

TABLE 1—EPA-APPROVED NORTH CAROLINA REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
<b>Subchapter 2D Air Pollution Control Requirements</b>				
*	*	*	*	*
<b>Section .0500 Emission Control Standards</b>				
*	*	*	*	*
Sect .0530 .....	Prevention of Significant Deterioration.	5/1/2008	8/10/2011 [Insert citation of publication].	15 NCAC .0530 incorporates by reference the regulations found at 40 CFR 51.166, with changes, as of June 13, 2007. This EPA action is approving the incorporation by reference with the exception of the phrase “except ethanol production facilities producing ethanol by natural fermentation under the North American Industry Classification System (NAICS) codes 325193 or 312140,” (as amended at 40 CFR 51.166(b)(1)(i)(a), (b)(1)(iii)(f), and (i)(1)(ii)(f).
Sect .0531 .....	Sources in Nonattainment Areas.	5/1/2008	8/10/2011 [Insert citation of publication].	15 NCAC .0531 incorporates by reference the regulations found at 40 CFR 51.165, with changes, as of June 13, 2007. This EPA action is approving the incorporation by reference with the exception of the phrase “except ethanol production facilities producing ethanol by natural fermentation under the North American Industry Classification System (NAICS) codes 325193 or 312140,” (as amended at 40 CFR 51.165(a)(1)(iv)(C)(20) and (a)(4)(xx).
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 [FR Doc. 2011–20167 Filed 8–9–11; 8:45 am]  
 BILLING CODE 6560–50–P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA–HQ–OPP–2009–0629; FRL–8882–5]

**Import Tolerances; Order Denying ABC’s Petition to Revoke Import Tolerances for Various Pesticides**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Order.

**SUMMARY:** In this Order, EPA denies a petition requesting that EPA revoke all pesticide “import” tolerances for cadusafos, cyproconazole, diazinon, dithianon, diquat, dimethoate, fenamiphos, mevinphos, methomyl, naled, phorate, terbufos, and dichlorvos (DDVP) under section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA). The petition was filed on July 23, 2009, by the American Bird Conservancy (ABC).

**DATES:** This order is effective August 10, 2011. Objections and requests for hearings must be received on or before October 11, 2011, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0629. To access the electronic docket, go to <http://www.regulations.gov>, select “Advanced Search,” then “Docket Search.” Insert the docket ID number where indicated and select the “Submit” button. Follow the instructions on the [regulations.gov](http://www.regulations.gov) Web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in [regulations.gov](http://www.regulations.gov). Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly

available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

**FOR FURTHER INFORMATION CONTACT:** Richard Dumas, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; *telephone number:* (703) 308–8015; *e-mail address:* [dumas.richard@epa.gov](mailto:dumas.richard@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this action apply to me?*

In this document EPA denies a petition by the American Bird Conservancy (ABC) to revoke pesticide tolerances. This action may also be of interest to agricultural producers, food

manufacturers, or pesticide manufacturers. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (North American Industrial Classification System (NAICS) code 111), *e.g.*, agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), *e.g.*, cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), *e.g.*, agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), *e.g.*, agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.
- Farm Product Warehousing and Storage (NAICS code 493130), *e.g.*, grain elevators, private and public food warehousing and storage.

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The NAICS codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### *B. How can I access electronic copies of this document?*

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

#### *C. Can I file an objection or hearing request?*

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this order and may also request a hearing on those objections. You must file your objection or request a hearing on this order in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2009-0692 in

the subject line on the first page of your submission. All requests must be in writing, and must be received by the Hearing Clerk as required by 40 CFR part 178 on or before October 11, 2011.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2009-0692, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

## **II. Introduction**

### *A. What action is the Agency taking?*

On July 23, 2009, the American Bird Conservancy (ABC) filed a petition with EPA which requested that EPA revoke the "import" tolerances established under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, for the following pesticides: cadusafos (banana); cyproconazole (green coffee beans); diazinon (kiwi fruit); dichlorvos (tomato); dithianon (fruit, pome, group 11; hop, dried cones); diquat (banana; green coffee beans); dimethoate (blueberry); fenamiphos (banana; fruit, citrus; garlic; grape; pineapple); mevinphos (broccoli; cabbage; cauliflower; celery; cucumber; grape; lettuce; melon; pea; pepper; spinach; squash, summer; strawberry; tomato; watermelon); methomyl (hop, dried cone); naled (cucumber; lettuce; tomato; pumpkin; squash, winter; turnip, tops); phorate (green coffee beans); and terbufos (green coffee beans). (Ref. 1). These tolerances are described as "import" tolerances because the

pesticide uses associated with the tolerances are not registered for use in the United States under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, and thus, in practical effect, their only purpose is to govern the amount of pesticide residues in imported food.

