NO. 17-71636

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 OF UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,

Respondents.

BRIEF FOR PETITIONERS LEAGUE OF UNITED LATIN AMERICAN CITIZENS *ET AL.*

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CORPORATE DISCLOSURE STATEMENT REQUIRED BY FRAP 26.1

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, Petitioner's League of United Latin American Citizens, *et al.* state that they have no parent, subsidiary, or affiliate that has issued shares or debt securities to the public.

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STATEMENT OF JURISDICTION

This case seeks review of the order issued by Environmental Protection Agency ("EPA") Administrator Scott Pruitt denying a 2007 Petition to cancel all tolerances for the pesticide chlorpyrifos. 82 Fed. Reg. 16,581, 16,583 (Apr. 5, 2017) ("Pruitt Order"). Within 60 days of issuance of that order, Petitioners League of United Latin American Citizens *et al.* ("LULAC") timely filed administrative objections with EPA and this petition for review, challenging the substance of the Pruitt Order. This Court has jurisdiction under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 346a(h)(1), and this Court should waive statutory exhaustion procedures as they would be futile and perpetuate the violations of the FFDCA. If this Court holds that judicial review pursuant to 21 U.S.C. § 346a(h)(1) must wait until the EPA Administrator rules on the objections, this Court has jurisdiction under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136n(b), because, in that event, meaningful and timely judicial review would not be obtainable under the FFDCA. *See* 21 U.S.C. 346a(h)(5) (where judicial review of an issue is obtainable under the FFDCA, it is not reviewable under any other provision of law).

Pursuant to the All Writs Act, 28 U.S.C. § 1651, this Court has authority to issue a writ of mandamus. It has jurisdiction to issue such a writ to stop EPA's delay in ruling on the objections because challenges to EPA's action on the

objections lie in this Court. *See In re Pesticide Action Network N. Am. ("PANNA")*, 532 F. App'x 649, 650 (9th Cir. 2013).

STATEMENT OF THE ISSUES ON APPEAL

1. Whether Administrator Pruitt exceeded his authority and acted contrary to the FFDCA and EPA's scientific findings that chlorpyrifos is unsafe, when he denied the 2007 Petition and left chlorpyrifos tolerances in place for five or more years?
2. Whether this Court can and should waive exhaustion of administrative remedies because it would be futile and would perpetuate the violations of the FFDCA to wait for EPA to rule on the objections?
3. If the Court lacks the authority to waive exhaustion under the FFDCA, whether it has jurisdiction under FIFRA because judicial review would otherwise be unobtainable?
4. In the alternative, whether EPA is unreasonably delaying ruling on the objections when it plans to put off deciding them until it takes regulatory action in four or five years?

STATUTORY ADDENDUM

An addendum containing relevant statutory provisions is bound to this brief.

STATEMENT OF THE CASE

This case seeks to put an end to EPA's failure to protect people—particularly children—from a pesticide that causes large numbers of acute poisonings every year and damages children's developing brains. It challenges the Pruitt Order, which denied a 2007 Petition to ban this pesticide and left chlorpyrifos tolerances in place for five or more years. Alternatively, this case challenges the Administrator's plan to delay ruling on objections to his order for the same five-year period. To put these delays in context, this brief begins by describing the FFDCA's mandates to protect children from unsafe pesticides; EPA's longstanding failure to comply with this standard despite extensive scientific evidence that early life exposures to chlorpyrifos damage children's brains; the agency's findings, upon evaluating the this evidence, that chlorpyrifos causes neurodevelopmental harm and is unsafe; its proposal to ban chlorpyrifos because it is unsafe; and the abrupt reversal and denial of the 2007 Petition by Administrator Pruitt, not because he found chlorpyrifos safe, but because he prefers to postpone regulatory action.

This Court is no stranger to this quest to protect children from neurodevelopmental harm. In 2015, this Court issued a writ of mandamus upon finding EPA's delay in acting on the 2007 Petition "egregious" and court-ordered deadlines "necessary to end this cycle of incomplete responses, missed deadlines,

and unreasonable delay." *In re PANNA v. EPA*, 798 F.3d 809, 811, 813 (9th Cir. 2015). This case challenges the substance of the Pruitt Order, which denied the Petition to revoke chlorpyrifos tolerances, or, in the alternative, the unreasonable delay inherent in the Administrator's plans to slow walk resolving the objections. Now as before "EPA has offered no acceptable justification for the considerable human interests prejudiced by the delay." *Id*. at 814.

I. THE FFDCA MANDATES ELIMINATING UNSAFE PESTICIDES, PARTICULARLY THOSE THAT HARM CHILDREN, FROM OUR FOOD SUPPLY.

Under the FFDCA, EPA must establish the maximum residue of a pesticide allowed on food, called a "tolerance," in order for a pesticide to be permitted on food that is imported or sold in interstate commerce. 21 U.S.C. § 346a(b) & (c). EPA must set tolerances at levels that ensure the food is safe. *Id*. § 346a(b)(2)(A)(i).

In 1996, Congress unanimously passed the Food Quality Protection Act ("FQPA") to respond to a seminal 1993 National Academy of Sciences ("NAS") report – Pesticides in the Diets of Infants and Children – recommending that EPA stop regulating pesticides based solely on their effects on adult men. The NAS report documented the ways that children are not little adults because of their unique exposures from the foods they eat, their play, their metabolism, and windows of developmental vulnerability. For example, six-month old children

drink seven times more per body weight than adults, inhale twice as much air, and put their hands in their mouths far more often than adults. In addition, during sensitive life stages (in utero, infancy, and adolescence), toxic chemicals can damage the developing brain at lower exposures than those that affect adults. AR 2180; ER 1880-04 (Declaration of Dr. Philip J. Landrigan (Sept. 7, 2016)).[1]

The FQPA strengthened the food safety standard, added provisions to protect children, and established timelines for EPA to ensure old pesticides are compliant. First, under the amended FFDCA, the EPA Administrator "may establish or leave in effect a tolerance for a pesticide chemical residue in or on 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." 21 U.S.C. § 346a(b)(2)(A)(i).

Second, safe "means the Administrator has determined 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." *Id*. § 346a(b)(2)(A)(ii). EPA

[1] "AR" refers to the certified index to the administrative record, ECF 32-2 and 36-2; "ER" to the excerpts of record filed concurrently with this brief. Dr. Landrigan chaired the NAS Committee that conducted the five-year study and published the 1993 NAS report. His declaration was submitted with LULAC's second set of comments on the proposed revocation rule. AR 1512.

must protect against aggregate exposures from all sources combined, whether from eating foods, drinking water, breathing air near the fields, or playing and rolling around on treated fields or carpets. *Id.* § 346a(b)(2)(A)(ii), (C)(i)(I), (D)(vi).

Third, EPA must make specific safety determinations for infants and children. *Id.* § 346a(b)(2)(C)(ii)(I) & (II). It must consider available information concerning "the special susceptibility of infants and children," including "neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals." *Id.* § 346a(b)(2)(C)(i)(II). EPA must also base its tolerance decisions on available information about "food consumption patterns unique to infants and children." *Id*. § 346a(b)(2)(C)(i)(I) & (III).

Fourth, EPA must account for children's sensitivities, scientific uncertainty, or gaps in available data. The statute requires that "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 post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children." *Id*. § 346a(b)(2)(C). EPA can depart from this requirement and use a different margin of safety "only if, on the basis of reliable data, such margin will be safe for infants and children." *Id.*

Finally, Congress gave EPA ten years, until August 2006, to bring old pesticides, like chlorpyrifos, into compliance with the food safety standards. *Id*. §

346a(q)(1). EPA must also continue to review pesticides every fifteen years, in a process called registration review, to ensure they meet FFDCA and other legal standards based on evolving scientific information. 7 U.S.C. § 136a(g)(1)(A)(i), (iii)(II).

II. EPA ENDED RESIDENTIAL USES OF CHLORPYRIFOS TO PROTECT CHILDREN FROM ACUTE POISONINGS, BUT FAILED TO PROTECT CHILDREN FROM NEURODEVELOPMENTAL HARM.

A. Chlorpyrifos Poisons People and Damages Children's Brains.

Chlorpyrifos is a widely used organophosphate pesticide first registered by EPA in 1965. It is used on an extensive variety of food and feed crops, including on foods eaten by children like apples, peaches, nectarines, pears, grapes, cherries, oranges, strawberries, and bananas. 40 C.F.R. §180.342 (chlorpyrifos tolerances); AR 1408, attachment 1 (EPA 2014 dietary risk assessment). People are exposed to chlorpyrifos when it forms residues on foods, concentrates in drinking water, and drifts through the air.

Organophosphates, developed as nerve agents in World War II, have deleterious effects on people through inhalation, ingestion, eye contact, and absorption through the skin. Organophosphates disrupt the proper functioning of the nervous system by suppressing an enzyme called acetylcholinesterase. When cholinesterase activity is inhibited, nerves are over-stimulated, causing people to experience symptoms such as headaches, nausea, dizziness, difficulty breathing,

vomiting, diarrhea, muscle spasms, seizures, skin rashes, and at very high exposures, convulsions, respiratory paralysis, comas, and even death. ER 1138. Chlorpyrifos is associated with a significant number of acute pesticide poisoning incidents every year. *See, e.g.*, ER 1521-28 (Washington State poisoning incidents); ER 1483-1511 (California poisoning incidents).

A growing body of published scientific research from both animal and epidemiology studies links exposure to chlorpyrifos with neurodevelopmental harm to children. Children's brains are particularly vulnerable to damage from low-dose exposures because the placenta is not a barrier to passage of many toxic chemicals, including chlorpyrifos, from the mother to the fetus. ER 1804-07. Experimental studies on laboratory animals reveal cognitive, motor control, and social behavior deficits from chlorpyrifos exposures. ER 309-403 (EPA evaluation of experimental toxicology data).

Three human population studies funded by the U.S. Centers for Children's Environmental Health produced more than a dozen peer-reviewed published articles correlating prenatal organophosphate exposure with learning disabilities in children. A long-term study conducted by the Columbia Center on Children's Environmental Health correlated chlorpyrifos levels in African American and Dominican pregnant women in New York City (measured in umbilical cord blood at the time of delivery) with adverse neurodevelopmental effects in their children.

The study began before and continued after the residential chlorpyrifos ban. The children born after the ban had dramatically lower chlorpyrifos levels. At age three, the highly exposed children had statistically significant delays in motor and mental development. At age seven, they experienced attention disorders, reduced IQ, and loss of working memory. At age eleven, the children had more arm tremors and reduced fine motor control that affected the children's ability to draw shapes. ER 404-565 (EPA detailed synthesis of three cohort studies); ER 1258-61 (2016 update). Subsequent testing using magnetic resonance imaging ("MRI") revealed physical brain abnormalities in an area of the brains of highly exposed children linked to learning, cognition, and social behaviors. AR 2196.

The Columbia study's findings are consistent with those of two other mother-child pair studies that correlated prenatal exposures to organophosphates with learning disabilities. A University of California-Berkeley study followed a cohort of children born to farmworkers in Salinas Valley, California, and found reduced IQ, verbal comprehension, perceptual reasoning, and working memory. A study conducted at Mount Sinai School of Medicine observed a New York City Hispanic population and found similar learning disabilities in the children. ER 404-565 (EPA synthesis), 1084-88 (EPA literature review).

B. EPA's Re-Registration of Chlorpyrifos Did Not Protect Children from Learning Disabilities.

The FQPA directs EPA to determine safety based on an assessment of the

pesticide's risk generally and specifically for infants and children. 21 U.S.C. § 346a(b)(2)(C) (EPA "shall assess the risk" of the pesticide). EPA's risk assessment process integrates information on toxicity and exposure. First, EPA determines the most sensitive critical effect and an exposure level that has no adverse effect, unless the pesticide causes harm at any exposure level. ER 1136. Second, EPA applies traditional safety factors to account for uncertainties in extrapolating from animal studies to people and for variations among human populations, and under the FQPA, EPA adds an additional margin of safety to account for potential pre- and post-natal toxicity and completeness of the toxicology and exposure data sets. Each safety factor is typically tenfold. ER 1137. When EPA applies all three safety factors, exposures must be 1000 times less than the no-effect level in order to be safe. *See Nat. Res. Def. Council v. EPA*, 658 F.3d 200, 201, 207-09 (2d Cir. 2011) (describing risk assessment process and congressional intent to add the FQPA safety factor to the traditional safety factors). The Second Circuit described use of a three-fold safety factor as "similar to an engineer who estimates that a bridge must hold X weight, and then designs the bridge in a way that she believes will hold 3X weight, to create a margin of safety based on prior engineering practice." *Id*. at 208. Third, EPA assesses whether predicted exposures, when aggregated, are less than the safe level. ER 1137-39.[2]

[2] EPA's process is rich in the use of acronyms. NOAEL refers to the no observed

If so, the scientific record supports finding reasonable certainty of no harm and setting the pesticide tolerance at this level.

EPA's initial risk assessments for chlorpyrifos assumed that 10% cholinesterase inhibition in red blood cells was the most sensitive endpoint. In 2000, EPA determined that children crawling on treated carpets and hugging pets after flea treatments faced unsafe chlorpyrifos exposures and ended all homeowner uses of chlorpyrifos. ER 28. When EPA issued its interim chlorpyrifos re-registration in 2001, it allowed uses to continue on many dozens of food crops. 40 C.F.R. § 180.342 (chlorpyrifos tolerances).

Public comments on EPA's 2001 interim re-registration determination for chlorpyrifos urged EPA to address the scientific evidence showing that neurodevelopmental impacts to children at doses lower than those that cause 10% cholinesterase inhibition. ER 87-120; AR 277, Exh. 2. In 2006, after releasing its cumulative organophosphate risk assessment, EPA finalized its re-registration of chlorpyrifos without protecting children from neurodevelopmental harm and without addressing the public comments.[3]

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adverse effect level, LOAEL to a low observed adverse effect level, point of departure is the low or no effect level for the most sensitive endpoint, tenfold safety factors are abbreviated to 10X, and reference dose or RfD is derived by applying safety factors to the point of departure and is what EPA deems to be safe. *See, e.g.*, ER 1136; ER 1270.

[3]EPA, Finalization of Interim Re-Registration Eligibility Determination for Chlorpyrifos (July 31, 2006), available at

III. THE 2007 PETITION TO BAN CHLORPYRIFOS AND EPA'S RESPONSES.

In September 2007, PANNA and Natural Resources Defense Council ("NRDC") petitioned EPA to ban chlorpyrifos based on the mounting evidence of risks from chlorpyrifos that were left unaddressed in EPA's 2001 and 2006 regulatory decisions. The 2007 Petition compiled evidence, including peer-reviewed scientific studies, showing that children and infants exposed prenatally to low doses of chlorpyrifos suffer from long-lasting learning disabilities. ER 6-9, 11-13, 22-13.[4]

Because the organophosphates pose complex scientific issues that EPA had not previously addressed, EPA prioritized registration review of the organophosphates. ER 1135. EPA moved chlorpyrifos to the head of the line in order to respond to the 2007 Petition and planned to propose regulatory actions in 2014 and finalize them in 2015. ER 28; AR 1437 (Final Work Plan); Decl. of Jack Housenger, Director of the Health Effects Division, EPA's Office of Pesticide Programs ¶ 13, *In re PANNA*, No. 12-71125 (9th Cir. July 23, 2012) (Dkt. 9-2).

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https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/ired_PC-059101_28-Sep-01.pdf.

[4] The 2007 Petition also sought protections for children and bystanders from chlorpyrifos that moves from fields where it is sprayed to schools, day cares, and homes and presented air monitoring data documenting chlorpyrifos concentrations above EPA's levels of concern near fields and in schoolyards. ER 17-21.

A. EPA's Findings that Chlorpyrifos Is Unsafe and Proposal To Revoke All Tolerances.

EPA engaged in what it repeatedly described as "a stepwise, objective and transparent approach to evaluate, interpret, and characterize the strengths and uncertainties associated with all the lines of scientific information related to the potential for adverse neurodevelopmental effects in infants and children as a result of prenatal exposure to chlorpyrifos." ER 202.

1. EPA's rigorous evaluations of the science and multiple peer reviews by its Scientific Advisory Panel repeatedly found that low-level exposures to chlorpyrifos cause neurodevelopmental harm to children.

In 2008, EPA initiated a rigorous, iterative review of the scientific evidence with several rounds of review by the Scientific Advisory Panel ("SAP"), established to provide peer review of science used by EPA in making pesticide determinations. 7 U.S.C. § 136w(d). With increasing confidence over time, EPA and the SAP repeatedly found that "chlorpyrifos is likely associated with adverse neurodevelopmental outcomes" from low-level exposures. ER 817 (SAP Minutes on EPA's Evaluation of Toxicity Profile of Chlorpyrifos (Sept. 2008)); *accord* ER 787, 811. EPA and the SAP first made this finding in 2008, when both called the Columbia study sound and robust, ER 786, 806, and Panel members expressed concerns that low-level exposures to chlorpyrifos, like lead and mercury, produce significant adverse effects when they previously were thought to be harmful only

at high levels. ER 817.

In 2012, the SAP reviewed EPA's comprehensive analysis of experimental animal studies and the three mother-child pair studies from Columbia, Mt. Sinai, and California. The SAP concluded that, in addition to laboratory animal studies showing significant, long-term adverse effects on neurobehavioral development, epidemiology "studies show some consistent associations relating exposure measures to abnormal reflexes in the newborn, pervasive development disorder at 24 or 36 months, mental development at 7-9 years, and attention and behavior problems at 3 and 5 years of age." ER 971 (SAP Minutes on EPA's Evaluation of Chlorpyrifos Health Effects (Apr. 2012)); ER 853-955 (EPA's 2012 analysis).

The Panel found that "multiple lines of evidence suggest chlorpyrifos can affect neurodevelopment at levels lower than those associated with [cholinesterase] inhibition." ER 973; *accord* ER 979 (cholinesterase inhibition could not have been responsible for the cognitive defects or developmental delays). The Panel advised EPA to explore ways to use the Columbia study to identify doses associated with the damage to the developing brain. ER 973-74.

