance (or exemption from the requirement of a tolerance) for the purposes of FFDCA section 408(a)(1) or (a)(2) and for the purposes of § 180.30.

(b) A request for a temporary tolerance or a temporary exemption from a tolerance by a person who has obtained or is seeking an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act shall be accompanied by such data as are available on subjects outlined in § 180.7(b) and an advance deposit to cover fees as provided in § 180.33.

(c) To obtain a temporary tolerance, a requestor must comply with the petition procedures specified in FFDCA section 408(d) and § 180.7 except as provided in this section.

(d) A temporary tolerance or exemption from a tolerance may be issued for a period designed to allow the orderly marketing of the raw agricultural commodities produced while testing a pesticide chemical under an experimental permit issued under authority of the Federal Insecticide, Fungicide, and Rodenticide Act if the Administrator concludes that the safety standard in FFDCA section 408(b)(2) or (c), as applicable, is met. Subject to the requirements of FFDCA section 408(e), a temporary tolerance or exemption from a tolerance may be revoked if the experimental permit is revoked, or may be revoked at any time if it develops that the application for a temporary tolerance contains a misstatement of a material fact or that new scientific data or experience with the pesticide chemical indicates that it does not meet the safety standard in FFDCA section 408(b)(2) or (c), as applicable.

(e) Conditions under which a temporary tolerance is established shall include:

(1) A limitation on the amount of the chemical to be used on the designated crops permitted under the experimental permit.

(2) A limitation for the use of the chemical on the designated crops to bona fide experimental use by qualified