ABC argues that the challenged tolerances allow use of pesticides hazardous to birds in Central and South American countries and thus EPA is obliged to revoke the challenged tolerances under Executive Order 13186, "Responsibilities of Federal Agencies to Protect Migratory Birds," Executive Order 13186, 66 FR. 3853 (Jan. 17, 2001), and the Endangered Species Act (ESA), 16 U.S.C. 1531 *et seq.* For the reasons stated below, EPA is denying the petition to revoke tolerances.

### *B. What is the Agency's authority for taking this action?*

Under section 408(d)(4) of the FFDCA, EPA is authorized to respond to a section 408(d) petition to revoke tolerances either by issuing a final rule revoking the tolerances, issuing a proposed rule, or issuing an order denying the petition. 21 U.S.C. 346a(d)(4).

## **III. Statutory and Regulatory Background**

### *A. Statutory Background*

1. *In general*. EPA establishes maximum residue limits, or "tolerances," for pesticide residues in food under section 408 of the FFDCA, 21 U.S.C. 346a. Without such a tolerance or an exemption from the requirement of a tolerance, a food containing a pesticide residue is "adulterated" under section 402 of the FFDCA and may not be legally moved in interstate commerce. 21 U.S.C. 331, 342. Monitoring and enforcement of pesticide tolerances are carried out by the U.S. Food and Drug Administration and the U.S. Department of Agriculture. Section 408 was substantially rewritten by the Food Quality Protection Act of 1996 (FQPA), which added provisions establishing a detailed safety standard for pesticides for protecting humans from pesticide residues in foods, including additional protections for infants and children.

EPA also regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* While the FFDCA authorizes the establishment of legal limits for pesticide residues in food, FIFRA requires the approval of pesticides prior to their sale and distribution in the

United States, 7 U.S.C. 136a(a), and establishes a registration regime for regulating the use of pesticides. FIFRA regulates pesticide use in conjunction with its registration scheme by requiring EPA review and approval of pesticide labels and specifying that use of a pesticide in a manner inconsistent with its label is a violation of Federal law. 7 U.S.C. 136j(a)(2)(G). As discussed below, the scope of FIFRA extends beyond the human safety concerns of FFDCA section 408 to encompass environmental factors as well.

2. *Safety standard for pesticide tolerances.* A tolerance permitting pesticide residues in food may only be promulgated by EPA if the tolerance is “safe.” 21 U.S.C. 346a(b)(2)(A)(i). Correspondingly, a tolerance must be revoked if it no longer meets this safety standard. (*Id.*). “Safe” is defined by the statute to mean 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.” 21 U.S.C. 346a(b)(2)(A)(ii). Thus, safety determinations under FFDCA section 408 turn on the safety to the “consumer” of the pesticide residue in food. 21 U.S.C. 346a(b)(2)(D)(vi). Although residues in food are to be aggregated with other pesticide exposures, the aggregation requirement is bounded by the limitation that these other exposures of the consumer to the pesticide residue be “non-occupational” in nature. *Id.* Additionally, FFDCA section 408 specifically requires that these aggregate safety standard determinations expressly focus on protection of “infants and children.” 21 U.S.C. 346a(b)(2)(C). In contrast, the focus of FIFRA is much broader. Among other things, a pesticide may not be registered under FIFRA if it poses “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 \* \* \*.” 7 U.S.C. 136(bb).

3. *Procedures for establishing, amending, or revoking tolerances.* Tolerances are established, amended, or revoked by rulemaking under the unique procedural framework set forth in the FFDCA. Generally, the rulemaking is initiated by the party seeking to establish, amend, or revoke a tolerance by means of filing a petition with EPA. See 21 U.S.C. 346a(d)(1). EPA publishes in the **Federal Register** a notice of the petition filing and requests public comment. 21 U.S.C. 346a(d)(3). After reviewing the petition, and any comments received on it, EPA may issue

a final rule establishing, amending, or revoking the tolerance, issue a proposed rule to do the same, or deny the petition. 21 U.S.C. 346a(d)(4). Once EPA takes final action on the petition by either establishing, amending, or revoking the tolerance or denying the petition, any affected party has 60 days to file objections with EPA and seek an evidentiary hearing on those objections. 21 U.S.C. 346a(g)(2). EPA’s final order on the objections is subject to judicial review. 21 U.S.C. 346a(h)(1).