EPA reviewed new studies as they were published, including one correlating chlorpyrifos with autism, ER 1784, and new information that reduced uncertainties to the point that EPA found any errors were more likely to underestimate, rather than overestimate, the association between chlorpyrifos exposures and harm to

children's brains. ER 923, 927, 951-52. EPA expanded its review to include the scientific literature on all organophosphate pesticides and found that low-level exposures to other organophosphates also damage children's brains. ER 1031-1131 (Literature Review of Neurodevelopmental Effects (Sept. 15, 2015). In its most recent proceedings in 2016, the SAP again found there is evidence from epidemiology and toxicology studies of "adverse health outcomes associated with chlorpyrifos exposures below levels that result in 10% red blood cell [cholinesterase] inhibition (*i.e.*, toxicity at lower doses)." ER 1191, 1195, 1198, 1225-26 (2016 SAP Minutes on Analysis of Chlorpyrifos Biomonitoring Data (July 20, 2016)).

2. EPA's risk assessments and proposed revocation rule find chlorpyrifos unsafe.

In 2011, EPA released a preliminary human health risk assessment for chlorpyrifos that focused on cholinesterase inhibition, not neurodevelopmental harm. This risk assessment documented risks of concern from drinking water and drift exposures. AR 1367; ER 1135.

In December 2014, EPA released its Revised Human Health Risk Assessment ("2014 Assessment"), finding, based on laboratory and human studies, that chlorpyrifos causes learning disabilities and other damage to children's brains at low-level exposures. ER 184, 209 ("a pattern of neurodevelopmental adverse outcomes emerges"); *id.*, ER 208, 210 (laboratory animal studies indicated "that

gestational and/or postnatal exposure may cause persistent behavioral effects into adulthood," including at doses in a recent study that would not induce cholinesterase inhibition). While EPA could not identify the mechanism by which chlorpyrifos causes brain damage from prenatal exposures, its policies do not allow EPA to ignore causality based on an inability to identify the mode of action. ER 231.

Drawing from its extensive review and the 2008 and 2012 SAP reports, EPA found that the three mother-child pair studies "are strong studies which support a conclusion that chlorpyrifos likely played a role in" causing the neurodevelopmental harm. ER 216. As to the Columbia study, EPA cited the findings of "a 2-4 fold increase in reduced mental and also psychomotor development in infants exposed to chlorpyrifos *in utero,*" "statistically significant evidence of differences in the proportion of pervasive developmental disorder diagnoses between children in the high and low exposures groups" at three years of age, and "reduced measures of intelligence" at seven years of age. ER 221. The similar findings in the California and Mt. Sinai studies of pervasive development disorders and reduced IQ from organophosphate exposures, reinforced the findings that "chlorpyrifos results in adverse neurodevelopmental outcomes in humans." ER 215, 221-23, 225, 232.

EPA, like the 2012 SAP, concluded that the exposures in the Columbia study were lower than those that cause cholinesterase inhibition. ER 224, 228; *see* ER 230 ("it is unlikely that [cholinesterase] would have been inhibited by any meaningful or measureable amount, if at all" in the studies). EPA's risk assessment therefore was not based on the most sensitive endpoint and did not protect against damage to children's brains because it used 10% cholinesterase inhibition to assess safety.[5] Because the mode of action and specific exposure level at which chlorpyrifos damages children's brains is uncertain, EPA retained the FQPA tenfold safety factor for infants, children, youth, and women of child-bearing years. ER 232.

Even without protecting children from learning disabilities, EPA's models showed that chlorpyrifos uses will result in exposures that exceed EPA's drinking water levels of concern, particularly in agricultural areas, and monitoring data confirmed the results. ER 194, 271-73, 276-78.[6]

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[5] Numerous scientific experts criticized EPA's risk assessment for using exposures associated with cholinesterase inhibition and not an exposure limit that would guard against damage to the developing brain. *See, e.g.*, ER 1514 (Professor Elaine Faustman, University of Washington (Apr. 30, 2015); ER 1335 (Comment submitted by Professors Robin M. Whyatt, Columbia University, Dale Hattis, Clark University and Theodore Slotkin, Duke University (Apr. 30, 2015); ER 1787 (comment from 49 scientists and health-care professionals); *see also* ER 1391 (Farmworker, Health, and Conservation Group Comments at 28-32 (Apr. 30, 2015)).

[6] The 2014 Assessment also found risks of concern to many workers who mix and apply chlorpyrifos or re-enter fields to perform tasks like picking and thinning after

B. In 2015, EPA Proposed Revoking All Tolerances Because Chlorpyrifos Is Unsafe.

In October 2015, reiterating the findings in the 2014 risk assessment, EPA proposed to revoke all chlorpyrifos tolerances because of drinking water contamination, effective 180 days after a final rule is published. ER 1133, 1135-36, 1159 (80 Fed. Reg. 69,080 (Nov. 6, 2015)). EPA "is unable to conclude that the risk from aggregate exposure from the use of chlorpyrifos meets the safety standard," with infants most at risk. ER 1134; *see also id*. ("EPA cannot, at this time, determine that aggregate exposure to residues of chlorpyrifos, including all anticipated dietary exposures and all non-occupational exposures for which there is reliable information, are safe."). "Because EPA is unable to determine at this time that aggregate exposures to chlorpyrifos are safe, EPA is proposing to revoke these tolerances." ER 1134.

The proposed rule acknowledged that the 2014 risk assessment fails to protect children from learning disabilities that occur at exposures below EPA's cholinesterase inhibition endpoint. ER 1140, 1143. EPA planned to continue reviewing the evidence of long-lasting damage to children's brains from low-level exposures in order to develop a more protective endpoint for its regulatory determination. ER 1148.

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chlorpyrifos has been sprayed on the crop. ER 195-96, 285-86, 288-90.

Based on its drinking water assessment, EPA found that drinking water exposures present risks of concern, particularly for infants and children in agricultural watersheds. ER 1136, 1150, 1156. EPA solicited mitigation proposals that might make some chlorpyrifos uses safe. *Id*. at 69,080, 69,085, 69,104, 69,106. Public comments continued to urge EPA to develop an endpoint or use additional safety measures to protect children from this harm. *See, e.g.*, ER 1529.

C. EPA's Further Assessment of Damage to Children's Brains Finds All Chlorpyrifos Exposures Unsafe.

After issuing the proposed rule, EPA sought to identify an exposure level that would protect against damage to children's brains from low-level exposures. In 2016, EPA used measurements of chlorpyrifos in cord blood from the Columbia study to derive a more protective endpoint. The SAP reviewed and did not support EPA's use of cord blood because of insufficient data on its relationship to the exposures at the time of the chlorpyrifos applications, although it continued to find that regulating to prevent 10% cholinesterase inhibition is "not adequately protective of human health." ER 1195; *accord* ER 1191, 1198, 1225.

In November 2016, EPA updated its risk assessment and strengthened its findings of harm to children. ER 1249, 1253-55, 1258, 1261 (2016 Update at (Nov. 3, 2016)). EPA reiterated its findings that damage to children's brains occurred below exposures that result in 10% cholinesterase inhibition. 2016 Update at 1262; ER 1290, 1291 (agreeing with the SAP that existing endpoint

based on 10% cholinesterase inhibition is "not sufficiently health protective").

Following the 2012 SAP's recommendation, EPA established an exposure level associated with neurodevelopmental harm by using data from the Columbia study and a model developed by Dow Agrosciences. EPA estimated exposures based on the chlorpyrifos application method used in the public housing at the time of exposure in the Columbia study and identified time-weighted average blood concentrations for the pregnant women in the Columbia study. ER 1252-53, 1262-65 (2016 Update).[7] Using this endpoint, EPA found that chlorpyrifos presents unacceptable safety risks through exposures from food, drinking water, spray drift, volatilization, and worker activities. Food-only exposures for chlorpyrifos were found to be unsafe for all populations, with young children facing the highest risks of concern. ER 1254, 1271-72. While adult exposures are an alarming 62 times higher than the safe level, children ages 1-2 face risks more than 140 times higher than safe levels. ER 1254, 1271. EPA continued to find that "the majority of estimated drinking water exposures from currently registered uses, including water exposures from non-food uses, continue to exceed safe levels even taking into

[7] EPA used a model developed by Dow Agrosciences (called a physiologically based pharmacokinetic model) to estimate doses in people associated with particular specified effects, like cholinesterase inhibition or neurodevelopmental harm. In applying that model in the update, EPA retained the FQPA tenfold safety factor based on its policy of accounting for uncertainty when using an exposure that caused some rather than no adverse effects. ER 1252, 1270.

account more refined drinking water exposures." ER 1291. Regarding spray drift, EPA found unsafe chlorpyrifos levels from the field's edge to distances of more than 300 feet from where the pesticide is sprayed. ER 1254, 1279. EPA also found unsafe levels of chlorpyrifos recorded in air monitoring in agricultural communities in California and Washington. ER 1254-55, 1279-82. In addition, EPA found unacceptable risks to all farmworkers who mix and apply chlorpyrifos or re-enter the fields within 18 days of chlorpyrifos spraying. ER 1255, 1284-86.

After releasing the 2016 Update, EPA reopened the comment period for its proposal to revoke chlorpyrifos tolerances and emphasized that its updated risk analysis "indicates that expected residues of chlorpyrifos on most individual food crops exceed the 'reasonable certainty of no harm' safety standard" and that most drinking water exposures "continue to exceed safe levels . . .." ER 1249, 1291 (81 Fed. Reg. 81,049, 81,050 (Nov. 17, 2016)). EPA reiterated that "it can only retain chlorpyrifos tolerances if it is able to conclude that such tolerances are safe" and its updated analysis "continues to indicate that the risk from the potential aggregate exposure does not meet the FFDCA safety standard." *Id*.

IV. EPA'S DENIAL OF THE 2007 PETITION AND DECISION TO LEAVE CHLORPYRIFOS IN PLACE FOR FIVE OR MORE YEARS.

EPA had a March 31, 2017 deadline from this Court to make a final decision on the 2007 Petition. As of early March 2017, EPA was on track to finalize the proposed revocation based on its findings that chlorpyrifos is unsafe. After Scott

Pruitt became EPA Administrator and his political assistants met with the Acting Administrator overseeing EPA's chemicals and pesticides programs, EPA's direction shifted 180 degrees.[8] At a meeting on March 3, 2017, the Administrator's chief of staff indicated he did not want EPA forced into a box by the 2007 Petition and directed the Acting Assistant Administrator to provide a briefing paper with other options. Exh. C at 1-2. He later told colleagues that EPA staff "are trying to strong arm us. I scared them Friday", "but they know where this is headed." Exh. B at 17. One option would have entailed a full or partial phase-out over time, but Dow resisted agreeing to a phase-out after the election. Exh. C at 1-2. The Chief of Staff chose another option described as "legalistic arg[uments]" pertaining to a new administration's ability to have different priorities. Exh. C at 2.[9] A draft denial was circulating by March 16, 2017,

[8] This paragraph is drawn from EPA records that have been made publicly available and are attached as Exhibits A-F to the Declaration of Marisa Ordonia (Jan. 19, 2018). They are relevant to LULAC's futility argument and request for mandamus relief, neither of which is reviewed on the basis of an administrative record. In addition, LULAC is filing a motion to complete the record by adding these documents to it.

[9] During this same period of time, the Administrator and members of the transition team met with the members of the American Farm Bureau Federation, who made a plea for "a reasonable approach" involving the agricultural sector in the chlorpyrifos decision. Exh. B at 1-5 (Summary of March 1, 2017 Meeting). Mr. Pruitt told the participants that "this is a new day, a new future, for a common sense approach to environmental protection." *Id*. The following week, Mr. Pruitt met with the CEO of Dow Agrosciences. Exh. A (Pruitt Calendar for March 9, 2017).

finalized and signed by the Administrator on March 29, 2017, and released with a press release announcing that EPA is "reversing the previous Administration's steps to ban one of the most widely used pesticides" and "the need to provide regulatory certainty to American farms that rely on chlorpyrifos." Exh. B at 22-35, 43.

The Pruitt Order denied the 2007 Petition "in full" and maintained chlorpyrifos tolerances. ER 25, 27 (82 Fed. Reg. 16,581 (Apr. 5, 2017)). It cut and pasted a series of prior interim responses to drift, volatilization, and other issues raised in the 2007 Petition.[10] As to the one issue EPA had not previously resolved — neurodevelopmental harm from chlorpyrifos — the Pruitt Order denied the Petition and left chlorpyrifos tolerances in place because of the significance of the decision given the widespread use of chlorpyrifos and a preference to engage in further study before finalizing the October 2015 proposed revocation rule or taking an alternative regulatory path. ER 34. The Pruitt Order neither revoked the proposed rule, nor revisited EPA's findings that chlorpyrifos is unsafe. It put off

[10] Much of the Pruitt Order defends EPA's 2006 re-registration determination, but EPA cannot rely on its 2006 safety finding in light of EPA's additional decade of analysis and subsequent findings that chlorpyrifos is unsafe. *See* 21 U.S.C. § 346a(d)(4) (EPA must assess available information); *id.* § 346a(b)(2)(C)-(D) (EPA must consider available information concerning such factors as toxicity, population sensitivities, and children's exposures). As this Court noted, EPA "has backtracked significantly from" its 2006 pronouncement of safety when it found chlorpyrifos unsafe in its 2014 risk assessment and determined its tolerances needed to be revoked. *In re PANNA*, 798 F.3d at 814.

chlorpyrifos tolerance decisions until as far off as October 1, 2022, when it must complete the review of all the older pesticides under the FIFRA timelines. ER 34.

Within 60 days, LULAC filed objections that initiated an administrative appeal and this lawsuit. ER 121-64. Several states also filed administrative objections. ER 165-83. The objections raise purely legal issues and do not seek an evidentiary hearing. EPA has yet to acknowledge receipt of the administrative objections. In a December 2017 response to a request from three U.S. Senators that it rule on the objections expeditiously, EPA indicated that it plans to prepare another risk assessment, seek public comments, propose a new regulatory decision, seek another round of comments, and then make a final regulatory decision for chlorpyrifos. It has offered no timeline for a final decision, but the timelines for the interim stages suggest a final decision in 2021-2022. Exh. D-F.

SUMMARY OF ARGUMENT

In the face of a series of unbroken EPA findings that chlorpyrifos is unsafe, Administrator Pruitt could not and did not purport to find chlorpyrifos safe. Nonetheless, he issued an order denying the Petition to ban chlorpyrifos and leaving chlorpyrifos tolerances in place for five or more years. In doing so, Administrator Pruitt exceeded his statutory authority under the FFDCA, which allows him to leave a tolerance in effect "only if [he] determines that the tolerance

is safe," and requires that he revoke tolerances determined to be unsafe. 21 U.S.C. § 346a(b)(2)(A)(i).

EPA's findings that chlorpyrifos is unsafe compel revocation of all chlorpyrifos tolerances. EPA found chlorpyrifos unsafe due to drinking water contamination in 2014, leading to the 2015 proposal to revoke all tolerances. When EPA set a regulatory endpoint that would prevent damage to children's developing brains, it found unsafe exposures in every way that people come into contact with chlorpyrifos – whether in food, in drinking water, or in the air—with infants most at risk. The record seals the fate of chlorpyrifos. It is arbitrary and capricious for EPA to act contrary to its own scientific findings and to deny the Petition for reasons other than safety, which is the only determinant under the FFDCA. The fact that there is some scientific uncertainty in pinpointing the precise exposure that causes brain damage to children is no defense. Nor is the 2022 deadline for completing registration review of all older pesticides a license to retain tolerances for this unsafe pesticide. The Court should reverse and remand to EPA with directions to revoke all chlorpyrifos tolerances.

Ordinarily, judicial review of a tolerance decision occurs after EPA rules on administrative objections, but exhaustion is not a jurisdictional prerequisite. This Court should waive exhaustion because it would be futile and perpetuate the legal violations in light of EPA's plans to engage in years of study before taking

regulatory action and ruling on the objections in four to five years. If exhaustion is required, review of EPA's illegal conduct is not obtainable under FFDCA and should proceed under FIFRA. Alternatively, if the Court believes a ruling on the objections is jurisdictionally required, it should issue a writ of mandamus directing EPA to rule on objections within 60 days.

STANDARD OF REVIEW

The Pruitt Order's compliance with the FFDCA is reviewed under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706. *Nw. Coal. for Alts. to Pesticides v. U.S. EPA*, 544 F.3d 1043, 1047 (9th Cir. 2008). Under the APA, the court shall hold unlawful and set aside an agency action found to be "in excess of statutory jurisdiction, authority, or limitation . . ." or "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A), (C). An agency decision is arbitrary and capricious if "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicles Mfrs Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Under FIFRA, a court shall uphold EPA's determination "if it is supported by substantial evidence when considered on the record as a whole." 7 U.S.C. § 136n(b); *see Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 528 (9th Cir. 2015). "Substantial evidence means more than a mere scintilla but less than a preponderance; it is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Nat. Res. Def. Council v. EPA*, 735 F.3d 873, 877 (9th Cir. 2013). The substantial evidence standard affords an agency less deference than the arbitrary and capricious standard. *See Universal Camera Corp. v. Nat'l Labor Relations Bd.*, 340 U.S. 474, 477 (1951); *Union Oil Co. of Cal. v. Fed. Power Comm'n*, 542 F.2d 1036, 1040–41 (9th Cir.1976). If EPA's determination is arbitrary and capricious, EPA cannot show it was supported by substantial evidence.

Whether a writ of mandamus should issue to put an end to an agency's unreasonable delay is reviewed under the factors established by the D.C. Circuit in *Telecomm. Research & Action Ctr. v. FCC*, 750 F.2d 70, 75 (D.C. Cir. 1984) (hereinafter "*TRAC*"); *see In re A Community Voice*, 878 F.3d 779 (9th Cir. 2017).

ARGUMENT

I. EPA EXCEEDED ITS STATUTORY AUTHORITY AND ACTED CONTRARY TO ITS SCIENTIFIC FINDINGS IN DENYING THE 2007 PETITION.

The FFDCA constrains EPA's discretion. It prohibits EPA from taking

actions that endanger food safety and expose children to dangerous pesticides whenever EPA finds a pesticide unsafe or is unable to make an affirmative safety finding. The Pruitt Order blatantly defies these statutory mandates and disregards years of EPA scientific findings that have progressively grown in linking low-level chlorpyrifos exposures with serious brain damage to children.

