

§ 165.T13–148 Safety Zones; Multiple Firework Displays in Captain of the Port, Puget Sound Area of Responsibility, WA

(a) *Safety Zones.* The following areas are designated as safety zones:

(1) All waters of Boston Harbor encompassed within a 200 yard radius around position 47° 08.5'N, 122° 54.2' W from 5 p.m. on July 3, 2010 until 1 a.m. on July 4, 2010.

(2) All waters of Boston Harbor encompassed within a 200 yard radius around position 47° 08.5' N, 122° 54.2' W from 5 p.m. on July 24, 2010 until 1 a.m. on July 25, 2010.

(3) All waters near Stuart Island encompassed within a 700 yard radius around position 48° 37.5' N, 121° 12.0' W from 5 p.m. on August 6, 2010 until 1 a.m. on August 7, 2010.

(b) *Regulations.* In accordance with the general regulations in § 165.23 of this Part, no person or vessel may enter, transit, moor, or anchor within the safety zones created in this section unless authorized by the Captain of the Port or his Designated Representative.

(c) *Authorization.* All persons or vessels who desire to enter the safety zones created in this section must obtain permission from the Captain of the Port or his Designated Representative by contacting either the on-scene patrol craft on VHF Ch 13 or Ch 16 or the Coast Guard Sector Seattle Joint Harbor Operations Center (JHOC) via telephone at 206–217–6002.

(d) *Effective Period.* The safety zones created in this section are effective on the dates and times noted in paragraph (a) unless canceled sooner by the Captain of the Port.

Dated: June 22, 2010.

S. W. Bornemann,

Captain, U. S. Coast Guard, Captain of the Port, Puget Sound.

[FR Doc. 2010–16118 Filed 7–1–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0801; FRL–8832–5]

Carbaryl; Order Denying Washington Toxics Coalition Petition to Revoke Tolerances and Notice of Availability of Denial of Request to Cancel Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Order and Notice of Availability.

SUMMARY: This order denies a petition requesting that EPA revoke all pesticide

tolerances for carbaryl under section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA). The petition was filed on January 10, 2005 by the Washington Toxics Coalition (WTC). This order also informs the public of the availability of a response to WTC's petition to cancel all uses of carbaryl.

DATES: This Order is effective July 2, 2010. Objections and requests for hearings must be received on or before August 31, 2010, 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–2006–0801. 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 www.regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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:

Jacqueline Guerry, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (215) 814–2184; e-mail address: guerry.jacqueline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including

environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. 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 also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

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–2006–0801 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before August 31, 2010.

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–2006–0801, 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?

The WTC filed a petition dated January 10, 2005 (WTC Petition) with EPA which, among other things, requested that EPA cancel all registrations for the pesticide carbaryl and revoke all carbaryl tolerances established under section 408 of the FFDCA, 21 U.S.C. 346a (Ref. 1). It should be noted that the WTC Petition generally raises a subset of identical issues raised by a petition submitted by the Natural Resources Defense Council (NRDC), which is also dated January 10, 2005 (Ref. 2). Indeed, most of the WTC Petition is virtually a verbatim recitation of the NRDC petition. The primary difference is that the WTC Petition does not address any of the tolerance-related issues raised in the NRDC petition; there is nothing in the WTC Petition which supports the request to revoke tolerances. Nonetheless, to the extent that the WTC Petition can be construed to raise tolerance-related issues, this Order relies on EPA's response to the NRDC petition and denies that portion of the WTC Petition that seeks the revocation of the carbaryl tolerances. This document also announces a notice of availability for EPA's response to WTC's Petition to cancel all uses of carbaryl, which may be found in docket number EPA-HQ-OPP-2006-0801.

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. FFDCA/FIFRA and Applicable Regulations

1. *In general.* EPA establishes maximum residue limits, or "tolerances," for pesticide residues in food and feed commodities 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 (FDA) and the U.S. Department of Agriculture (USDA). Section 408 was substantially rewritten by the Food Quality Protection Act of 1996 (FQPA), which added the provisions discussed below establishing a detailed safety standard for pesticides, additional protections for infants and children, and the estrogenic substances screening program. (Public Law 104-170, 110 Stat. 1489 (1996)).

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, (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 inconsistent with its label is a violation of Federal law. (7 U.S.C. 136j(a)(2)(G)). In the FQPA, Congress integrated action under the two statutes by requiring that the safety standard under the FFDCA be used as a criterion in FIFRA registration actions as to pesticide uses which result in dietary risk from residues in or on food, (7 U.S.C. 136(bb)), and directing that EPA coordinate, to the extent practicable, revocations of tolerances with pesticide cancellations under FIFRA. (21 U.S.C. 346a(l)(1)).

2. *Safety standard for pesticide tolerances.* A pesticide tolerance may only be promulgated or left in effect by EPA if the tolerance is "safe." (21 U.S.C. 346a(b)(2)(A)(i)). This standard applies both to petitions to establish and petitions to revoke tolerances. "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)). Section 408(b)(2)(D) directs EPA, in making a safety determination, to:

consider, among other relevant factors— ...