4. *Tolerance reassessment and FIFRA reregistration.* The FQPA requires, among other things, that EPA reassess the safety of all pesticide tolerances existing at the time of its enactment. 21 U.S.C. 346a(q). In this reassessment, EPA is required to review existing pesticide tolerances under the new “reasonable certainty that no harm will result” standard set forth in FFDCA section 408(b)(2)(A)(i). 21 U.S.C. 346a(b)(2)(A)(i). This reassessment was substantially completed by the August 3, 2006 deadline. Tolerance reassessment is generally handled in conjunction with a similar program involving reregistration of pesticides under FIFRA. 7 U.S.C. 136a–1. Reassessment and reregistration decisions are generally combined in a document labeled a Reregistration Eligibility Decision (“RED”).

#### IV. The Petition to Revoke Tolerances

The ABC Petition seeks the revocation of “import” tolerances for 13 pesticides. According to ABC, “[t]hese pesticides are highly toxic to birds, and are used in crops that many species of U.S. migratory birds use as habitat during the winter months when they migrate to Latin America.” ABC contends that maintenance of the specified import tolerances “is tantamount to giving U.S. approval to foreign countries for the use of the pesticides.” ABC objects to such “approval” claiming that, on the crops covered by the tolerances, EPA “has already determined [that these pesticides pose] unacceptable risks for protected U.S. migratory birds.” In support of these claims, ABC cites to various statements in REDs, for information on some of the pesticides’ toxicity, and to information on use by migratory birds of agricultural lands as habitat.

Based on these allegations, ABC argues that EPA should revoke the tolerances under Executive Order 13186, addressing federal agency responsibilities for protecting migratory birds, or the Endangered Species Act (ESA). According to ABC, Executive Order 13186 obligates EPA “to avoid or rescind regulatory actions that adversely

affect migratory birds.” The ESA, ABC argues, requires EPA to identify pesticide uses that may cause adverse impacts on endangered or threatened species and to implement mitigation measures to address those impacts, and to consult with the Fish and Wildlife Service before allowing the identified import tolerances to continue. Because EPA cannot implement mitigation measures in foreign countries, ABC contends that EPA must revoke the tolerances to meet its obligations under the ESA. Alternatively, ABC argues that if EPA determines the tolerances are “necessary,” EPA must consult with the Fish and Wildlife Service before allowing the tolerances to continue.

#### V. Public Comment

EPA published notice of the petition for comment on September 1, 2009. 74 FR 45200, September 1, 2009. EPA received 25 comments: 18 from individuals or wildlife protection organizations expressing general support for the petition; detailed comments in support of the petition from the Student Animal Legal Defense Fund (SALDF) at Lewis and Clark Law School; detailed comments in opposition to the petition from two organizations representing pesticide manufacturers and others and from 4 pesticide manufacturers; and supplemental information on the petition from ABC. (All comments are included in the docket for this action, EPA–HQ–OPP–2009–0629.)

The SALDF premises its arguments in support of the petition on its assertion that EPA, based on the assessments of risk from these pesticides to birds by EPA’s Office of Pesticide Programs, “has cancelled the use of the pesticides at issue in the United States.” Given these cancellations, SALDF claims that EPA is not complying with its duty to promote conservation of endangered species under ESA section 7(a)(1) or its duty under ESA section 7(a)(2) to ensure that no action authorized by EPA is deleterious to the conservation of endangered species; with its obligations under Executive Order 13186 regarding the conservation of migratory birds; and with the bar in the Migratory Bird Treaty Act (MBTA) on the taking of migratory birds.

Crop Life America, an association of pesticide manufacturers, makes a series of arguments in opposition to the petition: Executive Order 13186 does not provide a private right of action and cannot be enforced against EPA; Executive Order 13186, the ESA, and the MBTA do not provide a basis for revoking pesticide tolerances because ecological issues cannot be considered

under FFDCA section 408; and the Petition fails to establish a nexus between the pesticide tolerances at issue and the claimed effects of the pesticides when used in other countries.