A. EPA Lacks the Statutory Authority To Maintain Chlorpyrifos Tolerances in the Absence of an Affirmative Finding that Chlorpyrifos Is Safe.

Administrator Pruitt violated the law by leaving chlorpyrifos tolerances in place. Under the FFDCA, the EPA Administrator "may establish or leave in effect a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the tolerance is safe." 21 U.S.C. § 346a(b)(2)(A)(i); *see also id.* § 346a(b)(2)(A)(i) ("The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe."). FFDCA leaves EPA no discretion to define "safe." It defines "safe" to mean the Administrator has determined there is a reasonable certainty of no harm from aggregate exposures to the pesticide chemical residue. *Id.* § 346a(b)(2)(A)(ii).

Previously, in proposing to revoke all chlorpyrifos tolerances, EPA articulated the controlling legal standard, stating "because the FFDCA is a safety standard, EPA can only retain chlorpyrifos tolerances if it is able to conclude that such tolerances are safe." ER 1133; *accord* ER 1134 ("EPA may establish or leave

in effect a tolerance for pesticide only if it finds that the tolerance is safe"). EPA again acknowledged the operative standard when it reaffirmed its proposal to revoke the tolerances in 2016. ER 1291 ("EPA can only retain chlorpyrifos tolerances if it is able to conclude that such tolerances are safe.").

The legal standard is purged from the Pruitt Order. Nowhere does that Order acknowledge EPA's legal obligation to make an affirmative safety finding in order to retain chlorpyrifos tolerances. Nor does it purport to make a finding that chlorpyrifos is safe. And yet the Pruitt Order denied the 2007 Petition and left chlorpyrifos tolerances in place for five or more years. It did not withdraw the proposed rule or change its findings, but left it in legal limbo. The Pruitt Order reads as if EPA has discretion to leave tolerances in place in the face of findings that the pesticide is unsafe when the Administrator prefers to engage in further review of the science.

The FFDCA forecloses this course of action. If the Administrator has made no affirmative safety finding, he lacks authority to maintain the tolerances. This case is analogous to *Massachusetts v. EPA*, 549 U.S. 497, 533 (2007), where the Supreme Court held that the Clean Air Act authorized EPA to avoid taking regulatory action to limit greenhouse gas emissions from motor vehicles only if it determined that greenhouse gases do not contribute to climate change. EPA could not refuse to regulate for policy reasons unrelated to the scientific issue of

endangerment. *Id.* at 533-34.

Similarly, EPA lacks the authority to make tolerance decisions based on factors other than food safety. Nonetheless, the Pruitt Order cites the widespread use of chlorpyrifos as a reason to engage in further study before removing it from the market. 82 Fed. Reg. at 16,590. Congress decided long ago that the safety of our food cannot be sacrificed, *see Nat'l Coalition Against Misuse of Pesticides v. Thomas*, 809 F.2d 875, 881-83 (D.C. Cir. 1987) (EPA acted arbitrarily and capriciously in relying exclusively on foreign economic impacts in raising a tolerance), and in 1996, explicitly made safety the sole determinant. 21 U.S.C. § 346a(b)(2)(A)(i)-(ii); *see Whitman v. American Trucking Assoc.*, 531 U.S. 457, 468 (2001) (EPA needs, but lacks, textual authority to consider costs or implementation burdens in setting air pollution standards); *State Farm*, 463 U.S. at 43 (agency cannot base its decision "on factors which Congress has not intended it to consider"). The Administrator acted in blatant violation of FFDCA by denying the 2007 Petition and leaving chlorpyrifos tolerances in place without determining that the pesticide is safe.

B. EPA's Findings that Chlorpyrifos Is Unsafe Compel It To Revoke the Tolerances.

It is well-settled that an agency "must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43. Courts

have applied this rule to prevent EPA from making tolerance determinations at odds with its safety findings. *See Nat'l Corn Growers Assoc. v. EPA*, 613 F.3d 266, 275 (D.C. Cir. 2010) (arbitrary and capricious for EPA to revoke import tolerances when EPA found exposure to the pesticide from imported foods safe); *Nat'l Coalition*, 809 F.2d at 875 (EPA acted arbitrarily when it had no scientific basis for changing a zero tolerance into one permitting residues).

The Pruitt Order is wholly at odds with EPA's repeated findings, growing in strength over the years, that chlorpyrifos is unsafe. EPA's 2014 revised risk assessment found chlorpyrifos unsafe due to drinking water contamination, ER 231-32, 78-79, and it proposed to revoke all tolerances in 2015 because "EPA cannot determine that current dietary exposures to chlorpyrifos are safe." ER 1159; *see id*. ("EPA cannot find that any current tolerances are safe and is therefore proposing to revoke all chlorpyrifos tolerances"); ER 1150 ("food exposures, when aggregated with residential exposures and potentially more significant drinking water exposures do present a significant risk concern and support revocation of all chlorpyrifos tolerances").[11]

[11] The Pruitt Order engages in revisionist history when it recharacterizes the proposed revocation as based on uncertainty surrounding neurodevelopmental harm. ER 27, 34.

EPA and SAP have repeatedly found that using 10% cholinesterase inhibition as the regulatory endpoint, as the 2014 risk assessment does, fails to protect children from brain damage associated with lower exposures. ER 853 (2012 EPA analysis) ER 956 (2012 SAP report); ER 184 (2014 Risk Assessment); ER 1132 (proposed tolerance revocation); ER 1191, 1225-26 (2016 SAP). In its 2016 update to its risk assessment, EPA heeded the SAP's advice and reconstructed the exposures in the Columbia study at which learning disabilities occurred and found chlorpyrifos unsafe in virtually any way that people are exposed to it. ER 1271. In addition to unsafe drinking water exposures, EPA found unsafe food exposures, with the most exposed population – children 1-2 years of age – exposed to 140 times safe levels, and unsafe exposures from pesticide drift 300 or more feet from where the pesticide is sprayed. ER 1254-55, 1271-72, 1279-83. According to EPA's Federal Register notice reiterating its proposal to revoke chlorpyrifos tolerances, "[t]he revised analysis indicates that expected residues of chlorpyrifos on most individual food crops exceed the 'reasonable certainty of no harm' safety standard" and "the majority of estimated drinking water exposures from currently registered uses, including water exposures from non-food uses, continue to exceed safe levels even taking into account more refined drinking water exposures." ER 1291; *see id*. ("the risk from the potential aggregate exposure does not meet the FFDCA safety standard").

By issuing an order maintaining chlorpyrifos tolerances in the face of these findings, EPA acted contrary to the evidence. EPA made no mention of these relevant, indeed pivotal, findings, let alone make a rational connection between them and the decision to retain chlorpyrifos tolerances. The Pruitt Order is the epitome of arbitrary and capricious decision-making whether cast as failing to consider relevant factors, acting contrary to the findings in the record, or lacking a rational justification connecting the action to such findings.

The Pruitt Order scenario resembles *Chlorine Chemistry Council v. EPA*, 206 F.3d 1286 (D.C. Cir. 2000), where EPA had a 1998 deadline to set a maximum contaminant level goal under the Safe Drinking Water Act for drinking water disinfectant byproducts like chloroform. In 1994, EPA proposed a goal of zero based on its finding that any level of exposure could cause cancer. *Id.* at 1287. Subsequently, EPA found that chloroform likely causes human cancers only above a certain dose, yet it set a goal of zero because it wanted to engage in additional scientific review, including with its scientific advisory committee. *Id*. at 1288. The court held that EPA cannot act contrary to the best available scientific evidence at the time of its decision "simply because of the possibility of contradiction in the future by evidence unavailable at the time of action – a possibility that will *always* be present." *Id*. at 1290-91 (emphasis in original).

Chlorine Chemistry Council rejected EPA's contention that the risk

assessment at issue did not represent its ultimate conclusion, calling "these semantic somersaults pointless." 206 F.3d at 1291. As the court explained, "[a]ll scientific conclusions are subject to some doubt; future hypothetical findings always have the potential to resolve the doubt (the new resolution itself being subject, of course, to falsification by later findings)". *Id*.

As in *Chlorine Chemistry Council*, EPA made safety finding in its risk assessments, which is how EPA makes tolerance determinations and it has made no superseding agency findings. In the face of EPA's findings that chlorpyrifos is unsafe in every way that people are exposed to it, the Administrator must revoke the tolerances. *Id.* On this record, granting the Petition and revoking all chlorpyrifos tolerances is the only legally defensible course of action.

C. A Desire to Continue Studying the Science Is Not a Legally Permissible Reason To Leave Chlorpyrifos Tolerances in Place.

The Pruitt Order's primary justification for failing to revoke chlorpyrifos tolerances is: "EPA's preference is to fully explore approaches raised by the SAP and commenters on the proposed rule, and possibly seek additional authoritative peer review of EPA's risk assessment prior to finalizing any regulatory action in the course of registration review." ER 34. In alluding generally to scientific uncertainties, the Pruitt Order ignores how much progress has been made in assessing the large body of scientific evidence of neurodevelopmental harm from chlorpyrifos. EPA extensively reviewed chlorpyrifos and sought review by the

SAP three times. Each review found that chlorpyrifos damages children's developing brains at exposures far lower than EPA's regulatory endpoint. ER 785-86, 817-18 (2008 SAP); ER 971, 973 (2012 SAP); ER 224-26, 229 (2014 Assessment); ER 1191, 1198, 1225 (2016 SAP). As the reviews progressed and further studies were published, the degree of uncertainty diminished to the point that EPA concluded that the human population studies more likely under-estimated, rather than over-estimated the correlation. ER 923, 927, 951-52 (EPA 2012 comprehensive analysis).

While there is some scientific uncertainty as to the precise level of exposure that damages children's brains, both EPA and the SAP have found with confidence for many years that children are at risk at levels of exposure far below what EPA currently allows. This uncontested fact has led EPA to find chlorpyrifos unsafe. The Pruitt Order's invocation of scientific uncertainty rings hollow given the overwhelming scientific evidence and the unbroken EPA and SAP findings.

Scientific uncertainty offers no excuse for the Pruitt Order unless it is grounded in EPA's obligations under the underlying statute. The Supreme Court reversed EPA's inaction under the Clean Air Act in *Massachusetts v. EPA* with an admonition that EPA cannot

> avoid its statutory obligation by noting the uncertainty surrounding various features of climate change and concluding that it would therefore be better not to regulate at this time.. . . If the scientific uncertainty is so profound that it precludes EPA from making a reasoned judgment as to whether

> greenhouse gases contribute to global warming, EPA must say so. That EPA would prefer not to regulate greenhouse gases because of some residual uncertainty. . . is irrelevant.

549 U.S. at 533-34.

Here, Congress established a statutory standard that precludes delaying protection, particularly to children, due to scientific uncertainty when there is evidence of harm. Under the food safety standard, uncertainty compels revocation of tolerances since "safe" means that EPA "has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue," 21 U.S.C. § 346a(b)(2)(A)(ii), and EPA can "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." *Id*. § 346a(b)(2)(A)(i). If uncertainty prevented the Administrator from making an affirmative safety finding, his only option was to revoke the tolerances. This is in keeping with the longstanding burden of proving safety on EPA and industry groups seeking to retain food tolerances. *See Envtl. Def. Fund, Inc. v. U.S. Dep't of Health, Ed. & Welfare*, 428 F.2d 1083, 1092 n.27 (D.C. Cir. 1970) (burden of producing scientific data establishing safety is on those seeking to permit the residue).

Other statutory provisions prescribe how EPA must deal with scientific uncertainty. EPA must act on the basis of available information on the special susceptibility of infants and children, including neurological differences between

adults and infants and children, and EPA must apply an additional tenfold margin of safety to account for gaps in data or evidence of pre- or post-natal toxicity to children. 21 U.S.C. § 346a(b)(2)(C). Congress specifically directed EPA to assume that children face a ten times greater risk than adults unless it has reliable data showing a different margin will be safe for infants and children. *Nw. Coal. for Alts. to Pesticides*, 544 F.3d at 1046. As required, EPA retained the FQPA tenfold safety factor because of gaps in scientific information on the mode of action and exposure levels by which chlorpyrifos causes damage to children's brains.

Any uncertainties go to the precise exposure level or additional safety factors to use in establishing a regulatory endpoint that will protect children's brains. Such uncertainty offers no reason to retain tolerances. In 2014, even using an acute poisoning endpoint, EPA found chlorpyrifos unsafe due to drinking water contamination. When it developed a regulatory endpoint that would protect children's brains, it found chlorpyrifos unsafe every way people are exposed to it. More study will simply confirm how hazardous and devastating this pesticide can be. Congress decided not to expose children to such risks by precluding EPA from maintaining tolerances when it cannot find a reasonable certainty of no harm from the pesticide.

D. The Deadline for Completing Registration Review Is Not a License To Deny the Petition and Maintain Tolerances for Unsafe Pesticides.

The Pruitt Order claims that a new administration's prerogative to re-order priorities set by prior administrations allows EPA to issue an order keeping chlorpyrifos tolerances for five or more years until it completes its registration review of chlorpyrifos. ER 34; *see* 7 U.S.C. § 136a (g)(1)(A)(iii)(I) (registration review deadline). The fact that Congress established an October 1, 2022, deadline for EPA to complete registration review of all older pesticides is no license for EPA to deny the 2007 Petition and maintain chlorpyrifos tolerances without the ability to make the requisite safety finding.

Indeed, the registration review provision states that "[n]othing in this subsection shall prohibit the Administrator from undertaking any other review of a pesticide . . ." 7 U.S.C. § 136a(g)(1)(C). This clause prohibits EPA from invoking the registration review deadline to forestall other legally required or scientifically compelled regulatory action.[12]

EPA's review of chlorpyrifos has proceeded to a point of no return. The agency has completed human health risk assessments and found chlorpyrifos

[12] FIFRA establishes the registration review process to examine all uses of a pesticide, not only food uses, but also risks to wildlife, waterbodies, and workers. While EPA accelerated the chlorpyrifos food safety determination, other FIFRA assessments and decisions remained subject to the 2022 registration review deadline.

unsafe due to drinking water contamination in 2014 and 2015, *see, e.g.*, ER 1131, and it subsequently expanded the finding that chlorpyrifos is unsafe to every way people are exposed. ER 1291. The law is clear. EPA can leave food tolerances in place only if it can find the pesticide safe. The generally applicable registration review timeline does not over-ride this specific prohibition.

In claiming the authority to postpone revoking chlorpyrifos tolerances despite its own scientific findings, EPA cites the prerogative of a new presidential administration to make policy choices that differ from its predecessor, citing *Fed. Commc'n Comm'n v. Fox Television Stations*, 556 U.S. 502 (2009). ER 33. *Fox Television*, however, requires agencies to provide a reasoned explanation for such reversals that comports with *State Farm* and a more detailed explanation when it contradicts prior factual findings and circumstances that underlay or were engendered by the earlier agency decision. 556 U.S. at 515-16.

EPA reversed course without addressing its prior factual findings and the circumstances that undergirded the proposed revocation and timeline for the final rule. The salient facts and circumstances include EPA's prioritization of registration review of chlorpyrifos because of the need to respond to the 2007 Petition and address the weighty health issues it presented, 80 Fed. Reg. at 69,082, EPA's repeated findings that chlorpyrifos is unsafe, this Court's conclusion that "considerable human health interests [are] prejudiced by the delay," 798 F.3d at

814, and EPA's acknowledgment that "because the FFDCA is a safety standard, EPA can only retain chlorpyrifos tolerances if it is able to conclude that such tolerances are safe." ER 1131 (proposed revocation rule); *accord* ER 1291 (reaffirming and seeking further comment on the proposed revocation rule).

The Pruitt Order addresses none of these. As demonstrated above, EPA has failed to explain how it can retain chlorpyrifos tolerances in the absence of a safety finding and in the face of its repeated findings that chlorpyrifos is unsafe. EPA did not disavow EPA's previous findings that chlorpyrifos is unsafe. The Pruitt Order makes no mention of these findings, let alone make any attempt to provide a reasoned explanation for acting contrary to them. Under *Fox Television*, silence is not an option. *See Encino Motorcars v. Navarro*, 136 S. Ct. 2117, 2127 (2016). As this Court held in *Organized Village of Kake v. U.S. Dep't of Agric.*, 795 F.3d 956, 968-69 (9th Cir. 2015) (en banc), "[e]lections have policy consequences. But *State Farm* teaches that even when reversing a policy after an election, an agency may not simply discard prior factual findings without a reasoned explanation." Whatever leeway a new administration has to make its own policy choices does not extend to acting in blatant disregard of the agency's previous factual determinations, like EPA's findings that chlorpyrifos is unsafe. Nor does that latitude allow the new administration to break the law by leaving tolerances in place in the face of findings of such serious harm to children.

II. THIS COURT HAS JURISDICTION TO REVIEW THE SUBSTANCE OF THE PRUITT ORDER.

While the motions panel denied EPA's motion to dismiss for failure to exhaust administrative remedies, LULAC addresses the issue because it goes to jurisdiction. This Court has jurisdiction to hear this case under the FFDCA and should waive statutory exhaustion. In the alternative, this Court has jurisdiction under FIFRA because meaningful and timely review is not obtainable under the FFDCA.[13]

A. This Court Should Waive Exhaustion and Hear this Case under the FFDCA.

The FFDCA establishes an administrative objections process and provides for judicial review at the culmination of that process. The Supreme Court and this Court have excused compliance with statutory exhaustion procedures when, as here, pursing them would be futile and would allow an agency to violate clear statutory prohibitions.

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[13] Petitioners have standing because eliminating harmful exposures to chlorpyrifos furthers the organizations' missions and they have members who have been and will continue to be exposed to chlorpyrifos as a result of the Pruitt Order. Declarations of Brent Wilkes, Hector Sanchez, Mark Magaña, Erik Nicholson, Ramon Ramirez, Margaret Reeves, Jennifer Sass, Elena Rios, Virginia Ruiz, Anne Katten, Eugenia Economos, Maureen Swanson, Esteban Ortiz, Sylvia Youngblood, Martha Moriarty, Jaime Estrada, Beverly Johns, Diana Perez, Monica Ramirez, Javier Ceja, Amadeo Sumano, Jose Cruz, Gerardo Rios, Ofelia Aguilar, Judy Fishman, Sharon Bolton, Bonnie Wirtz; *see Friends of the Earth v. Laidlaw Envtl. Servs.*, 528 U.S. 167, 180-81 (2000); *Citizens for Better Forestry v. U.S. Dep't of Agric.*, 341 F.3d 961, 969 (9th Cir. 2003).