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

(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;

(21 U.S.C. 346a(b)(2)(D)(v), (vi) and (viii)).

EPA must also consider, in evaluating the safety of tolerances, "safety factors which . . . are generally recognized as appropriate for the use of animal experimentation data." (21 U.S.C. 346a(b)(2)(D)(ix)).

Risks to infants and children are given special consideration. Specifically, section 408(b)(2)(C) states that EPA:

shall assess the risk of the pesticide chemical based on—

(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....

(21 U.S.C. 346a(b)(2)(C)(i)(II) and (III)).

This provision also creates a presumptive additional safety factor for the protection of infants and children. Specifically, it directs that "in the case of threshold effects, ... 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." (21 U.S.C. 346a(b)(2)(C)). EPA is permitted to "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." (Id.). The additional safety margin for infants and children is referred to

throughout this Order as the “FQPA Safety Factor.”

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, a tolerance 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 establishing, amending, or revoking the tolerance or denying the petition, any party may file objections with EPA and seek an evidentiary hearing on those objections. (21 U.S.C. 346a(g)(2)). Objections and hearing requests must be filed within 60 days. (Id.). The statute provides that EPA shall “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.” (21 U.S.C. 346a(g)(2)(B)). EPA regulations make clear that hearings will only be granted where it is shown that there is “a genuine and substantial issue of fact,” the requestor has identified evidence “which, if established, resolve one or more of such issues in favor of the requestor,” and the issue is “determinative” with regard to the relief requested. (40 CFR 178.32(b)). 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 required that EPA reassess the safety of all pesticide tolerances existing at the time of its enactment. (21 U.S.C. 346a(q)). EPA was given 10 years to reassess the approximately 10,000 tolerances in existence in 1996. In this reassessment, EPA was required to review existing pesticide tolerances under the new “reasonable certainty that no harm will result” standard set forth in 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 was generally handled in conjunction with a similar program involving reregistration of pesticides under FIFRA. (7 U.S.C. 136a-1).

Tolerance reassessment and reregistration decisions were generally combined in a Reregistration Eligibility Decision (“RED”) document.

B. EPA’s Approach to Dietary Risk Assessment and Science Policy Considerations

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. In addition, EPA applies a number of policy considerations with respect to determining the appropriate children’s safety factor, cholinesterase inhibition as a regulatory endpoint, and the use of a bench mark dose approach. EPA has discussed these in great detail in its response to an earlier and virtually identical petition file by NRDC. EPA hereby incorporates and relies upon that discussion. See Carbaryl: Order Denying NRDC’s Petition to Revoke Tolerances, dated September 30, 2008 (October 29, 2008, 73 FR 64229).

IV. Carbaryl Tolerances

A. Regulatory Background

Carbaryl is a carbamate insecticide and molluscicide that was first registered in 1959 for use on cotton. Carbaryl has many trade names, but is most commonly known as Sevin®. In 1980, the Agency published a position document summarizing its conclusions from a Special Review of carbaryl, and concluded that risk concerns, particularly those related to teratogenicity, did not warrant cancellation of the registration for carbaryl. A Registration Standard, issued for carbaryl in 1984 and revised in 1988, described the terms and conditions for continued registration of carbaryl. At the time carbaryl was assessed for purposes of reregistration, carbaryl was registered for use on over 400 agricultural and non-agricultural use sites, and there were more than 140 tolerances for carbaryl in the Code of Federal Regulations (40 CFR 180.169). For example, carbaryl was registered for domestic outdoor uses on lawns and gardens, and indoors in kennels and on pet sleeping quarters. It was also registered for direct application to cats and dogs (collar, powder, and dip) to control fleas and ticks.

EPA completed an Interim Reregistration Eligibility Decision (IRED) for carbaryl on June 30, 2003 (2003 IRED, Ref. 3). The Agency amended the IRED on October 22, 2004 (2004 Amended IRED, Ref. 4), and published a formal Notice of Availability for the document which provided for a 60-day public comment period (69 FR 62663; docket EPA-HQ-

OPP-2003-0376). EPA received numerous comments on the carbaryl IRED, including two nearly identical petitions from the WTC and the NRDC requesting that EPA cancel all carbaryl registrations and revoke all tolerances (Refs. 1 and 2). The Agency published a Notice of Availability for the WTC Petition in the **Federal Register**, which provided a public comment period. See “Petition to Revoke or Modify Tolerances Established for Carbaryl; Notice of Availability,” October 13, 2006 (71 FR 60511).

The 2004 Amended IRED for carbaryl specified mitigation of risks from residential uses including the following: Canceling liquid broadcast applications to home lawns pending EPA review of pharmacokinetic data to refine post-application risk estimates; home garden/ornamental dust products must be packaged in ready-to-use shaker can containers, with no more than 0.05 lbs. active ingredient per container; cancellation of the following uses and application methods: all pet uses (dusts and liquids) except collars, aerosol products for various uses, belly grinder applications of granular and bait products for lawns, hand applications of granular and bait products for ornamentals and gardens.