The Pesticide Policy Coalition, an organization representing a wide array of food- and pesticide-related industries, claims that the ABC petition has not met the regulatory requirements for a petition because ABC does not have a "substantial interest" in the tolerances challenged and because the petition is premised on a factor, ecological impacts, that is irrelevant to FFDCA section 408.

Syngenta Crop Protection, Inc., which is the manufacturer of cyproconazole and diquat, commented that both of these pesticides are registered in the United States and have been cleared by EPA after consideration of potential effects on birds. BASF Corporation, the manufacturer of dithianon, commented that, although dithianon is not registered in the United States, the lack of a FIFRA registration is not due to cancellation of such a registration by EPA but based on business decisions made by the company. BASF also noted that it was unaware of any EPA assessments that found dithianon to pose a hazard to birds. Bayer Crop Science provided comments regarding the pesticide fenamiphos. Bayer argued that "[e]cological risk assessments have strong spatial and temporal components associated with them" and that country-specific risk assessments would need to be conducted to determine the risks posed to birds. Bayer noted several of the risk mitigation requirements that appear on fenamiphos labels in Central and South American countries expressly for the purpose of reducing exposure to birds.

During the comment period, ABC filed additional information with EPA pertaining to use of agricultural fields in Latin America by migratory birds. According to ABC, these data showed 206 migratory bird species used agricultural fields as habitat and those 206 species included 12 ESA listed species and 54 bird species of conservation concern.

## VI. ABC's Allegations Concerning the Harmful Nature of the Challenged Pesticides

As noted above, ABC contends that EPA has already determined in Reregistration Eligibility Documents that the pesticides challenged in this petition present "unacceptable risks for protected U.S. migratory birds" when used on the crops covered by the challenged import tolerances. This claim, however, is not supported by

ABC's petition and records cited therein.

ABC admits that EPA has made no finding as to the risk to birds for four of the pesticides (cadusafos, cyproconazole, dithianon, and mevinphos). (Refs. 1, 2, and 3). As to another four of the pesticides (diquat, methomyl, naled, terbufos), ABC does not identify any EPA findings on the risks those pesticides pose to birds, and instead merely cites EPA's conclusions regarding human risk. (Refs. 1, 4, 5, 6, and 7). For the remaining five pesticides (diazinon, dichlorvos, dimethoate, fenamiphos, phorate), ABC cites to statements in the relevant REDs in which the pesticides are characterized as "highly toxic" to birds. (Ref. 1.) However, as to each of these pesticides, the RED concluded that the pesticide met the standard for reregistration for outdoor uses in the United States so long as various steps were taken to mitigate exposure to birds. (Refs. 8, 9, 10, 11, and 12). Moreover, in none of those REDs did EPA conclude that the pesticides posed unacceptable risks to birds with regard to the specific crops covered by the challenged import tolerances.

## VII. Ruling on Petition

ABC's petition requests that EPA revoke "import" tolerances for 13 pesticides due to the risks these pesticides pose to birds in countries outside of the United States. In filing its request, ABC does not cite to anything in FFDCA section 408, the statutory provision authorizing EPA to establish such tolerances, which compels revocation of the challenged tolerances. Rather, ABC argues that EPA must revoke the challenged FFDCA tolerances due to provisions in EO 13186 and the Endangered Species Act. For the reasons explained below, EPA has concluded that these authorities do not support ABC's contentions.

### A. Executive Order 13186

ABC's primary focus in its petition to revoke tolerances is EPA's obligations under Executive Order 13186. While ABC believes that EPA has an obligation under Executive Order 13186 "to avoid or rescind regulatory actions that adversely affect migratory birds", it provides no rationale for why it believes that the Executive Order compels that action. EPA concludes, however, that EO 13186 does not compel EPA to take action to revoke the challenged tolerances, and it does not even provide EPA authority to do so.