1. The Exhaustion and Judicial Review Provisions

Within 60 days of an order by the Administrator denying a petition to establish, modify, or revoke tolerances, any person may file objections with the Administrator presenting grounds for a different outcome that were not already presented in comments. 21 U.S.C. § 346a(g)(2)(A). The objections may seek an evidentiary hearing on factual issues, *id*. § 346a(g)(2)(B), but neither LULAC nor the State Objectors sought an evidentiary hearing because their objections raise purely legal questions.

"As soon as practicable after receiving the arguments of the parties, the Administrator shall issue an order stating the action taken upon each objection. . .." *Id*. § 346a(g)(2)(C). Any person adversely affected may obtain judicial review in the court of appeals. *Id*. § 346a(h)(1).

2. The FFDCA's exhaustion procedure is, like that of most statutes, non-jurisdictional and subject to waiver.

As the Supreme Court established in *Weinberger v. Salfi*, 422 U.S. 749, 764-66 (1975), statutory exhaustion requirements may be waived on equitable grounds unless they are central to the grant of subject matter jurisdiction. Even where an exhaustion requirement is stated in mandatory terms, it is rarely jurisdictional. *See, e.g.*, *Reed Elsevier v. Muchnick*, 559 U.S. 154, 163-66 (2010) (jurisdiction over unregistered copyright despite provision stating "no civil action for infringement of the copyright in any United States work shall be instituted until the preregistration

or registration of the copyright has been made"); *Bethesda Hosp. Ass'n v. Bowen*, 485 U.S. 399, 403-05 (1988) (Medicare provider can obtain hearing over reimbursement without obtaining review by a fiscal intermediary even though the statute provided for a hearing when dissatisfied with a final determination of such a fiscal intermediary regarding the reimbursement).

The Supreme Court has distinguished federal court jurisdiction in administrative cases from the elements of the claim for relief. *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 513-14 (2006). "Claim-processing rules," like filing deadlines and exhaustion procedures, speak to the obligations of litigants, not the power of the court, and are rarely jurisdictional. *Id*. at 513-16; *see Reed Elsevier*, 559 U.S. at 161; *Henderson v. Shinseki*, 562 U.S. 428, 434-35 (2011).

In keeping with this direction, this Court has repeatedly held that exhaustion requirements are not jurisdictional even under statutes using what looks like mandatory exhaustion language. *See, e.g.*, *Anderson v. Babbitt*, 230 F.3d 1158, 1162 (9th Cir. 2000) ("[n]o decision which at the time of its rendition is subject to appeal to the Director or an Appeals Board shall be considered final so as to be agency action subject to judicial review under 5 U.S.C. §704."); *Rumbles v. Hill*, 182 F.3d 1064, 1067 (9th Cir. 1999) ("[n]o action shall be brought . . . until such administrative remedies as are available are exhausted").

Admittedly, in holding that EPA has done what this Court ordered it to do in

an earlier mandamus action, this Court stated that "[n]ow that EPA has issued its denial, substantive objections must first be made through the administrative process mandated by statute." *In re PANNA*, 863 F.3d 1131, 1132 (9th Cir. 2017). The Court was distinguishing between the timing of EPA's action and a challenge to its substance. The Court recited the exhaustion provisions without applying *Weinberger* and its progeny to determine whether exhaustion is jurisdictional. Nor did the Court address whether, once LULAC filed objections, it would be futile to await EPA's resolution.[14] Moreover, the only case to address whether the FFDCA objection requirement is jurisdictional held that it was not. In *National Coalition*, the D.C. Circuit refused to require exhaustion under the analogous, predecessor objection provision, stating "[f]irst and foremost, the language of the specific provision on which EPA relies (§ 346a(d)(5)), is permissive, not mandatory. Where the language, as here, is clear, that should be the end of the matter." 809 F.2d at 879.

3. Exhaustion Should Be Waived.

As an element of the cause of action, rather than a jurisdictional prerequisite, "[t]his court, along with every other circuit to consider the issue, has held that there is no exhaustion requirement if resort to the agency would be futile." *SAIF*

[14] *Nader v. U.S. EPA*, 859 F.2d 747 (9th Cir. 1988), also described the FFDCA's predecessor exhaustion requirements without addressing whether they are jurisdictional.

Corp./Oregon Ship v. Johnson, 908 F.2d 1434, 1441 (9th Cir. 1990); *see McBride Cotton & Cattle Corp. v. Veneman*, 290 F.3d 973, 976 (9th Cir. 2002). Here, this Court should waive exhaustion because it would futile and would perpetuate the legal violations and harm that Congress has prohibited.

First, the legal violation at the heart of both the objections and this case is EPA's decision to leave chlorpyrifos tolerances in place in the absence of a safety finding for five or more years. This case argues that the delay in revoking tolerances without safety findings is in flagrant violation of the law. Deferring judicial review until the Administrator rules on the objections would perpetuate EPA's illegal conduct. The Administrator violated the statutory prohibition on retaining chlorpyrifos tolerances because he preferred to continue studying the science and put off revoking the tolerances until October 1, 2022. EPA is using the objection process to accomplish this illegal outcome. In response to a request from U.S. Senators for an expeditious resolution of the objections, EPA laid out a plan to conduct another risk assessment, another proposed rule, and eventual final regulatory action over many years. Under EPA's plan, a ruling on the objections would come when EPA completes registration review of chlorpyrifos in 2021 or 2022. This course of action will deprive LULAC of any opportunity to challenge the Administrator's decision to put off regulatory action on chlorpyrifos. Using the objection process to perpetuate EPA's illegal delay renders the process a sham and

deprives LULAC of the ability to halt EPA's violation of the law. *See Pac. Mar. Ass'n v. Nat'l Labor Relations Bd.*, 827 F.3d 1203, 1211 (9th Cir. 2016) (no adequate means within petitioners' control to seek judicial review).

Second, requiring exhaustion would allow EPA to violate Congress's prohibition on maintaining pesticide tolerances without a safety finding. Whether it is legally impermissible to leave chlorpyrifos tolerances in place without a safety finding is a purely legal question that will neither be informed nor advanced by EPA's ruling on the objections in four years or more. Courts have dispensed 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. *See Leedom v. Kyne*, 358 U.S. 184, 187-89 (1958) (violation of statute); *Oestereick v. Selective Serv. System Local Bd. No. 11*, 393 U.S. 233, 238 (1966) (clear departure from statutory mandate); *Chamber of Commerce of U.S. v. Reich*, 74 F.3d 1322 (D.C. Cir. 1996) (challenge to executive order's violation of statute). When an agency exceeds its statutory authority, it is the province of the courts to step in. *See Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 680 (1986) ("[w]e ordinarily presume that Congress intends the executive to obey its statutory commands and, accordingly, that it expects the courts to grant relief when an executive agency violates such a command.").

Finally, waiting for EPA to rule on the objections would continue to expose the public to risks of acute poisonings and damage to children's brains from a pesticide that EPA has found unsafe. If the Administrator had finalized the proposed revocation rule, it would have become effective at the end of September 2017, and growers would have stopped spraying foods with chlorpyrifos well before that deadline to avoid leaving residues on the food and rendering the food adulterated and subject to seizure and penalties. ER 1159 (proposed revocation rule).

Because the Administrator has no intention of ruling on the objections for years, the objections and this case present purely legal issues, and the harm Congress has forbidden is occurring, this Court should waive any exhaustion procedures and hear this case before the Administrator rules on the objections.

B. If Exhaustion Is Required, Review of the Legality of Leaving Chlorpyrifos Tolerances in Place Is Not Obtainable under the FFDCA, Giving Rise to Review under FIFRA.

If the Court determines that petitioners cannot challenge the Pruitt Order under the FFDCA before the Administrator rules on the objections, jurisdiction is available under FIFRA. 7 U.S.C. § 136n(b).[15] While the FFDCA regulates

[15] Under FIFRA's jurisdictional provision, 7 U.S.C. § 136n(b), parties to administrative proceedings may obtain judicial review of EPA orders issued after a hearing in the court of appeals. LULAC participated in the administrative process by submitting public comments. *See, e.g.*, ER 1391-1513, 1529-54, 1716-1783; *see United Farm Workers v. Adm'r, Envtl. Prot. Agency*, 592 F.3d 1080, 1082 (9th

residues of pesticides on food, FIFRA regulates use of pesticides. In order to register or maintain a registration for a pesticide under FIFRA, EPA must find the pesticide will not generally cause "unreasonable adverse effects on the environment." 7 U.S.C. §136a(c)(5); *see also id*. §136d(b) (providing for cancellation of registrations of pesticides that pose unreasonable adverse effects). FIFRA defines "unreasonable adverse effects" 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 the FFDCA." 7 U.S.C. §136(bb). The Pruitt Order leaves chlorpyrifos tolerances and registrations in place, even though chlorpyrifos poses human dietary risks that are inconsistent with the safety standard. In doing so, the Pruitt Order violates FIFRA.

In keeping with the presumption in favor of judicial review of agency action, the FFDCA requires adherence to its objection procedure only when review of an issue would be obtainable through that route. It provides that "[a]ny 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." *Id*. §346a(h)(5).[16] If this Court

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Cir. 2010) (public comment period is a "hearing" under § 136n(b)).

[16] This standard furthers the presumption in favor of judicial review and is analogous to the APA, which authorizes review where there is no other adequate remedy at law and where no statute expressly precludes review. In recent years, the Supreme Court has rejected wooden interpretations of statutory review provisions that would deny litigants review of actions having direct and

holds that judicial review under 21 U.S.C. § 346a(h) must wait until the Administrator rules on the administrative objections, meaningful and timely judicial review of the Pruitt Order's violation of the FIFRA prohibition on registering a pesticide that runs afoul of the FFDCA's safety standard, and therefore would be appropriate under FIFRA.

In *Nat. Res. Def. Council v. Johnson*, 461 F.3d 164, 176 (2d Cir. 2008), the Second Circuit held that 21 U.S.C. § 346a(h)(5) precluded judicial review under FIFRA of issues that could be fully reviewed under the FFDCA; the jurisdictional defect arose because the case had been brought in district court, rather than the court of appeals. The *NRDC* petitioners never argued, nor was there any indication, that submitting, and waiting for EPA to rule on, objections would be futile. Nor was EPA keeping tolerances in place in the face of agency findings that the "human dietary risk from residues" are "inconsistent with" the food safety standard, making the pesticide ineligible for FIFRA registration.[17] If this Court holds that LULAC cannot obtain judicial review under the FFDCA until EPA rules

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appreciable legal consequences. *See Sackett v. EPA*, 566 U.S. 120 (2012); *U.S. Army Corps of Engineers v. Hawkes Co., Inc.*, 136 S.Ct. 1807 (2016).

[17] *Nader v. EPA*, 859 F.2d 747, never addressed whether review was obtainable as required under 21 U.S.C. 346a(h)(5). Nor would review under FIFRA have been available because the FQPA amended FIFRA in 1996 to define unreasonable adverse effects to include human dietary risks prohibited under the FQPA. Pub. L. No. 104–170, August 3, 1996, 110 Stat 1489.

on the objections, judicial review of EPA's ongoing violation would be unobtainable under the FFDCA and therefore appropriate under FIFRA.

III. IF THIS COURT DETERMINES IT LACKS JURISDICTION, IT SHOULD ISSUE A WRIT OF MANDAMUS DIRECTING EPA TO DECIDE LULAC'S OBJECTIONS WITHIN 60 DAYS.

This case follows a series of unreasonable delay cases that culminated in this Court's finding that EPA's delay in acting on the 2007 Petition was "egregious." *In re PANNA*, 798 F.3d at 811. This Court held EPA's delay unreasonable after EPA found that chlorpyrifos damages children's brains at low-level exposures, is unsafe in drinking water, and poses unacceptable risks to the workers who apply it to or harvest our food. *Id.* at 814

While EPA met this Court's deadline for issuing a decision on the Petition, that decision postpones revoking chlorpyrifos tolerances or taking other regulatory action for five years or longer. Additionally, EPA now plans to delay ruling on the objections until after it engages in up to five more years of study and regulatory proceedings. And so EPA's record of unreasonable delay continues.

To determine whether an agency has unreasonably delayed taking agency action, this Court applies the six-factor balancing test set out by the D.C. Circuit in *TRAC*:

(1) the time agencies take to make decisions must be governed by a "rule of reason";
(2) where Congress has provided a timetable or other indication of the speed

with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason;

(3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake;

(4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority;

(5) the court should also take into account the nature and extent of the interests prejudiced by the delay; and

(6) the court need not "find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed."

TRAC, 750 F.2d at 80.

A. EPA's Plan To Postpone Action for Five Years Violates the Rule of Reason (Factor 1).

Unreasonable delay cases generally begin by assessing the length of the delay. If measured from when the objections were filed, the delay to date has been relatively short. However, the current delay builds upon delay this Court called "unreasonable" and "egregious," which spanned nearly ten years and ended only because this Court ordered EPA to act on the 2007 Petition by specific deadlines.

A delay is unreasonable if it is "tantamount" or "equivalent to a final denial" and is inflicting harm the agency is charged with avoiding. *Pub. Citizen Health Research Grp. v. Comm'r, Food & Drug Admin.*, 740 F.2d 21, 32, 35 (D.C. Cir. 1984). EPA's "action" is not the action compelled by the law, but a refusal to take that action for five or more years. The Pruitt Order denied the Petition because EPA chose to engage in further study and put off acting on the proposed revocation

until October 1, 2022, the general registration review deadline for older pesticides. EPA recently unveiled a course of action in which it will revise its chlorpyrifos risk assessment, seek public comment, propose another regulatory action and seek another round of comment, and eventually take final regulatory action on chlorpyrifos and rule on the administrative objections by that same 2022 deadline. Ordonia Exh. F. In other words, EPA has made taking final regulatory action on chlorpyrifos synonymous with deciding the administrative objections.

"The reasonableness of the delay must be judged 'in the context of the statute' which authorizes the agency's action." *Pub. Citizen Health Research Grp. v. Auchter*, 702 F.2d 1150, 1158 n.30 (D.C. Cir. 1983). The FFDCA prohibits maintaining tolerances for pesticides without a safety finding or in the face of findings that the pesticide is unsafe. EPA has completed the resource-intensive task of conducting risk assessments and making findings that chlorpyrifos is unsafe. All that remains to be done is taking the congressionally mandated action of revoking the tolerances. Delaying revocation of chlorpyrifos tolerances and ruling on the objections for five or more years is unreasonable in light of Congress's mandate to protect children and EPA's history of egregious delay. Any "claim of premature rulemaking has come and gone," as this Court held in *In re PANNA*, 840 F.3d 1014 (9th Cir. 2016).

B. The Statutory Scheme Calls for Speedy Action (Factor 2).

In addition to its strong mandates to protect our food and children's health, the FFDCA evinces Congress's intent that EPA act expeditiously when it has such strong evidence a pesticide is unsafe. EPA has a mandatory duty to act on the objections and to do so "as soon as practicable." 21 U.S.C. § 346a(g)(2)(C).

While EPA may conduct an evidentiary hearing to resolve factual issues, the objections raise the same purely legal questions presented in this case and do not seek an evidentiary hearing. It should take months, but certainly not years, for EPA to decide what action to take on the objections, particularly given that the FFDCA constrains EPA's discretion and mandates tolerance revocation.

If judicial review must await EPA's decision on the objections, EPA's inaction leaves LULAC "stuck in administrative limbo; it enjoys neither a favorable ruling on its petition nor the opportunity to challenge an unfavorable one." *In re People's Mojahedin Organization of Iran*, 680 F.3d 832, 837 (D.C. Cir. 2012) (delay in resolving petition for revocation of terrorist listing insulated decision from judicial review); *see also In re American Rivers*, 372 F.3d 413, 420 (D.C. Cir. 2004) (judicial intervention to end FERC's "marathon round of administrative keep-away").

C. The Health Risks and Prejudice They Cause Make the Delay Unreasonable (Factors 3 and 5).

It is well-settled that "[w]hen the public health may be at stake, the agency

must move expeditiously to consider and resolve the issues before it." *Pub. Citizen Health Research Grp.*, 740 F.2d at 34-35. EPA has denied people protection from chlorpyrifos, despite finding it unsafe in food, drinking water, and pesticide drift because it poses unacceptable risks of pesticide poisonings and learning disabilities in children. It made these findings for drinking water in 2014, along with findings that workers are exposed to unsafe exposures. ER 194-96, 271-73, 276-78, 285-90. The delay has become only more serious and indefensible as EPA strengthened its findings that chlorpyrifos damages children's brains every way children are exposed to the pesticide. ER 1254-55, 1271-72, 1279-82.

The Pruitt Order purports to seek greater scientific certainty as to the magnitude of the risks of neurodevelopmental harm before taking regulatory action. This is an insufficient reason to delay as a matter of fact since, even without protecting children against such harm, EPA found chlorpyrifos unsafe in drinking water, and the correlation between low-level exposures and damage to children's brains is well-established in a robust body of scientific literature and findings by EPA and its SAP. *See supra* at 13-21. It is also insufficient as a matter of law as "[t]he risk to human life need not be a certainty to justify expedition [of agency action]." *Pub. Citizen Health Research Grp.*, 702 F.2d at 1158 n.26. When the agency's review has spanned years and progressed to the extent it has here, "scientific uncertainties and technical complexities, while no doubt

considerable, can no longer justify delay." *Pub. Citizen Health Research Grp. v. Chao*, 314 F.3d 143, 156 (3d Cir. 2002).

As this Court previously found, "considerable human health risks" caused by exposure to chlorpyrifos are "prejudiced by the delay," *In re PANNA*, 798 F.3d at 814, and favor mandamus relief. That harm takes two forms.