Executive Order 13186 was issued by President Clinton in 2001, pursuant to the authority provided in the

Constitution and the laws of the United States, and in furtherance of the purposes of the MBTA, the Bald and Golden Eagle Protection Acts, the Fish and Wildlife Coordination Act, the Endangered Species Act, NEPA, and "other pertinent statutes." Executive Order No. 13186, 66 FR. 3853 (Jan. 17, 2001). The purpose of the Executive Order is to "direct executive departments and agencies to take actions to further implement the Migratory Bird Treaty Act." *Id.* at section 1. The Executive Order fulfills this purpose by directing each federal agency that is "taking actions that have, or are likely to have, a measurable negative effect on migratory bird populations \* \* \* to develop and implement, within 2 years, a Memorandum of Understanding (MOU) with the Fish and Wildlife Service (Service) that shall promote the conservation of migratory bird populations." *Id.* at section 3(a). The Executive Order directs that certain procedural provisions be included in the MOU. *See id.* at section 3(c) and (d). The Executive Order also directs agencies to adopt certain substantive provisions in their MOUs, "to the extent permitted by law and subject to the availability of appropriations and within Administration budgetary limits, and in harmony with agency missions." *Id.* at section 3(e). Thereafter, Executive Order 13186 and the MOU "are intended to be implemented when new actions \* \* \* are initiated \* \* \*." *Id.* at section 3(c). Actions are defined as including rules, although the Executive Order allows each agency to further define what action means and what programs should be included in the MOU. *Id.* at section 2(h).

As an initial matter, ABC cannot compel the Agency to take any action under EO 13186 because there is no private right of action under this Executive Order. On its face, EO 13186 expressly precludes such a right. Section 5(b) of Executive Order 13186 states:

This order is intended only to improve the internal management of the executive branch and does not create any right or benefit, substantive or procedural, separately enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

In fact, one court has confirmed explicitly this provision precludes any party from obtaining judicial review of any claim alleging violations of EO 13186. *See Defenders of Wildlife v. Jackson*, No. 09-1814 (D.D.C. June 14, 2011). For this reason alone, any claim that EPA must revoke pesticide

tolerance regulations because EPA is violating EO 13186 fails.

Nonetheless, even once an MOU is finalized, that MOU would not provide a basis for EPA to revoke the challenged tolerances. The MOU could not compel EPA to take action that it does not otherwise have the statutory authority to take. As discussed in Unit VII.B., EPA does not have discretion under the FFDCA in assessing the safety of a pesticide tolerance to consider whether tolerances would be “likely to have a measurable negative effect” on U.S. migratory birds that winter in foreign countries.

### B. Endangered Species Act

ABC also argues that EPA has a statutory obligation under the Endangered Species Act, 16 U.S.C 1531 et seq., to “identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures to address the adverse impacts.” Presumably, ABC is referring here to EPA’s obligations under ESA section 7. According to ABC, because EPA cannot require “pesticide use mitigation measures” in foreign countries, EPA should fulfill its ESA obligations by revoking tolerances allowing commodities containing such pesticides to be distributed in the United States or, at a minimum consult with the FWS prior to allowing the tolerances to remain in effect. However, ABC’s claim that the ESA provides authority for revoking FFDCA tolerances is incorrect.

ESA obligations only apply where EPA has “existing discretionary authority;” the ESA does not “override express statutory mandates.” *Home Builders’ Ass’n v. EPA*, 551 U.S. 644, 487 (2007); 50 CFR 402.03. EPA establishes pesticide residue tolerances under section 408 of the FFDCA. Section 408 authorizes EPA to set “safe” exposure levels for pesticide residue levels in foods distributed in the United States. Thus, under FFDCA section 408, EPA does not regulate use of pesticides; rather, EPA regulates levels of pesticide residues in food distributed in interstate commerce. ABC’s petition would override these statutory mandates in FFDCA section 408, and, in effect, rewrite section 408 as a provision addressing environmental effects of pesticide use in foreign countries.

As noted, the FFDCA scheme is explicitly directed at the pesticide residue in food when the food is in interstate commerce. FFDCA section 408 establishes that if a food contains a pesticide residue for which there is no tolerance, or a pesticide residue at a level exceeding the applicable tolerance,

then the food is deemed “unsafe” as a matter of law. 21 U.S.C. 346a(a). Foods deemed “unsafe” on these grounds are considered “adulterated.” 21 U.S.C. 342(a)(2)(B). It is unlawful under the FFDCA to “introduc[e] or deliver[] for introduction into interstate commerce any food \* \* \* that is adulterated \* \* \*.” 21 U.S.C. 331(a). Additionally, adulterated food is subject to seizure “when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce \* \* \*.” 21 U.S.C. 334(a)(1).