First, every year, chlorpyrifos causes acute poisonings that make people sick with symptoms ranging from diarrhea and vomiting to seizures, fainting, and worse. Poison reporting in California and Washington regularly documents incidents associated with chlorpyrifos with pesticide drift being a frequent cause of poisonings. ER 1521-28 (Washington State poisoning incidents); ER 1483-1511 (California poisoning incidents); Reeves Decl. ¶¶ 7-12; Katten Decl. ¶¶ 10-12. In one incident in May 2017, chlorpyrifos traveled one-half mile from a farm, sickening dozens of people and leading to a fine exceeding $30,000. Reeves Decl. ¶ 27; Katten Decl. ¶ 11.

Second, low-level exposures to chlorpyrifos damage the developing brains of children, leading to the kinds of learning disabilities that plague one in six children in the United States. Swanson Decl. ¶ 6. Learning disabilities impede the ability of children to achieve their potential and take their toll on families, schools, social services, and health care systems. Moriarty Decl. ¶¶ 2-3; Youngblood Decl. ¶¶ 4-6. For example, it costs as much on average to educate children with learning

disabilities, and one third of children in the U.S. juvenile justice system have one or more learning or behavioral disorders. Swanson Decl. ¶ 8; ER 1811-12 (studies estimating economic losses from reduced IQ and learning disabilities).

As long as EPA allows chlorpyrifos to be sprayed on our food, people will be unable to prevent exposures to chlorpyrifos and the risk of harm. People cannot avoid chlorpyrifos when it contaminates their drinking water. ER 276-79 (2014 Risk Assessment) (drinking water monitoring confirms chlorpyrifos is unsafe); AR 2136 (California water monitoring detected chlorpyrifos in 17.7% of samples, with 9.9% exceeding the state's concentration limit).

Nor can they avoid it in food given its widespread use and pervasive residues. In food sampling in 2015, the U.S. Department of Agriculture detected chlorpyrifos on 12 different types of fruits and vegetables, including on fruits like peaches, nectarines, grapes, and strawberries that are popular with children. Sass Decl. ¶¶ 39-41. Apples, the top fruit consumed by children, have residues even after they are washed, and chlorpyrifos residues persist on citrus and melons even after they are washed and peeled. Sass. Dec. ¶ 40.

Chlorpyrifos also makes its way into our air when it travels windborne from where it is sprayed to schools, day cares, and homes. In 2016, EPA found unsafe exposures in air monitoring of chlorpyrifos. ER 1279-82. In California, air monitoring showed chlorpyrifos as having one of the highest number of detections

in 2011-2015, and in 2015, 61% of the air samples taken at a high school detected chlorpyrifos. ER 131-32. EPA found in its 2016 risk assessment that people are exposed to unsafe chlorpyrifos levels more than 300 feet from where it is applied, much further than the buffers EPA required in 2012 to reduce exposures from spray drift, ER 1254, 1278-80, and poisoning reports and a recent evaluation by the California Department of Pesticide Regulation confirm that chlorpyrifos drifts in toxic amounts at greater distances. ER 1521; Katten Decl. ¶ 11; Sass Decl. ¶ 49; Reeves Decl. ¶ 26 (California draft evaluation of chlorpyrifos for designation as a toxic air contaminant). Farmworker children are also exposed to chlorpyrifos when their parents track residues home on their shoes and clothing. ER 1447-48; ER 1680-1710.

Not only is chlorpyrifos making its way into our food, drinking water, and air, but it is also already in our bodies. Center for Disease Control monitoring through urine testing reveals that members of the U.S. population – across all ages, sex and ethnicities – carry chlorpyrifos metabolites in their bodies. Reeves Decl. ¶¶ 16, 28.[18]

[18] When this Court issued a writ of mandamus in 2015, it referenced the risks to farmworkers from many activities performed in the field. 798 F.3d at 814. EPA's 2016 risk assessment finds farmworkers are exposed to unsafe levels of chlorpyrifos from all handling activities and field work. ER 1284-86. In addition, NOAA Fisheries recently released a biological opinion finding that chlorpyrifos is likely to jeopardize the survival and recovery and adversely modify the critical habitat of all 28 Pacific salmon and steelhead populations on the Endangered

Chlorpyrifos is ubiquitous and impossible to avoid, making EPA's delay and exposure of children to risks of brain damage unconscionable. "Lack of alternative means of eliminating or reducing the hazard necessarily adds to unreasonableness of a delay." *See Cutler v. Hayes*, 818 F.2d 879, 898 (D.C. Cir. 1987).

D. No Competing Priorities Justify EPA's Delay (Factor 4).

EPA would be hard pressed to offer other higher priorities that could justify delaying taking regulatory action on chlorpyrifos. Congress made protecting children the highest of priorities when it adopted the health-based mandates in the FQPA.

EPA recently identified several deregulatory and delay actions that it is undertaking that will weaken public health protections from toxic pesticides like chlorpyrifos. Ordonia Exh. F. Complying with the congressional mandate to revoke tolerances for unsafe pesticides takes precedence over discretionary actions to weaken public health safeguards.

E. EPA Appears to be Delaying for Improper Reasons (Factor 6).

While the Court need not find any impropriety "lurking behind EPA's lassitude" to grant mandamus relief, *TRAC*, 750 F.2d at 80, it appears that EPA

Species Act list, necessitating substantial changes to allowable uses of chlorpyrifos in salmon habitat. https://earthjustice.org/sites/default/files/files/Final%20BiOp_Chlorpyrifos.compressed.pdf.

denied the Petition for improper reasons. EPA staff, after a decade of review, drafted a final revocation rule based on EPA's findings. Less than a month before the court-ordered deadline, political aides to the new Administrator directed staff to reverse course and draft a denial order. Exh. B at 12, 17; Exh. C at 1-2. The Pruitt Order and EPA's press release highlight the widespread use and agricultural community's desire to retain chlorpyrifos, factors that cannot lawfully be the basis for tolerance decisions. *Id*. at 43; 82 Fed. Reg. at 16,590.

In sum, under the *TRAC* factors, EPA's delay in ruling on the objections is unreasonable. It is appropriate for this Court to issue another writ of mandamus, ordering EPA to decide the objections within 60 days, and "let [the] agency know, in no uncertain terms, that enough is enough." *Pub. Citizen Health Research Grp. v. Brock*, 823 F.2d 626, 627 (D.C. Cir. 1987).

CONCLUSION

This Court should hold that Administrator Pruitt exceeded his authority and acted contrary to the FFDCA and the record in denying the 2007 Petition and remand with directions to revoke all tolerances and cancel all registrations within 60 days. In the alternative, if the Court decides it lacks jurisdiction to review the substance of the Pruitt Order, it should issue a writ of mandamus directing Administrator Pruitt to rule on the objections within 60 days.

/s/Patti A. Goldman

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STATEMENT OF RELATED CASE

This case is related to *In re PANNA v. EPA*, No. 14-72794, because the two cases raise the same or closely related issues and involve the same events, namely EPA's failure to ban chlorpyrifos in response to the 2007 Petition. This case also is a comeback case within the meaning of Ninth Circuit Rule 1.12. This Court previously heard *In re PANNA*, and issued a writ of mandamus directing EPA to respond to the 2007 Petition by specified deadlines. *See* Ninth Circuit Rule 28-2.6 - Statement of Related Cases. This case seeks review of EPA's 2017 denial of the 2007 Petition and, in the alternative, seeks another writ of mandamus compelling EPA to decide administrative objections forthwith.

CERTIFICATE OF COMPLIANCE

This brief complies with the length limits permitted by Ninth Circuit Rule 28.1-1. The brief is 13,956 words, excluding the portions exempted by Fed. R. App. P. 32(f), if applicable. The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6).

/s/Patti A. Goldman
Patti A. Goldman

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 January 23rd, 2018.

I further certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Patti A. Goldman
Patti A. Goldman

ADDENDUM

STATUTES

5 U.S.C. §706

7 U.S.C. §136

7 U.S.C. §136(a)

7 U.S.C. §136(d)

7 U.S.C. §136(n)

21 U.S.C. §346a

denied on the ground that it is against the United States or that the United States is an indispensable party. The United States may be named as a defendant in any such action, and a judgment or decree may be entered against the United States: *Provided*, That any mandatory or injunctive decree shall specify the Federal officer or officers (by name or by title), and their successors in office, personally responsible for compliance. Nothing herein (1) affects other limitations on judicial review or the power or duty of the court to dismiss any action or deny relief on any other appropriate legal or equitable ground; or (2) confers authority to grant relief if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought.

(Pub. L. 89–554, Sept. 6, 1966, 80 Stat. 392; Pub. L. 94–574, §1, Oct. 21, 1976, 90 Stat. 2721.)

HISTORICAL AND REVISION NOTES

Derivation	*U.S. Code*	*Revised Statutes and Statutes at Large*
.....	5 U.S.C. 1009(a).	June 11, 1946, ch. 324, §10(a), 60 Stat. 243.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface to the report.

AMENDMENTS

1976—Pub. L. 94–574 removed the defense of sovereign immunity as a bar to judicial review of Federal administrative action otherwise subject to judicial review.

§ 703. Form and venue of proceeding

The form of proceeding for judicial review is the special statutory review proceeding relevant to the subject matter in a court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus, in a court of competent jurisdiction. If no special statutory review proceeding is applicable, the action for judicial review may be brought against the United States, the agency by its official title, or the appropriate officer. Except to the extent that prior, adequate, and exclusive opportunity for judicial review is provided by law, agency action is subject to judicial review in civil or criminal proceedings for judicial enforcement.

(Pub. L. 89–554, Sept. 6, 1966, 80 Stat. 392; Pub. L. 94–574, §1, Oct. 21, 1976, 90 Stat. 2721.)

HISTORICAL AND REVISION NOTES

Derivation	*U.S. Code*	*Revised Statutes and Statutes at Large*
.....	5 U.S.C. 1009(b).	June 11, 1946, ch. 324, §10(b), 60 Stat. 243.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface to the report.

AMENDMENTS

1976—Pub. L. 94–574 provided that if no special statutory review proceeding is applicable, the action for judicial review may be brought against the United States, the agency by its official title, or the appropriate officer as defendant.

§ 704. Actions reviewable

Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority.

(Pub. L. 89–554, Sept. 6, 1966, 80 Stat. 392.)

HISTORICAL AND REVISION NOTES

Derivation	*U.S. Code*	*Revised Statutes and Statutes at Large*
.....	5 U.S.C. 1009(c).	June 11, 1946, ch. 324, §10(c), 60 Stat. 243.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface of this report.

§ 705. Relief pending review

When an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review. On such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court, including the court to which a case may be taken on appeal from or on application for certiorari or other writ to a reviewing court, may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings.

(Pub. L. 89–554, Sept. 6, 1966, 80 Stat. 393.)

HISTORICAL AND REVISION NOTES

Derivation	*U.S. Code*	*Revised Statutes and Statutes at Large*
.....	5 U.S.C. 1009(d).	June 11, 1946, ch. 324, §10(d), 60 Stat. 243.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface of this report.

§ 706. Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

(Pub. L. 89–554, Sept. 6, 1966, 80 Stat. 393.)

HISTORICAL AND REVISION NOTES

Derivation	*U.S. Code*	*Revised Statutes and Statutes at Large*
.....	5 U.S.C. 1009(e).	June 11, 1946, ch. 324, §10(e), 60 Stat. 243.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface of this report.

ABBREVIATION OF RECORD

Pub. L. 85–791, Aug. 28, 1958, 72 Stat. 941, which authorized abbreviation of record on review or enforcement of orders of administrative agencies and review on the original papers, provided, in section 35 thereof, that: ''This Act [see Tables for classification] shall not be construed to repeal or modify any provision of the Administrative Procedure Act [see Short Title note set out preceding section 551 of this title].''

CHAPTER 8—CONGRESSIONAL REVIEW OF AGENCY RULEMAKING

§ 801. Congressional review

(a)(1)(A) Before a rule can take effect, the Federal agency promulgating such rule shall submit to each House of the Congress and to the Comptroller General a report containing—

(i) a copy of the rule;

(ii) a concise general statement relating to the rule, including whether it is a major rule; and

(iii) the proposed effective date of the rule.

(B) On the date of the submission of the report under subparagraph (A), the Federal agency promulgating the rule shall submit to the Comptroller General and make available to each House of Congress—

(i) a complete copy of the cost-benefit analysis of the rule, if any;

(ii) the agency's actions relevant to sections 603, 604, 605, 607, and 609;

(iii) the agency's actions relevant to sections 202, 203, 204, and 205 of the Unfunded Mandates Reform Act of 1995; and

(iv) any other relevant information or requirements under any other Act and any relevant Executive orders.

(C) Upon receipt of a report submitted under subparagraph (A), each House shall provide copies of the report to the chairman and ranking member of each standing committee with jurisdiction under the rules of the House of Representatives or the Senate to report a bill to amend the provision of law under which the rule is issued.

(2)(A) The Comptroller General shall provide a report on each major rule to the committees of jurisdiction in each House of the Congress by the end of 15 calendar days after the submission or publication date as provided in section 802(b)(2). The report of the Comptroller General shall include an assessment of the agency's compliance with procedural steps required by paragraph (1)(B).

(B) Federal agencies shall cooperate with the Comptroller General by providing information relevant to the Comptroller General's report under subparagraph (A).

(3) A major rule relating to a report submitted under paragraph (1) shall take effect on the latest of—

(A) the later of the date occurring 60 days after the date on which—

(i) the Congress receives the report submitted under paragraph (1); or

(ii) the rule is published in the Federal Register, if so published;

(B) if the Congress passes a joint resolution of disapproval described in section 802 relating to the rule, and the President signs a veto of such resolution, the earlier date—

(i) on which either House of Congress votes and fails to override the veto of the President; or

(ii) occurring 30 session days after the date on which the Congress received the veto and objections of the President; or

(C) the date the rule would have otherwise taken effect, if not for this section (unless a joint resolution of disapproval under section 802 is enacted).

(4) Except for a major rule, a rule shall take effect as otherwise provided by law after submission to Congress under paragraph (1).

(5) Notwithstanding paragraph (3), the effective date of a rule shall not be delayed by operation of this chapter beyond the date on which either House of Congress votes to reject a joint resolution of disapproval under section 802.

(b)(1) A rule shall not take effect (or continue), if the Congress enacts a joint resolution of disapproval, described under section 802, of the rule.

(2) A rule that does not take effect (or does not continue) under paragraph (1) may not be reissued in substantially the same form, and a new rule that is substantially the same as such a rule may not be issued, unless the reissued or new rule is specifically authorized by a law enacted after the date of the joint resolution disapproving the original rule.

(c)(1) Notwithstanding any other provision of this section (except subject to paragraph (3)), a

deliveries of insecticides and fungicides exempted by the Secretary.

SUBCHAPTER II—ENVIRONMENTAL PESTICIDE CONTROL

§§ 135 to 135k. Omitted

CODIFICATION

Sections 135 to 135k, acts June 25, 1947, ch. 125, §§ 2–13, 61 Stat. 163–172; Aug. 7, 1959, Pub. L. 86–139, § 2, 73 Stat. 286; May 12, 1964, Pub. L. 88–305, §§ 1–6, 78 Stat. 190–193; Oct. 15, 1970, Pub. L. 91–452, title II, § 204, 84 Stat. 928; Dec. 30, 1970, Pub. L. 91–601, § 6(b), formerly § 7(b), 84 Stat. 1673, renumbered, Aug. 13, 1981, Pub. L. 97–35, title XII, § 1205(c), 95 Stat. 716, which related to economic poison control, were superseded by the amendments made to act June 25, 1947, by Pub. L. 92–516, Oct. 21, 1972, 86 Stat. 975. See section 4 of Pub. L. 92–516, set out as a note under section 136 of this title. The provisions of act June 25, 1947, as amended by Pub. L. 92–516, are set out in section 136 et seq. of this title.

Section 135 provided definitions for the purposes of this subchapter.

Section 135a related to prohibited acts.

Section 135b related to registration of economic poisons.

Section 135c related to access, inspection, and use in criminal prosecutions of books and records.

Section 135d related to rules and regulations, examination of economic poisons or devices, notification to violators, certification to United States attorney, duty of attorney, and publication of judgments.

Section 135e related to exemptions from penalties.

Section 135f provided for penalties.

Section 135g related to seizure, disposal, and award of costs against claimant.

Section 135h related to refusal of admission of imports.

Section 135i related to delegation of duties.

Section 135j related to authorization of appropriations and expenditure of funds.

Section 135k related to cooperation between departments and agencies.

§ 136. Definitions

For purposes of this subchapter—

(a) Active ingredient

The term ''active ingredient'' means—

(1) in the case of a pesticide other than a plant regulator, defoliant, desiccant, or nitrogen stabilizer, an ingredient which will prevent, destroy, repel, or mitigate any pest;

(2) in the case of a plant regulator, an ingredient which, through physiological action, will accelerate or retard the rate of growth or rate of maturation or otherwise alter the behavior of ornamental or crop plants or the product thereof;

(3) in the case of a defoliant, an ingredient which will cause the leaves or foliage to drop from a plant;

(4) in the case of a desiccant, an ingredient which will artificially accelerate the drying of plant tissue; and

(5) in the case of a nitrogen stabilizer, an ingredient which will prevent or hinder the process of nitrification, denitrification, ammonia volatilization, or urease production through action affecting soil bacteria.

(b) Administrator

The term ''Administrator'' means the Administrator of the Environmental Protection Agency.

(c) Adulterated

The term ''adulterated'' applies to any pesticide if—

(1) its strength or purity falls below the professed standard of quality as expressed on its labeling under which it is sold;

(2) any substance has been substituted wholly or in part for the pesticide; or

(3) any valuable constituent of the pesticide has been wholly or in part abstracted.

(d) Animal

The term ''animal'' means all vertebrate and invertebrate species, including but not limited to man and other mammals, birds, fish, and shellfish.

(e) Certified applicator, etc.

(1) Certified applicator

The term ''certified applicator'' means any individual who is certified under section 136i of this title as authorized to use or supervise the use of any pesticide which is classified for restricted use. Any applicator who holds or applies registered pesticides, or uses dilutions of registered pesticides consistent with subsection (ee) of this section, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served is not deemed to be a seller or distributor of pesticides under this subchapter.