Consistent with this narrow focus on pesticide residues in food in interstate commerce, the standard for establishing and revoking tolerances is directed solely at the safety of the pesticide residues in food to the food consumer, taking into account other sources of pesticide exposure to the consumer as well. Specifically, the statute provides that “[t]he 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.” 21 U.S.C. 346a(b)(2)(A)(i). Invariably, FFDCA section 408 directs EPA to consider factors relevant to the safety of the pesticide residue in food (aggregated with other sources of exposure to the pesticide residue), placing particular emphasis on human dietary risk. See, e.g., 21 U.S.C. 346a(b)(2)(B) (addressing an exception to the safety standard for pesticide residues as to which EPA “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”); 21 U.S.C. 346a(b)(2)(C) (requiring special safety findings as to “infants and children” regarding their “disproportionately high consumption of foods” and their “special susceptibility \* \* \* to pesticide chemical residues”); 21 U.S.C. 346a(b)(2)(D)(iii) (requiring consideration of the relationship between toxic effects found in pesticide studies and human risk); 21 U.S.C. 346a(b)(2)(D)(iv), (vi), and (vii) (requiring consideration of available information on “dietary consumption patterns of consumers,” “aggregate exposure levels of consumers,” and the “variability of the sensitivities of major identifiable subgroups of consumers”); 21 U.S.C. 346a(b)(2)(D)(vi) (requiring consideration of “non-occupational” sources of exposure); 21 U.S.C. 346a(b)(2)(D)(viii) (requiring consideration of information bearing on whether a pesticide “may have an effect in humans that is similar to an effect

produced by a naturally occurring estrogen or other endocrine effects”); 21 U.S.C. 346a(l)(2) and (3) (requiring revocation or suspension of tolerances where associated FIFRA registration is canceled or suspended “due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on that food”). In no place, does section 408 explicitly or implicitly authorize EPA to consider environmental factors in addition to factors bearing on the safety of pesticide residues in food in interstate commerce. Thus, under section 408, EPA has no authority to revoke a pesticide residue food tolerance found to contain safe levels of pesticide residues in food based upon a conclusion that the use of the pesticide has negative impacts on endangered or threatened species of birds. Because EPA has no discretion to insert environmental considerations into decisions on FFDCA section 408 tolerances, the ESA, under the Supreme Court’s holding in *Homebuilders* and the applicable regulations, is inapplicable to decisions made under FFDCA section 408.

Even if the ESA did apply to FFDCA section 408 decisions, ABC’s petition fails because ABC has not offered evidence on an element critical to demonstrating that the existence of the tolerances in question have either a direct or indirect effect on endangered species of birds within the jurisdiction of the ESA. See 50 CFR 402.02. Clearly, pesticide tolerances in food do not have a direct impact on wildlife. Tolerances establish the legality of pesticide residues in food moved through interstate commerce in the United States and have no applicability to wildlife. ABC has not claimed otherwise.

Nor has ABC shown that the challenged tolerances have an indirect effect on endangered birds. Applicable regulations define an “indirect effect” as those that are caused by the action and that are later in time, but still are “reasonably certain to occur.” 50 CFR 402.02 (defining “Effects of the action”). ABC argues that the challenged tolerances are reasonably certain to cause an effect on migratory birds, some of which are endangered, because “[m]aintaining a U.S. import tolerance allows Central and South American countries to continue using these pesticides on crops for which the U.S. has already determined there are unacceptable risks for protected U.S. migratory birds.” To support this argument, ABC has proffered evidence that the pesticides can be toxic to birds and that birds may use agricultural lands in these foreign countries. However, even assuming this evidence

is unassailable, ABC still has failed to support a critical aspect of its claim because it offered no evidence to show the pesticides are used in these countries on crops intended for export to the United States, the conditions under which the pesticides are used (e.g., application methods, application rates, environmental conditions), and why those conditions of use are a threat to endangered birds. In the absence of such evidence, there is no basis to conclude that the tolerances are “reasonably certain to cause” an effect on endangered birds. Essentially, ABC’s petition asks EPA to assume that the tolerances *cause* the pesticide to be used on crops for export to the United States, and, more importantly, *cause* the pesticide to be used in a manner that is reasonably certain to affect endangered bird species. On the latter point, ABC’s argument fails to take into consideration the fact that use of challenged pesticides in the foreign country would be governed by that country. As a policy matter, EPA would not presume that the mere existence of a U.S. tolerance carries such overriding weight that it is reasonably certain to cause independent sovereign governments to abandon regulatory oversight of the pesticide and uncritically permit its use under conditions that are reasonably certain to have an effect on endangered migratory birds. Yet, this is the very premise of ABC’s petition. Finally, ABC’s claim that these pesticides will have an impact on endangered birds in Central and South America is not rescued by its assertion that these pesticides have been found by EPA to pose unacceptable risks to birds on the crops covered by the tolerances. As noted above in Unit VI., this is a significant overstatement.