(2) Private applicator

The term ''private applicator'' means a certified applicator who uses or supervises the use of any pesticide which is classified for restricted use for purposes of producing any agricultural commodity on property owned or rented by the applicator or the applicator's employer or (if applied without compensation other than trading of personal services between producers of agricultural commodities) on the property of another person.

(3) Commercial applicator

The term ''commercial applicator'' means an applicator (whether or not the applicator is a private applicator with respect to some uses) who uses or supervises the use of any pesticide which is classified for restricted use for any purpose or on any property other than as provided by paragraph (2).

(4) Under the direct supervision of a certified applicator

Unless otherwise prescribed by its labeling, a pesticide shall be considered to be applied under the direct supervision of a certified applicator if it is applied by a competent person acting under the instructions and control of a certified applicator who is available if and when needed, even though such certified applicator is not physically present at the time and place the pesticide is applied.

(f) Defoliant

The term ''defoliant'' means any substance or mixture of substances intended for causing the leaves or foliage to drop from a plant, with or without causing abscission.

(g) Desiccant

The term ''desiccant'' means any substance or mixture of substances intended for artificially accelerating the drying of plant tissue.

(h) Device

The term ''device'' means any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.

(i) District court

The term ''district court'' means a United States district court, the District Court of Guam, the District Court of the Virgin Islands, and the highest court of American Samoa.

(j) Environment

The term ''environment'' includes water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these.

(k) Fungus

The term ''fungus'' means any non-chlorophyll-bearing thallophyte (that is, any non-chlorophyll-bearing plant of a lower order than mosses and liverworts), as for example, rust, smut, mildew, mold, yeast, and bacteria, except those on or in living man or other animals and those on or in processed food, beverages, or pharmaceuticals.

***(l)* Imminent hazard**

The term ''imminent hazard'' means a situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened by the Secretary pursuant to the Endangered Species Act of 1973 [16 U.S.C. 1531 et seq.].

(m) Inert ingredient

The term ''inert ingredient'' means an ingredient which is not active.

(n) Ingredient statement

The term ''ingredient statement'' means a statement which contains—

(1) the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in the pesticide; and

(2) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic.

***(o)* Insect**

The term ''insect'' means any of the numerous small invertebrate animals generally having the body more or less obviously segmented, for the most part belonging to the class insecta, comprising six-legged, usually winged forms, as for example, beetles, bugs, bees, flies, and to other allied classes of arthropods whose members are wingless and usually have more than six legs, as for example, spiders, mites, ticks, centipedes, and wood lice.

(p) Label and labeling

(1) Label

The term ''label'' means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

(2) Labeling

The term ''labeling'' means all labels and all other written, printed, or graphic matter—

(A) accompanying the pesticide or device at any time; or

(B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

(q) Misbranded

(1) A pesticide is misbranded if—

(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

(B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;

(C) it is an imitation of, or is offered for sale under the name of, another pesticide;

(D) its label does not bear the registration number assigned under section 136e of this title to each establishment in which it was produced;

(E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment;

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment; or

(H) in the case of a pesticide not registered in accordance with section 136a of this title and intended for export, the label does not contain, in words prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) as to render it likely to be noted by the ordinary individual under customary conditions of purchase and use, the following: ''Not Registered for Use in the United States of America''.

(2) A pesticide is misbranded if—

(A) the label does not bear an ingredient statement on that part of the immediate container (and on the outside container or wrapper of the retail package, if there be one, through which the ingredient statement on the immediate container cannot be clearly read) which is presented or displayed under customary conditions of purchase, except that a pesticide is not misbranded under this subparagraph if—

(i) the size or form of the immediate container, or the outside container or wrapper of the retail package, makes it impracticable to place the ingredient statement on the part which is presented or displayed under customary conditions of purchase; and

(ii) the ingredient statement appears prominently on another part of the immediate container, or outside container or wrapper, permitted by the Administrator;

(B) the labeling does not contain a statement of the use classification under which the product is registered;

(C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing—

(i) the name and address of the producer, registrant, or person for whom produced;

(ii) the name, brand, or trademark under which the pesticide is sold;

(iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; and

(iv) when required by regulation of the Administrator to effectuate the purposes of this subchapter, the registration number assigned to the pesticide under this subchapter, and the use classification; and

(D) the pesticide contains any substance or substances in quantities highly toxic to man, unless the label shall bear, in addition to any other matter required by this subchapter—

(i) the skull and crossbones;

(ii) the word ''poison'' prominently in red on a background of distinctly contrasting color; and

(iii) a statement of a practical treatment (first aid or otherwise) in case of poisoning by the pesticide.

(r) Nematode

The term ''nematode'' means invertebrate animals of the phylum nemathelminthes and class nematoda, that is, unsegmented round worms with elongated, fusiform, or saclike bodies covered with cuticle, and inhabiting soil, water, plants, or plant parts; may also be called nemas or eelworms.

(s) Person

The term ''person'' means any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not.

(t) Pest

The term ''pest'' means (1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest under section 136w(c)(1) of this title.

(u) Pesticide

The term ''pesticide'' means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer, except that the term ''pesticide'' shall not include any article that is a ''new animal drug'' within the meaning of section 321(w)[1] of title 21, that has been determined by the Secretary of Health and Human Services not to be a new animal drug by a regulation establishing conditions of use for the article, or that is an animal feed within the meaning of section 321(x)[1] of title 21 bearing or containing a new animal drug. The term ''pesticide'' does not include liquid chemical sterilant products (including any sterilant or subordinate disinfectant claims on such products) for use on a critical or semi-critical device, as defined in section 321 of title 21. For purposes of the preceding sentence, the term ''critical device'' includes any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body and the term ''semi-critical device'' includes any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

(v) Plant regulator

The term ''plant regulator'' means any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof, but shall not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments. Also, the term ''plant regulator'' shall not be required to include any of such of those nutrient mixtures or soil amendments as are commonly known as vitamin-hormone horticultural products, intended for improvement, maintenance, survival, health, and propagation of plants, and as are not for pest destruction and are nontoxic, nonpoisonous in the undiluted packaged concentration.

(w) Producer and produce

The term ''producer'' means the person who manufactures, prepares, compounds, propagates, or processes any pesticide or device or active ingredient used in producing a pesticide. The term ''produce'' means to manufacture, prepare, compound, propagate, or process any pesticide or device or active ingredient used in producing a

[1] See References in Text note below.

pesticide. The dilution by individuals of formulated pesticides for their own use and according to the directions on registered labels shall not of itself result in such individuals being included in the definition of ''producer'' for the purposes of this subchapter.

(x) Protect health and the environment

The terms ''protect health and the environment'' and ''protection of health and the environment'' mean protection against any unreasonable adverse effects on the environment.

(y) Registrant

The term ''registrant'' means a person who has registered any pesticide pursuant to the provisions of this subchapter.

(z) Registration

The term ''registration'' includes reregistration.

(aa) State

The term ''State'' means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, and American Samoa.

(bb) Unreasonable adverse effects on the environment

The term ''unreasonable adverse effects on the environment'' means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) 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. The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide.

(cc) Weed

The term ''weed'' means any plant which grows where not wanted.

(dd) Establishment

The term ''establishment'' means any place where a pesticide or device or active ingredient used in producing a pesticide is produced, or held, for distribution or sale.

(ee) To use any registered pesticide in a manner inconsistent with its labeling

The term ''to use any registered pesticide in a manner inconsistent with its labeling'' means to use any registered pesticide in a manner not permitted by the labeling, except that the term shall not include (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling unless the labeling specifically prohibits deviation from the specified dosage, concentration, or frequency, (2) applying a pesticide against any target pest not specified on the labeling if the application is to the crop, animal, or site specified on the labeling, unless the Administrator has required that the labeling specifically state that the pesticide may be used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable adverse effect on the environment, (3) employing any method of application not prohibited by the labeling unless the labeling specifically states that the product may be applied only by the methods specified on the labeling, (4) mixing a pesticide or pesticides with a fertilizer when such mixture is not prohibited by the labeling, (5) any use of a pesticide in conformance with section 136c, 136p, or 136v of this title, or (6) any use of a pesticide in a manner that the Administrator determines to be consistent with the purposes of this subchapter. After March 31, 1979, the term shall not include the use of a pesticide for agricultural or forestry purposes at a dilution less than label dosage unless before or after that date the Administrator issues a regulation or advisory opinion consistent with the study provided for in section 27(b) of the Federal Pesticide Act of 1978, which regulation or advisory opinion specifically requires the use of definite amounts of dilution.

(ff) Outstanding data requirement

(1) In general

The term ''outstanding data requirement'' means a requirement for any study, information, or data that is necessary to make a determination under section 136a(c)(5) of this title and which study, information, or data—

(A) has not been submitted to the Administrator; or

(B) if submitted to the Administrator, the Administrator has determined must be resubmitted because it is not valid, complete, or adequate to make a determination under section 136a(c)(5) of this title and the regulations and guidelines issued under such section.

(2) Factors

In making a determination under paragraph (1)(B) respecting a study, the Administrator shall examine, at a minimum, relevant protocols, documentation of the conduct and analysis of the study, and the results of the study to determine whether the study and the results of the study fulfill the data requirement for which the study was submitted to the Administrator.

(gg) To distribute or sell

The term ''to distribute or sell'' means to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver. The term does not include the holding or application of registered pesticides or use dilutions thereof by any applicator who provides a service of controlling pests without delivering any unapplied pesticide to any person so served.

(hh) Nitrogen stabilizer

The term ''nitrogen stabilizer'' means any substance or mixture of substances intended for preventing or hindering the process of nitrification, denitrification, ammonia volatilization, or urease production through action upon soil bacteria. Such term shall not include—

(1) dicyandiamide;
(2) ammonium thiosulfate; or
(3) any substance or mixture of substances.—[2]
(A) that was not registered pursuant to section 136a of this title prior to January 1, 1992; and
(B) that was in commercial agronomic use prior to January 1, 1992, with respect to which after January 1, 1992, the distributor or seller of the substance or mixture has made no specific claim of prevention or hindering of the process of nitrification, denitrification, ammonia volatilization[3] urease production regardless of the actual use or purpose for, or future use or purpose for, the substance or mixture.

Statements made in materials required to be submitted to any State legislative or regulatory authority, or required by such authority to be included in the labeling or other literature accompanying any such substance or mixture shall not be deemed a specific claim within the meaning of this subsection.

(jj)[4] Maintenance applicator

The term ''maintenance applicator'' means any individual who, in the principal course of such individual's employment, uses, or supervises the use of, a pesticide not classified for restricted use (other than a ready to use consumer products pesticide); for the purpose of providing structural pest control or lawn pest control including janitors, general maintenance personnel, sanitation personnel, and grounds maintenance personnel. The term ''maintenance applicator'' does not include private applicators as defined in subsection (e)(2) of this section; individuals who use antimicrobial pesticides, sanitizers or disinfectants; individuals employed by Federal, State, and local governments or any political subdivisions thereof, or individuals who use pesticides not classified for restricted use in or around their homes, boats, sod farms, nurseries, greenhouses, or other noncommercial property.

(kk) Service technician

The term ''service technician'' means any individual who uses or supervises the use of pesticides (other than a ready to use consumer products pesticide) for the purpose of providing structural pest control or lawn pest control on the property of another for a fee. The term ''service technician'' does not include individuals who use antimicrobial pesticides, sanitizers or disinfectants; or who otherwise apply ready to use consumer products pesticides.

***(ll)* Minor use**

The term ''minor use'' means the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where—
(1) the total United States acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; or
(2) the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and—
(A) there are insufficient efficacious alternative registered pesticides available for the use;
(B) the alternatives to the pesticide use pose greater risks to the environment or human health;
(C) the minor use pesticide plays or will play a significant part in managing pest resistance; or
(D) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The status as a minor use under this subsection shall continue as long as the Administrator has not determined that, based on existing data, such use may cause an unreasonable adverse effect on the environment and the use otherwise qualifies for such status.

(mm) Antimicrobial pesticide

(1) In general

The term ''antimicrobial pesticide'' means a pesticide that—
(A) is intended to—
(i) disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or
(ii) 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; and
(B) in the intended use is exempt from, or otherwise not subject to, a tolerance under section 346a of title 21 or a food additive regulation under section 348 of title 21.

(2) Excluded products

The term ''antimicrobial pesticide'' does not include—
(A) a wood preservative or antifouling paint product for which a claim of pesticidal activity other than or in addition to an activity described in paragraph (1) is made;
(B) an agricultural fungicide product; or
(C) an aquatic herbicide product.

(3) Included products

The term ''antimicrobial pesticide'' does include any other chemical sterilant product (other than liquid chemical sterilant products exempt under subsection (u) of this section), any other disinfectant product, any other industrial microbiocide product, and any other preservative product that is not excluded by paragraph (2).

(nn) Public health pesticide

The term ''public health pesticide'' means any minor use pesticide product registered for use and used predominantly in public health programs for vector control or for other recognized health protection uses, including the prevention or mitigation of viruses, bacteria, or other microorganisms (other than viruses, bacteria, or

[2] So in original. Period probably should not appear.
[3] So in original. Probably should be followed by '', or''.
[4] So in original. No subsec. (ii) was enacted.

other microorganisms on or in living man or other living animal) that pose a threat to public health.

(*oo*) Vector

The term ''vector'' means any organism capable of transmitting the causative agent of human disease or capable of producing human discomfort or injury, including mosquitoes, flies, fleas, cockroaches, or other insects and ticks, mites, or rats.

(June 25, 1947, ch. 125, §2, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 975; amended Pub. L. 93–205, §13(f), Dec. 28, 1973, 87 Stat. 903; Pub. L. 94–140, §9, Nov. 28, 1975, 89 Stat. 754; Pub. L. 95–396, §1, Sept. 30, 1978, 92 Stat. 819; Pub. L. 100–532, title I, §101, title VI, §601(a), title VIII, §801(a), Oct. 25, 1988, 102 Stat. 2655, 2677, 2679; Pub. L. 102–237, title X, §1006(a)(1), (2), (b)(3)(A), (B), Dec. 13, 1991, 105 Stat. 1894, 1895; Pub. L. 104–170, title I, §§105(a), 120, title II, §§210(a), 221, 230, title III, §304, Aug. 3, 1996, 110 Stat. 1490, 1492, 1493, 1502, 1508, 1512.)

REFERENCES IN TEXT

The Endangered Species Act of 1973, referred to in subsec. (*l*), is Pub. L. 93–205, Dec. 28, 1973, 87 Stat. 884, as amended, which is classified generally to chapter 35 (§1531 et seq.) of Title 16, Conservation. For complete classification of this Act to the Code, see Short Title note set out under section 1531 of Title 16 and Tables.

Section 321 of title 21, referred to in subsec. (u), was subsequently amended, and subsecs. (w) and (x) of section 321 no longer define the terms ''new animal drug'' and ''animal feed'', respectively. However, such terms are defined elsewhere in that section.

Section 27(b) of Federal Pesticide Act of 1978, referred to in subsec. (ee), is section 27(b) of Pub. L. 95–396, Sept. 30, 1978, 92 Stat. 841, which was formerly set out as a note under section 136w–4 of this title.

PRIOR PROVISIONS

A prior section 2 of act June 25, 1947, was classified to section 135 of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

AMENDMENTS

1996—Subsec. (a)(1). Pub. L. 104–170, §105(a)(1)(A), substituted ''defoliant, desiccant, or nitrogen stabilizer'' for ''defoliant, or desiccant''.

Subsec. (a)(5). Pub. L. 104–170, §105(a)(1)(B)–(D), added par. (5).

Subsec. (u). Pub. L. 104–170, §§105(a)(2), 221(1), struck out ''and'' before ''(2)'', inserted ''and (3) any nitrogen stabilizer,'' after ''desiccant,'', and inserted at end ''The term 'pesticide' does not include liquid chemical sterilant products (including any sterilant or subordinate disinfectant claims on such products) for use on a critical or semi-critical device, as defined in section 321 of title 21. For purposes of the preceding sentence, the term 'critical device' includes any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body and the term 'semi-critical device' includes any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.''

Subsec. (bb). Pub. L. 104–170, §304, which directed amendment of section 2(bb) by inserting ''(1)'' after ''means'' and adding cl. (2), without specifying the Act being amended, was executed to this subsection, which is section 2(bb) of the Federal Insecticide, Fungicide, and Rodenticide Act, to reflect the probable intent of Congress.

Pub. L. 104–170, §230(a), inserted at end ''The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide.''

Subsec. (hh). Pub. L. 104–170, §105(a)(3), added subsec. (hh).

Subsecs. (jj), (kk). Pub. L. 104–170, §120, added subsecs. (jj) and (kk).

Subsec. (*ll*). Pub. L. 104–170, §210(a), added subsec. (*ll*).

Subsec. (mm). Pub. L. 104–170, §221(2), added subsec. (mm).

Subsecs. (nn), (*oo*). Pub. L. 104–170, §230(b), added subsecs. (nn) and (*oo*).

1991—Subsec. (e)(1). Pub. L. 102–237, §1006(a)(1), substituted ''section 136i'' for ''section 136b'' and ''uses dilutions'' for ''use dilutions'' and made technical amendment to reference to subsection (ee) of this section involving corresponding provision of original act.

Subsec. (e)(2). Pub. L. 102–237, §1006(b)(3)(A), substituted ''the applicator or the applicator's'' for ''him or his''.

Subsec. (e)(3). Pub. L. 102–237, §1006(b)(3)(B), substituted ''the applicator'' for ''he''.

Subsec. (q)(2)(A)(i). Pub. L. 102–237, §1006(a)(2), substituted ''size or form'' for ''size of form''.

1988—Subsec. (c). Pub. L. 100–532, §801(a)(1), substituted ''if—'' for ''if:''.

Subsec. (p)(2)(B). Pub. L. 100–532, §801(a)(2), substituted ''Health and Human Services'' for ''Health, Education, and Welfare''.

Subsec. (q)(2)(A). Pub. L. 100–532, §801(a)(3), substituted ''if—'' for ''if:''.

Subsec. (q)(2)(C)(iii). Pub. L. 100–532, §801(a)(4), substituted '', except that'' for '': *Provided*, That''.

Subsec. (u). Pub. L. 100–532, §801(a)(5), substituted '', except that'' for '': *Provided*, That'', struck out ''(1)(a)'' after ''include any article'' and ''or (b)'' after ''section 321(w) of title 21,'', and substituted ''Health and Human Services'' for ''Health, Education, and Welfare'', ''or that is'' for ''or (2) that is'', and ''a new animal drug'' for ''an article covered by clause (1) of this proviso''.

Subsec. (ee). Pub. L. 100–532, §§601(a)(1), 801(a)(6), substituted '', except that'' for '': *Provided*, That'', inserted ''unless the labeling specifically prohibits deviation from the specified dosage, concentration, or frequency'' and ''unless the labeling specifically states that the product may be applied only by the methods specified on the labeling'', substituted ''labeling, (4) mixing'' for ''labeling, or (4) mixing'', '', (5)'' for '': *Provided further*, That the term also shall not include'', ''or (6) any use'' for ''or any use'', and ''. After'' for '': *And provided further*, That after''.

Subsec. (ff). Pub. L. 100–532, §101, added subsec. (ff).

Subsec. (gg). Pub. L. 100–532, §601(a)(2), added subsec. (gg).

1978—Subsec. (e)(1). Pub. L. 95–396, §1(1), inserted provision deeming an applicator not a seller or distributor of pesticides when providing a service of controlling pests.

Subsec. (e)(3). Pub. L. 95–396, §1(2), substituted ''an applicator'' for ''a certified applicator''.

Subsec. (q)(1)(H). Pub. L. 95–396, §1(3), added subpar. (H).

Subsec. (w). Pub. L. 95–396, §1(4), (5), amended definition of ''producer'' and ''produce'' to include reference to active ingredient used in producing a pesticide and inserted provision that an individual did not become a producer when there was dilution of a pesticide for personal use according to directions on registered labels.

Subsec. (dd). Pub. L. 95–396, §1(6), inserted ''or active ingredient used in producing a pesticide''.

Subsec. (ee). Pub. L. 95–396, §1(7), added subsec. (ee).

1975—Subsec. (u). Pub. L. 94–140 inserted proviso which excluded from term ''pesticide'' any article designated as ''new animal drug'' and any article denominated as animal feed.

1973—Subsec. (*l*). Pub. L. 93–205 substituted ''or threatened by the Secretary pursuant to the Endangered Species Act of 1973'' for ''by the Secretary of the Interior under Public Law 91–135''.

EFFECTIVE DATE OF 1988 AMENDMENT

Section 901 of Pub. L. 100–532 provided that: ''Except as otherwise provided in this Act, the amendments made by this Act [see Short Title of 1988 Amendment note below] shall take effect on the expiration of 60 days after the date of enactment of this Act [Oct. 25, 1988].''

EFFECTIVE DATE OF 1973 AMENDMENT

Amendment by Pub. L. 93–205 effective Dec. 28, 1973, see section 16 of Pub. L. 93–205, set out as an Effective Date note under section 1531 of Title 16, Conservation.

EFFECTIVE DATE

Section 4 of Pub. L. 92–516, as amended by Pub. L. 94–140, § 4, Nov. 28, 1975, 89 Stat. 752; Pub. L. 95–396, § 28, Sept. 30, 1978, 92 Stat. 842, provided that:

''(a) Except as otherwise provided in the Federal Insecticide, Fungicide, and Rodenticide Act [this subchapter], as amended by this Act and as otherwise provided by this section, the amendments made by this Act [see Short Title note set out below] shall take effect at the close of the date of the enactment of this Act [Oct. 21, 1972], provided if regulations are necessary for the implementation of any provision that becomes effective on the date of enactment, such regulations shall be promulgated and shall become effective within 90 days from the date of enactment of this Act.

''(b) The provisions of the Federal Insecticide, Fungicide, and Rodenticide Act [this subchapter] and the regulations thereunder as such existed prior to the enactment of this Act shall remain in effect until superseded by the amendments made by this Act and regulations thereunder.

''(c)(1) Two years after the enactment of this Act the Administrator shall have promulgated regulations providing for the registration and classification of pesticides under the provisions of this Act and thereafter shall register all new applications under such provisions.

''(2) Any requirements that a pesticide be registered for use only by a certified applicator shall not be effective until five years from the date of enactment of this Act.

''(3) A period of five years from date of enactment shall be provided for certification of applicators.

''(A) One year after the enactment of this Act the Administrator shall have prescribed the standards for the certification of applicators.

''(B) Each State desiring to certify applicators shall submit a State plan to the Administrator for the purpose provided by section 4(b).

''(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 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

Section 1 of Pub. L. 104–170 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

Section 1(a) of Pub. L. 100–532 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

Section 29 of Pub. L. 95–396 provided that: ''This Act [enacting sections 136w–1 to 136w–4 of this title, amending this section and sections 136a to 136f, 136h, 136j, 136*l*, 136*o*, 136q, 136r, 136u to 136w, 136x, and 136y of this title, enacting provisions set out as notes under sections 136a, 136*o*, 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

Section 1 of Pub. L. 92–516 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'.''

Section 1(a) of act June 25, 1947, as added by Pub. L. 92–516, § 2, 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

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(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 pub-

lic 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 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 registration 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 pe-

riod 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 additional 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 136*o*(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.—(i) 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

Section 2(b) of Pub. L. 95–396 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

Section 1498 of Pub. L. 101–624 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.

94–140, §10, Nov. 28, 1975, 89 Stat. 754; Pub. L. 95–396, §10, Sept. 30, 1978, 92 Stat. 828; Pub. L. 100–532, title VIII, §801(d), (q)(1)(D), Oct. 25, 1988, 102 Stat. 2681, 2683; Pub. L. 102–237, title X, §1006(b)(1), Dec. 13, 1991, 105 Stat. 1895.)

PRIOR PROVISIONS

A prior section 5 of act June 25, 1947, was classified to section 135c of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

AMENDMENTS

1991—Subsecs. (b), (e), (f). Pub. L. 102–237 substituted ''the Administrator'' for ''he'' before ''may'' in subsec. (b), before ''finds'' in subsec. (e), and before ''may'' in subsec. (f).

1988—Subsec. (f). Pub. L. 100–532, §801(q)(1)(D), substituted ''136i'' for ''136b''.

Subsec. (g). Pub. L. 100–532, §801(d), substituted ''require. Such pesticide'' for ''require: *Provided*, That such pesticide''.

1978—Subsec. (a). Pub. L. 95–396, §10(1), provided for review of application, issuance or nonissuance of experimental use permit within prescribed period including reasons for denial, correction of application, and waiver of conditions and substituted provision for filing an application for experimental use permit at any time for prior provision for filing at the time of or before or after an application for registration is filed.

Subsec. (f). Pub. L. 95–396, §10(2), substituted in first sentence ''shall'' for ''may'' where first appearing.

1975—Subsec. (g). Pub. L. 94–140 added subsec. (g).

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

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

§ 136d. Administrative review; suspension

(a) Existing stocks and information

(1) Existing stocks

The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or canceled under this section, or section 136a or 136a–1 of this title, to such extent, under such conditions, and for such uses as the Administrator determines that such sale or use is not inconsistent with the purposes of this subchapter.

(2) Information

If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator.

(b) Cancellation and change in classification

If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this subchapter or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of the Administrator's intent either—

(1) to cancel its registration or to change its classification together with the reasons (including the factual basis) for the Administrator's action, or

(2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

Such notice shall be sent to the registrant and made public. In determining whether to issue any such notice, the Administrator shall include among those factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy. At least 60 days prior to sending such notice to the registrant or making public such notice, whichever occurs first, the Administrator shall provide the Secretary of Agriculture with a copy of such notice and an analysis of such impact on the agricultural economy. If the Secretary comments in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator shall publish in the Federal Register (with the notice) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator may notify the registrant and make public the notice at any time after such 30-day period notwithstanding the foregoing 60-day time requirement. The time requirements imposed by the preceding 3 sentences may be waived or modified to the extent agreed upon by the Administrator and the Secretary. Notwithstanding any other provision of this subsection and section 136w(d) of this title, in the event that the Administrator determines that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, then upon such a finding the Administrator may waive the requirement of notice to and consultation with the Secretary of Agriculture pursuant to this subsection and of submission to the Scientific Advisory Panel pursuant to section 136w(d) of this title and proceed in accordance with subsection (c) of this section. When a public health use is affected, the Secretary of Health and Human Services should provide available benefits and use information, or an analysis thereof, in accordance with the procedures followed and subject to the same conditions as the Secretary of Agriculture in the case of agricultural pesticides. The proposed action shall become final and effective at the end of 30 days from receipt by the registrant, or publication, of a notice issued under paragraph (1), whichever occurs later, unless within that time either (i) the registrant makes the necessary corrections, if possible, or (ii) a request for a hearing is made by a person adversely affected by the notice. In the event a hearing is held pursuant to such a request or to the Administrator's determination under paragraph (2), a decision pertaining to registration or classification issued after completion of such hearing shall be final. In taking any final action under this subsection, the Administrator shall consider restricting a pesticide's use or uses as an alternative to cancellation and shall fully explain the reasons for these restrictions, and shall in-

clude among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such impact.

(c) Suspension

(1) Order

If the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation or change in classification proceedings, the Administrator may, by order, suspend the registration of the pesticide immediately. Except as provided in paragraph (3), no order of suspension may be issued under this subsection unless the Administrator has issued, or at the same time issues, a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b) of this section. Except as provided in paragraph (3), the Administrator shall notify the registrant prior to issuing any suspension order. Such notice shall include findings pertaining to the question of ''imminent hazard''. The registrant shall then have an opportunity, in accordance with the provisions of paragraph (2), for an expedited hearing before the Administrator on the question of whether an imminent hazard exists.

(2) Expedite hearing

If no request for a hearing is submitted to the Administrator within five days of the registrant's receipt of the notification provided for by paragraph (1), the suspension order may be issued and shall take effect and shall not be reviewable by a court. If a hearing is requested, it shall commence within five days of the receipt of the request for such hearing unless the registrant and the Administrator agree that it shall commence at a later time. The hearing shall be held in accordance with the provisions of subchapter II of chapter 5 of title 5, except that the presiding officer need not be a certified administrative law judge. The presiding officer shall have ten days from the conclusion of the presentation of evidence to submit recommended findings and conclusions to the Administrator, who shall then have seven days to render a final order on the issue of suspension.

(3) Emergency order

Whenever the Administrator determines that an emergency exists that does not permit the Administrator to hold a hearing before suspending, the Administrator may issue a suspension order in advance of notification to the registrant. The Administrator may issue an emergency order under this paragraph before issuing a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b) of this section and the Administrator shall proceed to issue the notice under subsection (b) of this section within 90 days of issuing an emergency order. If the Administrator does not issue a notice under subsection (b) of this section within 90 days of issuing an emergency order, the emergency order shall expire. In the case of an emergency order, paragraph (2) shall apply except that (A) the order of suspension shall be in effect pending the expeditious completion of the remedies provided by that paragraph and the issuance of a final order on suspension, and (B) no party other than the registrant and the Administrator shall participate except that any person adversely affected may file briefs within the time allotted by the Agency's rules. Any person so filing briefs shall be considered a party to such proceeding for the purposes of section 136n(b) of this title.

(4) Judicial review

A final order on the question of suspension following a hearing shall be reviewable in accordance with section 136n of this title, notwithstanding the fact that any related cancellation proceedings have not been completed. Any order of suspension entered prior to a hearing before the Administrator shall be subject to immediate review in an action by the registrant or other interested person with the concurrence of the registrant in an appropriate district court, solely to determine whether the order of suspension was arbitrary, capricious or an abuse of discretion, or whether the order was issued in accordance with the procedures established by law. The effect of any order of the court will be only to stay the effectiveness of the suspension order, pending the Administrator's final decision with respect to cancellation or change in classification. This action may be maintained simultaneously with any administrative review proceedings under this section. The commencement of proceedings under this paragraph shall not operate as a stay of order, unless ordered by the court.

(d) Public hearings and scientific review

In the event a hearing is requested pursuant to subsection (b) of this section or determined upon by the Administrator pursuant to subsection (b) of this section, such hearing shall be held after due notice for the purpose of receiving evidence relevant and material to the issues raised by the objections filed by the applicant or other interested parties, or to the issues stated by the Administrator, if the hearing is called by the Administrator rather than by the filing of objections. Upon a showing of relevance and reasonable scope of evidence sought by any party to a public hearing, the Hearing Examiner shall issue a subpena to compel testimony or production of documents from any person. The Hearing Examiner shall be guided by the principles of 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, the subpena may be enforced by an appropriate United States district court in accordance with the principles stated herein. Upon the request of any party to a public hearing and when in the Hearing Examiner's judgment it is necessary or desirable, the Hearing Examiner shall at any time before the hearing record is closed refer to a Committee of the National Academy of Sciences the relevant ques-

tions of scientific fact involved in the public hearing. No member of any committee of the National Academy of Sciences established to carry out the functions of this section shall have a financial or other conflict of interest with respect to any matter considered by such committee. The Committee of the National Academy of Sciences shall report in writing to the Hearing Examiner within 60 days after such referral on these questions of scientific fact. The report shall be made public and shall be considered as part of the hearing record. The Administrator shall enter into appropriate arrangements with the National Academy of Sciences to assure an objective and competent scientific review of the questions presented to Committees of the Academy and to provide such other scientific advisory services as may be required by the Administrator for carrying out the purposes of this subchapter. As soon as practicable after completion of the hearing (including the report of the Academy) but not later than 90 days thereafter, the Administrator shall evaluate the data and reports before the Administrator and issue an order either revoking the Administrator's notice of intention issued pursuant to this section, or shall issue an order either canceling the registration, changing the classification, denying the registration, or requiring modification of the labeling or packaging of the article. Such order shall be based only on substantial evidence of record of such hearing and shall set forth detailed findings of fact upon which the order is based.

(e) Conditional registration

(1) The Administrator shall issue a notice of intent to cancel a registration issued under section 136a(c)(7) of this title if (A) the Administrator, at any time during the period provided for satisfaction of any condition imposed, determines that the registrant has failed to initiate and pursue appropriate action toward fulfilling any condition imposed, or (B) at the end of the period provided for satisfaction of any condition imposed, that condition has not been met. The Administrator may permit the continued sale and use of existing stocks of a pesticide whose conditional registration has been canceled under this subsection to such extent, under such conditions, and for such uses as the Administrator may specify if the Administrator determines that such sale or use is not inconsistent with the purposes of this subchapter and will not have unreasonable adverse effects on the environment.

(2) A cancellation proposed under this subsection shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to cancel unless during that time a request for hearing is made by a person adversely affected by the notice. If a hearing is requested, a hearing shall be conducted under subsection (d) of this section. The only matters for resolution at that hearing shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or whether the condition or conditions have been satisfied within the time provided, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this subchapter. A decision after completion of such hearing shall be final. Notwithstanding any other provision of this section, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing.

(f) General provisions

(1) Voluntary cancellation

(A) A registrant may, at any time, request that a pesticide registration of the registrant be canceled or amended to terminate one or more pesticide uses.

(B) Before acting on a request under subparagraph (A), the Administrator shall publish in the Federal Register a notice of the receipt of the request and provide for a 30-day period in which the public may comment.

(C) In the case of a pesticide that is registered for a minor agricultural use, if the Administrator determines that the cancellation or termination of uses would adversely affect the availability of the pesticide for use, the Administrator—

(i) shall publish in the Federal Register a notice of the receipt of the request and make reasonable efforts to inform persons who so use the pesticide of the request; and

(ii) may not approve or reject the request until the termination of the 180-day period beginning on the date of publication of the notice in the Federal Register, except that the Administrator may waive the 180-day period upon the request of the registrant or if the Administrator determines that the continued use of the pesticide would pose an unreasonable adverse effect on the environment.

(D) Subject to paragraph (3)(B), after complying with this paragraph, the Administrator may approve or deny the request.

(2) Publication of notice

A notice of denial of registration, intent to cancel, suspension, or intent to suspend issued under this subchapter or a notice issued under subsection (c)(4) or (d)(5)(A) of section 136a–1 of this title shall be published in the Federal Register and shall be sent by certified mail, return receipt requested, to the registrant's or applicant's address of record on file with the Administrator. If the mailed notice is returned to the Administrator as undeliverable at that address, if delivery is refused, or if the Administrator otherwise is unable to accomplish delivery of the notice to the registrant or applicant after making reasonable efforts to do so, the notice shall be deemed to have been received by the registrant or applicant on the date the notice was published in the Federal Register.

(3) Transfer of registration of pesticides registered for minor agricultural uses

In the case of a pesticide that is registered for a minor agricultural use:

(A) During the 180-day period referred to in paragraph (1)(C)(ii), the registrant of the pesticide may notify the Administrator of an agreement between the registrant and a

person or persons (including persons who so use the pesticide) to transfer the registration of the pesticide, in lieu of canceling or amending the registration to terminate the use.

(B) An application for transfer of registration, in conformance with any regulations the Administrator may adopt with respect to the transfer of the pesticide registrations, must be submitted to the Administrator within 30 days of the date of notification provided pursuant to subparagraph (A). If such an application is submitted, the Administrator shall approve the transfer and shall not approve the request for voluntary cancellation or amendment to terminate use unless the Administrator determines that the continued use of the pesticide would cause an unreasonable adverse effect on the environment.

(C) If the Administrator approves the transfer and the registrant transfers the registration of the pesticide, the Administrator shall not cancel or amend the registration to delete the use or rescind the transfer of the registration, during the 180-day period beginning on the date of the approval of the transfer unless the Administrator determines that the continued use of the pesticide would cause an unreasonable adverse effect on the environment.

(D) The new registrant of the pesticide shall assume the outstanding data and other requirements for the pesticide that are pending at the time of the transfer.

(4) Utilization of data for voluntarily canceled pesticide

When an application is filed with the Administrator for the registration of a pesticide for a minor use and another registrant subsequently voluntarily cancels its registration for an identical or substantially similar pesticide for an identical or substantially similar use, the Administrator shall process, review, and evaluate the pending application as if the voluntary cancellation had not yet taken place except that the Administrator shall not take such action if the Administrator determines that such minor use may cause an unreasonable adverse effect on the environment. In order to rely on this subsection, the applicant must certify that it agrees to satisfy any outstanding data requirements necessary to support the reregistration of the pesticide in accordance with the data submission schedule established by the Administrator.