#### VIII. Response to Comments

SALDF makes many of the same arguments made by ABC in its petition, and EPA disagrees with these claims for the reasons provided in Unit VII. Also like ABC, SALDF premises its comments on the incorrect assertion that the challenged pesticides are “banned in the U.S.” due to the risk they pose to birds. Apparently going beyond ABC’s petition, SALDF alleges that EPA has an obligation to comply with provisions of EO 13186, which relate to international activities. EPA disagrees with this allegation because, as discussed in Unit VII.A., the Executive Order does not provide a basis for revoking the challenged tolerances under the FFDCA. Finally, SALDF argues that the MBTA compels EPA to revoke the tolerances. This argument, however, is without legal basis. There is no violation of the MBTA

when the Federal government action is not directly causing or will not directly cause the take of any migratory birds. Courts have found that Federal government actions that only impact migratory bird habitat without directly taking migratory birds (e.g., timber sales occurring in the United States approved by the U.S. government) do not violate the MBTA. See *Newton County Wildlife Ass’n v. U.S. Forest Serv.*, 113 F.3d 110 (8th Cir. 1997) (finding that government approval of timber sales only “indirectly results in the death of migratory birds”; MBTA is concerned more with “physical conduct of the sort engaged in by hunters and poachers”); *Seattle Audubon Soc’y v. Evans*, 781 F. Supp. 1502 (9th Cir. 1991) (finding no government liability in approving timber sales that affected migratory bird habitat). EPA’s retention of the challenged tolerances does not involve any physical conduct directed at killing migratory birds nor does it directly result in the take or killing of any migratory birds. EPA’s action is even further removed from any possible bird deaths than the timber sales directly resulting in destruction of migratory bird habitat that were found not to be covered by the MBTA in *Newtown County Wildlife* and *Seattle Audubon Society*. In fact, SALDF, by admitting that EPA “is unable to directly regulate pesticide use in sovereign nations,” has essentially conceded that there is no direct action by EPA that causes the take of migratory birds in Central and South American countries. After all, it is regulatory action by EPA (i.e., retention of tolerances) that SALDF cites as the basis for its MBTA argument. Rather than allege direct action by EPA against migratory birds, SALDF states only that revoking the tolerances would “contribute to the protection of migratory birds.” The possibility that removing a tolerance might contribute to the protection of migratory birds falls far short of demonstrating that the continuance of a tolerance is a “take” under the MBTA and, as discussed in Unit VII.B., is not a basis for revoking tolerances under the FFDCA.

EPA generally agrees with the comments from CropLife America, the Pesticide Policy Council, and the various pesticide manufacturers. That agreement is reflected in Units VI., VII., and VIII. EPA would note, however, that the Pesticide Policy Council is mistaken in its claim that only pesticide registrants may petition to revoke tolerances under EPA regulations. According to the Pesticide Policy Council, EPA regulations specify that a petitioner must show a “substantial

interest” in the challenged tolerance and the regulations also define FIFRA registrants or applicants for registration of a pesticide as the only party with a substantial interest in a tolerance for that pesticide. The Council errs by concluding that the regulation’s provision that evidence of registration or application for registration “will be regarded as evidence that a person has a substantial interest” defines the universe of persons with a substantial interest. 40 CFR 180.32(b). In fact, the regulation merely defines one person who does have a substantial interest in a tolerance without in any way limiting persons with a substantial interest only to registrants or applicants.

#### IX. Regulatory Assessment Requirements

As indicated previously, this action announces the Agency’s order denying a petition filed under section 408(d) of FFDCA. As such, this action is an adjudication and not a rule. The regulatory assessment requirements imposed on rulemaking do not, therefore, apply to this action.