(g) Notice for stored pesticides with canceled or suspended registrations

(1) In general

Any producer or exporter of pesticides, registrant of a pesticide, applicant for registration of a pesticide, applicant for or holder of an experimental use permit, commercial applicator, or any person who distributes or sells any pesticide, who possesses any pesticide which has had its registration canceled or suspended under this section shall notify the Administrator and appropriate State and local officials of—

(A) such possession,

(B) the quantity of such pesticide such person possesses, and

(C) the place at which such pesticide is stored.

(2) Copies

The Administrator shall transmit a copy of each notice submitted under this subsection to the regional office of the Environmental Protection Agency which has jurisdiction over the place of pesticide storage identified in the notice.

(h) Judicial review

Final orders of the Administrator under this section shall be subject to judicial review pursuant to section 136n of this title.

(June 25, 1947, ch. 125, §6, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 984; amended Pub. L. 94–140, §1, Nov. 28, 1975, 89 Stat. 751; Pub. L. 95–251, §2(a)(2), Mar. 27, 1978, 92 Stat. 183; Pub. L. 95–396, §§11, 12, Sept. 30, 1978, 92 Stat. 828; Pub. L. 98–620, title IV, §402(4)(A), Nov. 8, 1984, 98 Stat. 3357; Pub. L. 100–532, title II, §201, title IV, §404, title VIII, §801(e), (q)(2)(B), Oct. 25, 1988, 102 Stat. 2668, 2673, 2681, 2683; Pub. L. 101–624, title XIV, §1494, Nov. 28, 1990, 104 Stat. 3628; Pub. L. 102–237, title X, §1006(a)(5), (b)(1), (2), (3)(C)–(E), Dec. 13, 1991, 105 Stat. 1895, 1896; Pub. L. 104–170, title I, §§102, 106(a), title II, §§210(g), (h), 233, Aug. 3, 1996, 110 Stat. 1489, 1491, 1500, 1509.)

CODIFICATION

''Subchapter II of chapter 5 of title 5'', referred to in subsec. (c)(2), was in the original ''subchapter II of Title 5'', and was editorially changed to reflect the probable intent of Congress.

PRIOR PROVISIONS

A prior section 6 of act June 25, 1947, was classified to section 135d of this title prior to amendment of act June 25, 1947, by Pub. L. 92–516.

AMENDMENTS

1996—Subsec. (a). Pub. L. 104–170, §106(a)(1), substituted ''Existing stocks and information'' for ''Cancellation after five years'' in heading.

Subsec. (a)(1). Pub. L. 104–170, §106(a)(2), amended heading and text generally. Prior to amendment, text read as follows: ''The Administrator shall cancel the registration of any pesticide at the end of the five-year period which begins on the date of its registration (or at the end of any five year period thereafter) unless the registrant, or other interested person with the concurrence of the registrant, before the end of such period, requests in accordance with regulations prescribed by the Administrator that the registration be continued in effect. The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is canceled under this subsection or subsection (b) of this section to such extent, under such conditions, and for such uses as the Administrator may specify if the Administrator determines that such sale or use is not inconsistent with the purposes of this subchapter and will not have unreasonable adverse effects on the environment. The Administrator shall publish in the Federal Register, at least 30 days prior to the expiration of such five-year period, notice that the registration will be canceled if the registrant or other interested person with the concurrence of the registrant does not request that the registration be continued in effect.''

Subsec. (b). Pub. L. 104–170, §233, inserted ''When a public health use is affected, the Secretary of Health

and Human Services should provide available benefits and use information, or an analysis thereof, in accordance with the procedures followed and subject to the same conditions as the Secretary of Agriculture in the case of agricultural pesticides.'' before ''The proposed action shall become final''.

Subsec. (c)(1). Pub. L. 104–170, § 102(a), amended second sentence generally. Prior to amendment, second sentence read as follows: ''No order of suspension may be issued unless the Administrator has issued or at the same time issues notice of the Administrator's intention to cancel the registration or change the classification of the pesticide.''

Subsec. (c)(3). Pub. L. 104–170, § 102(b), inserted after first sentence ''The Administrator may issue an emergency order under this paragraph before issuing a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b) of this section and the Administrator shall proceed to issue the notice under subsection (b) of this section within 90 days of issuing an emergency order. If the Administrator does not issue a notice under subsection (b) of this section within 90 days of issuing an emergency order, the emergency order shall expire.'' and substituted ''In the case of an emergency order'' for ''In that case''.

Subsec. (f)(1)(C)(ii). Pub. L. 104–170, § 210(g)(1), substituted ''180-day'' for ''90-day'' in two places.

Subsec. (f)(3)(A). Pub. L. 104–170, § 210(g)(2), substituted ''180-day'' for ''90-day''.

Subsec. (f)(4). Pub. L. 104–170, § 210(h), added par. (4).

1991—Subsec. (a)(1). Pub. L. 102–237, § 1006(b)(1), substituted ''the Administrator'' for ''he'' before ''may specify'' and before ''determines''.

Subsec. (a)(2). Pub. L. 102–237, § 1006(b)(3)(C), substituted ''the registrant'' for ''he'' before ''shall''.

Subsec. (b). Pub. L. 102–237, § 1006(b)(1), (2), substituted ''the Administrator's'' for ''his'' in introductory provisions and par. (1), and ''the Administrator'' for ''he'' before ''shall publish'' in last sentence.

Subsec. (c)(1). Pub. L. 102–237, § 1006(b)(1), (2), substituted ''the Administrator'' for ''he'' before ''may'' and ''the Administrator's'' for ''his'' before ''intention''.

Subsec. (c)(3). Pub. L. 102–237, § 1006(b)(1), (3)(D), substituted ''the Administrator'' for ''he'' before ''may'' and ''the Administrator'' for ''him'' after ''permit''.

Subsec. (d). Pub. L. 102–237, § 1006(b)(2), (3)(E), in penultimate sentence substituted ''the Administrator's'' for ''his'' and ''the Administrator'' for ''him'' before ''and issue''.

Subsec. (f)(3)(B). Pub. L. 102–237, § 1006(a)(5), substituted ''adverse effect'' for ''adverse affect''.

1990—Subsec. (f)(1). Pub. L. 101–624, § 1494(1), amended par. (1) generally. Prior to amendment, par. (1) read as follows: ''A registrant at any time may request that any of its pesticide registrations be canceled or be amended to delete one or more uses. Before acting on such request, the Administrator shall publish in the Federal Register a notice of the receipt of the request. Thereafter, the Administrator may approve such a request.''

Subsec. (f)(3). Pub. L. 101–624, § 1494(2), added par. (3).

1988—Subsec. (a)(1). Pub. L. 100–532, § 801(e)(1), substituted ''effect. The Administrator'' for ''effect: *Provided*, That the Administrator''.

Subsec. (c). Pub. L. 100–532, § 801(e)(2)–(4), in par. (1) directed that undesignated paragraph beginning ''Except as provided'' be run into sentence ending ''of the pesticide.'' and substituted ''before the Administrator'' for ''before the Agency'', in par. (2) substituted ''submitted to the Administrator'' for ''submitted to the Agency'' and ''and the Administrator'' for ''and the Agency'', and in par. (3) substituted ''(A)'' for ''(i)'', ''and the Administrator'' for ''and the Agency'', and ''(B)'' for ''(ii)''.

Subsec. (e). Pub. L. 100–532, § 801(e)(5), (6), in par. (1), substituted ''met. The Administrator'' for ''met: *Provided*, That the Administrator'', and in par. (2), substituted ''section. The only'' for ''section: *Provided*, That the only''.

Subsec. (f). Pub. L. 100–532, § 201, added subsec. (f). Former subsec. (f) redesignated (h).

Subsec. (f)(2). Pub. L. 100–532, § 801(q)(2)(B), made a technical amendment to the reference to section 136a–1 of this title to reflect the renumbering of the corresponding section of the original act.

Subsec. (g). Pub. L. 100–532, § 404, added subsec. (g).

Subsec. (h). Pub. L. 100–532, § 201, redesignated former subsec. (f) as (h).

1984—Subsec. (c)(4). Pub. L. 98–620 struck out provisions requiring petitions to review orders on the issue of suspension to be advanced on the docket of the court of appeals.

1978—Subsec. (b). Pub. L. 95–396, § 11, required the Administrator, in taking any final action under subsec. (b), to consider restricting a pesticide's use or uses as an alternative to cancellation and to fully explain the reasons for the restrictions.

Subsec. (c)(2). Pub. L. 95–251 substituted ''administrative law judge'' for ''hearing examiner''.

Subsecs. (e), (f). Pub. L. 95–396, § 12, added subsec. (e) and redesignated former subsec. (e) as (f).

1975—Subsec. (b). Pub. L. 94–140 established criteria which Administrator must use in determining the issuance of a suspension of registration notice and the time periods relating to such notice, set forth required procedures to be followed by Administrator prior to publication of such notice, required procedures when the Secretary elects to comment or fails to comment on suspension notice, waiver or modification of time periods in specified required procedures, required procedures for waiver of notice and consent by Secretary for suspension of registration, and established criteria for Secretary taking any final action.

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 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

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

§ 136e. Registration of establishments

(a) Requirement

No person shall produce any pesticide subject to this subchapter or active ingredient used in producing a pesticide subject to this subchapter in any State unless the establishment in which it is produced is registered with the Administrator. The application for registration of any establishment shall include the name and address of the establishment and of the producer who operates such establishment.

(b) Registration

Whenever the Administrator receives an application under subsection (a) of this section, the Administrator shall register the establishment and assign it an establishment number.

(c) Information required

(1) Any producer operating an establishment registered under this section shall inform the Administrator within 30 days after it is registered of the types and amounts of pesticides and, if applicable, active ingredients used in producing pesticides—

(A) which the producer is currently producing;

(II) owned any quantity of the pesticide for purposes of—

(aa) distributing or selling it; or

(bb) further processing it for distribution or sale directly to an end user;

suffered a loss by reason of the suspension or cancellation of the pesticide; and

(iv) the Administrator determines on the basis of a claim of loss submitted to the Administrator by the person, that the seller—

(I) did not provide the notice specified in subparagraph (A) to such person; and

(II) is and will continue to be unable to provide reimbursement to such person, as provided under subparagraph (A), for the loss referred to in clause (iii), as a result of the insolvency or bankruptcy of the seller and the seller's resulting inability to provide such reimbursement;

the person shall be entitled to an indemnity payment under this subsection for such quantity of the pesticide.

(C) If an indemnity payment is made by the United States under this paragraph, the United States shall be subrogated to any right that would otherwise be held under this paragraph by a seller who is unable to make a reimbursement in accordance with this paragraph with regard to reimbursements that otherwise would have been made by the seller.

(3) Source

Any payment required to be made under paragraph (1) or (2) shall be made from the appropriation provided under section 1304 of title 31.

(4) Administrative settlement

An administrative settlement of a claim for such indemnity may be made in accordance with the third paragraph of section 2414 of title 28 and shall be regarded as if it were made under that section for purposes of section 1304 of title 31.

(c) Amount of payment

(1) In general

The amount of an indemnity payment under subsection (a) or (b) to any person shall be determined on the basis of the cost of the pesticide owned by the person (other than the cost of transportation, if any) immediately before the issuance of the notice to the registrant referred to in subsection (a)(1)(A), (b)(1)(A), or (b)(2)(B)(i), except that in no event shall an indemnity payment to any person exceed the fair market value of the pesticide owned by the person immediately before the issuance of the notice.

(2) Special rule

Notwithstanding any other provision of this subchapter, the Administrator may provide a reasonable time for use or other disposal of the pesticide. In determining the quantity of any pesticide for which indemnity shall be paid under this section, proper adjustment shall be made for any pesticide used or otherwise disposed of by the owner.

(June 25, 1947, ch. 125, §15, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 993; amended Pub. L. 100–532, title V, §501(a), Oct. 25, 1988, 102 Stat. 2674.)

AMENDMENTS

1988—Pub. L. 100–532 amended section generally, in subsec. (a), substituting provisions relating to general indemnification for provisions relating to requirements for payment, adding subsec. (b), and redesignating provisions of former subsec. (b), with further amendment, as subsec. (c).

EFFECTIVE DATE OF 1988 AMENDMENT

Pub. L. 100–532, title V, §501(a), Oct. 25, 1988, 102 Stat. 2674, provided that amendment made by Pub. L. 100–532 is effective 180 days after Oct. 25, 1988.

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.

INTERIM PAYMENTS

Pub. L. 100–532, title V, §501(b), Oct. 25, 1988, 102 Stat. 2676, provided that:

''(1) SOURCE.—Any obligation of the Administrator to pay an indemnity arising under section 15 [this section], as it existed prior to the effective date of the amendment made by this section [see Effective Date of 1988 Amendment note above], shall be made from the appropriation provided under section 1304 of title 31, United States Code.

''(2) ADMINISTRATIVE SETTLEMENT.—An administrative settlement of a claim for such indemnity may be made in accordance with the third paragraph of section 2414 of title 28, United States Code, and shall be regarded as if it were made under that section for purposes of section 1304 of title 31, United States Code.''

§ 136n. Administrative procedure; judicial review

(a) District court review

Except as otherwise provided in this subchapter, the refusal of the Administrator to cancel or suspend a registration or to change a classification not following a hearing and other final actions of the Administrator not committed to the discretion of the Administrator by law are judicially reviewable by the district courts of the United States.

(b) Review by court of appeals

In the case of actual controversy as to the validity of any order issued by the Administrator following a public hearing, any person who will be adversely affected by such order and who had been a party to the proceedings may obtain judicial review by filing in the United States court of appeals for the circuit wherein such person resides or has a place of business, within 60 days after the entry of such order, a petition praying that the order be set aside in whole or in part. A copy of the petition 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 Administrator's 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 court shall consider all evidence of record. The order of the Administrator shall be sustained if it is supported by substantial evidence when considered on the record as a whole. The judgment of the court af-

firming 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.

(c) Jurisdiction of district courts

The district courts of the United States are vested with jurisdiction specifically to enforce, and to prevent and restrain violations of, this subchapter.

(d) Notice of judgments

The Administrator shall, by publication in such manner as the Administrator may prescribe, give notice of all judgments entered in actions instituted under the authority of this subchapter.

(June 25, 1947, ch. 125, §16, as added Pub. L. 92–516, §2, Oct. 21, 1972, 86 Stat. 994; amended Pub. L. 98–620, title IV, §402(4)(C), Nov. 8, 1984, 98 Stat. 3357; Pub. L. 100–532, title VIII, §801(i), Oct. 25, 1988, 102 Stat. 2682; Pub. L. 102–237, title X, §1006(b)(1), (2), (3)(P), Dec. 13, 1991, 105 Stat. 1895, 1896.)

AMENDMENTS

1991—Subsec. (b). Pub. L. 102–237, §1006(b)(1), (2), (3)(P), substituted ''the Administrator'' for ''he'' before ''based'', ''the Administrator's'' for ''his'', and ''the Administrator'' for ''him'' after ''designated by''.

Subsec. (d). Pub. L. 102–237, §1006(b)(1), substituted ''the Administrator'' for ''he'' before ''may''.

1988—Subsec. (a). Pub. L. 100–532 amended subsec. (a) generally. Prior to amendment, subsec. (a) read as follows: ''Except as is otherwise provided in this subchapter, Agency refusals to cancel or suspend registrations or change classifications not following a hearing and other final Agency actions not committed to Agency discretion by law are judicially reviewable in the district courts.''

1984—Subsec. (b). Pub. L. 98–620 struck out provisions requiring the court to advance on the docket and expedite the disposition of all cases filed pursuant to this section.

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 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

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

§ 136*o*. Imports and exports

(a) Pesticides and devices intended for export

Notwithstanding any other provision of this subchapter, no pesticide or device or active ingredient used in producing a pesticide intended solely for export to any foreign country shall be deemed in violation of this subchapter—

(1) when prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of such pesticides and devices and active ingredients used in producing pesticides shall be subject to sections 136(p), 136(q)(1)(A), (C), (D), (E), (G), and (H), 136(q)(2)(A), (B), (C)(i) and (iii), and (D), 136e, and 136f of this title; and

(2) in the case of any pesticide other than a pesticide registered under section 136a or sold under section 136d(a)(1) of this title, if, prior to export, the foreign purchaser has signed a statement acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under this subchapter.

A copy of that statement shall be transmitted to an appropriate official of the government of the importing country.

(b) Cancellation notices furnished to foreign governments

Whenever a registration, or a cancellation or suspension of the registration of a pesticide becomes effective, or ceases to be effective, the Administrator shall transmit through the State Department notification thereof to the governments of other countries and to appropriate international agencies. Such notification shall, upon request, include all information related to the cancellation or suspension of the registration of the pesticide and information concerning other pesticides that are registered under section 136a of this title and that could be used in lieu of such pesticide.

(c) Importation of pesticides and devices

(1) In general

The Secretary of the Treasury shall notify the Administrator of the arrival of pesticides and devices and shall deliver to the Administrator, upon the Administrator's request, samples of pesticides or devices which are being imported into the United States, giving notice to the owner or consignee, who may appear before the Administrator and have the right to introduce testimony. If it appears from the examination of a sample that it is adulterated, or misbranded or otherwise violates the provisions set forth in this subchapter, or is otherwise injurious to health or the environment, the pesticide or device may be refused admission, and the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any pesticide or device refused delivery which shall not be exported by the consignee within 90 days from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe. The Secretary of the Treasury may deliver to the consignee such pesticide or device pending examination and decision in the matter on execution of bond for the amount of the full invoice value of such pesticide or device, together with the duty thereon, and on refusal to return such pesticide or device for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of said bond. All charges for storage, cartage, and labor on pesticides or devices which are refused admission

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 modification, 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 exemp-

tion 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 substance 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

[1] See References in Text note below.

(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, 2012, 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 peti-

tion 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

[3] So in original. Probably should be ''subsection''.

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.)

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

2007—Subsec. (m)(3). Pub. L. 110–94 added par. (3).

1998—Subsec. (j)(4). Pub. L. 105–324 added par. (4).

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 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

Section 301 of Pub. L. 104–170 provided that:

''(a) IN GENERAL.—The Secretary of Agriculture, in consultation with the Administrator of the Environmental 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