#### X. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule for purposes of 5 U.S.C. 804(3).

#### XI. References

1. American Bird Conservancy, Petition to Revoke Import Tolerances of 13 Pesticides (July 23, 2009).
2. Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision: Cadusafos (June 2000).
3. Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Report on FQPA Tolerance Reassessment Progress and Interim Risk Management Decision: Mevinphos (September 2000).
4. Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED): Diquat Dibromide (April 25, 2002).
5. Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Reregistration Eligibility Decision (RED): Methomyl (December 1998).
6. Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Interim Reregistration Eligibility Decision for Naled (January 2002).
7. Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Interim Reregistration Eligibility Decision for Terbufos (September 2001).

8. Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Interim Reregistration Eligibility Decision: Diazinon (May 2004).
9. Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Interim Reregistration Eligibility Decision for Dichlorvos (DDVP) (June 2006).
10. Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Interim Reregistration Eligibility Decision for Dimethoate (June 12, 2006).
11. Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Interim Reregistration Eligibility Decision: Fenamiphos (May 2002).
12. Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, Interim Reregistration Eligibility Decision for Phorate (March 2001).

#### List of Subjects in 40 CFR Part 180

Environmental protection,  
Endangered species, Pesticides and pest.

Dated: July 29, 2011.

**Steven Bradbury,**

*Director, Office of Pesticide Programs.*

[FR Doc. 2011-20200 Filed 8-9-11; 8:45 am]

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 300

[EPA-HQ-SFUND-2000-0003; FRL-9450-4]

#### National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of International Smelting and Refining Superfund Site

**AGENCY:** Environmental Protection Agency.

**ACTION:** Direct final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) Region 8 is publishing a direct final Notice of Deletion of the International Smelting and Refining Superfund Site (Site), located in Tooele, Utah, from the National Priorities List (NPL). The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). This direct final deletion is being published by EPA with the concurrence of the state of Utah, through the Utah Department of Environmental Quality (UDEQ) because EPA has determined that all appropriate response actions under CERCLA, other than operation, maintenance, and five-year reviews, have been completed. However, this deletion does not

preclude future actions under Superfund.

**DATES:** This direct final deletion is effective October 11, 2011 unless EPA receives adverse comments by September 9, 2011. If adverse comments are received, EPA will publish a timely withdrawal of the direct final deletion in the **Federal Register** informing the public that the deletion will not take effect.

**ADDRESSES:** Submit your comments, identified by Docket ID no. EPA-HQ-SFUND-2000-0003, by one of the following methods:

- <http://www.regulations.gov>. Follow online instructions for submitting comments.
- *E-mail:* Erna Waterman, Remedial Project Manager, [waterman.erna@epa.gov](mailto:waterman.erna@epa.gov).
- *Fax:* 303-312-7151.
- *Mail:* Erna Waterman, Remedial Project Manager, U.S. Environmental Protection Agency, Region 8, EPR-SR, 1595 Wynkoop Street, Denver, Colorado 80202-1129.

• *Hand delivery:* U.S. Environmental Protection Agency, Region 8, EPR-SR, 1595 Wynkoop Street, Denver, Colorado. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to Docket ID no. EPA-HQ-SFUND-2000-0003. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA

cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

*Docket:* All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in the hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at: U.S. EPA, Region 8, Records Center, 1595 Wynkoop Street, Denver, Colorado 80202-1129 (303) 312-6473, Hours: M-F 8 a.m. to 4 p.m. Tooele City Library, 128 West Vine Street, Tooele, Utah 84074, (435) 882-2182, Hours: T-F 10 a.m. to 8 p.m. and Saturdays 10:30 a.m. to 6 p.m.

**FOR FURTHER INFORMATION CONTACT:** Erna Waterman, Remedial Project Manager, U.S. Environmental Protection Agency, Region 8, EPR-SR, 1595 Wynkoop Street, Denver, Colorado 80202-1129, (303) 312-6762, *e-mail:* [waterman.erna@epa.gov](mailto:waterman.erna@epa.gov).

#### SUPPLEMENTARY INFORMATION:

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- I. Introduction
- II. NPL Deletion Criteria
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- IV. Basis for Site Deletion
- V. Deletion Action

##### I. Introduction

EPA Region 8 is publishing this direct final Notice of Deletion of the International Smelting and Refining Superfund Site, (Site), from the National Priorities List (NPL). The NPL constitutes Appendix B of 40 CFR part 300, which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980, as amended. EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund (Fund). As described in 300.425(e) (3) of the NCP, sites deleted from the NPL remain eligible for Fund-financed