On March 9, 2005, EPA issued a cancellation order for the liquid broadcast use of carbaryl on residential turf to address post-application risk to toddlers (Ref. 5). In March 2005, EPA also issued generic and product-specific data call-ins (DCIs) for carbaryl. The carbaryl generic DCI required several confirmatory studies of the active ingredient carbaryl, including additional toxicology, worker exposure monitoring, data to support the use of carbaryl in pet collars, and environmental fate data. The product-specific DCI required acute toxicity and product chemistry data for all pesticide products containing carbaryl; these data are being used for product labeling. EPA has received numerous studies in response to these DCIs, and, where appropriate, these studies were considered in the tolerance reassessment.

In response to the DCIs, many carbaryl registrants chose to voluntarily cancel their carbaryl products, rather than revise their labels or conduct studies to support these products. EPA published a notice of receipt of these requests in the **Federal Register** on October 28, 2005 (70 FR 62112), followed by a cancellation order issued on July 3, 2006. One technical registrant, Burlington Scientific, chose to cancel its technical product, leaving Bayer CropScience (Bayer) as the sole

technical registrant for carbaryl. Approximately two-thirds of all of the carbaryl products registered at the time of the 2003 IRED were canceled through this process.

In addition, Bayer, the sole remaining technical registrant responsible for developing data, requested waivers of required exposure monitoring or residue studies because the following use scenarios were not on any Bayer technical or product labels or were to be deleted from Bayer labels: Carbaryl use in or on pea and bean, succulent shelled (subgroup 6B); millet; wheat; pre-plant root dip for sweet potato; pre-plant root dip/drench for nursery stocks, vegetable transplants, bedding plants, and foliage plants; use of granular formulations on leafy vegetables (except Brassica); ultra low volume (ULV) application for adult mosquito control; and dust applications in agriculture.

Bayer subsequently requested that all of its carbaryl registrations bearing any of the uses just mentioned be amended to delete these uses. EPA notified all affected registrants that these uses and application methods must be deleted from their carbaryl product labels. EPA identified 34 product labels from 14 registrants (other than Bayer) bearing these end uses. All of these registrants requested that their affected carbaryl product registrations be amended to delete these uses. EPA published Notices of receipt of these requests from Bayer and the other 14 registrants in the **Federal Register** on August 20, 2008 and October 15, 2008. On March 18, 2009, the Agency published an order granting the requests to delete uses (74 FR 11553).

Further, in November 2009, Bayer submitted a waiver request for the dermal and inhalation exposure studies required for aerial application of carbaryl bait used in the USDA Rangeland Grasshopper and Mormon Cricket Suppression Program due to a recent reduction in the maximum application rate, which eliminated remaining uncertainties associated with this use scenario. The Agency accepted the waiver request in January 2010.

Carbaryl is a member of the N-methyl carbamate (NMC) class of pesticides, which share a common mechanism of toxicity by affecting the nervous system via cholinesterase inhibition.

Specifically, carbaryl is a reversible inhibitor of Acetylcholinesterase (AChE). A cumulative risk assessment, which evaluates exposures based on a common mechanism of toxicity, was conducted to evaluate risk from food, drinking water, residential use, and other non-occupational exposures

resulting from registered uses of NMC pesticides, including carbaryl.

In June 2006, EPA determined that the uses associated with 120 of the existing carbaryl tolerances were not significant contributors to the overall NMC cumulative risk and, as a result, these tolerances would have no effect on the retention or revocation of other NMC tolerances. Therefore, EPA considered these 120 tolerances for carbaryl as reassessed on June 29, 2006, and posted this decision on the Agency's internet site. (See http://www.epa.gov/pesticides/cumulative/carbamates_commodity.pdf).

In late November 2006, EPA received data from a carbaryl comparative cholinesterase study conducted to determine the comparative sensitivity of adults and offspring to cholinesterase inhibition by carbaryl. These data were used to revise the FQPA Safety Factor for carbaryl for the NMC cumulative risk assessment and to select new toxicology endpoints or points of departure (PODs) for the risk assessment. The Agency determined that it was appropriate to use the new FQPA Safety Factor and revised PODs in both the NMC cumulative risk assessment and the carbaryl-specific human health risk assessment. Because this necessitated a revision of the carbaryl human health aggregate risk assessment, EPA also considered additional new data generated in response to the DCI, new methodologies, and other new information in performing its most recent assessment of carbaryl and in responding to this Petition. EPA has thus, in effect, revised the carbaryl single chemical assessment in response to the issues raised during the public comment process as well as based upon more recent data and analytical methods.

On September 26, 2007, EPA issued the NMC cumulative risk assessment (Ref. 6). EPA concluded that the cumulative risks associated with the NMC pesticides meet the safety standard set forth in section 408(b)(2) of the FFDCFA, provided that the mitigation specified in the NMC cumulative risk assessment is implemented. EPA has therefore terminated the tolerance reassessment process under 408(q) of the FFDCFA. (See 72 FR 54656). In conjunction with the NMC cumulative risk assessment, EPA completed a Reregistration Eligibility Decision (RED) for carbaryl on September 24, 2007 (Ref. 7) and issued this RED on October 17, 2007 with a formal Notice of Availability in the **Federal Register** (72 FR 58844). In addition to relying on the NMC cumulative risk assessment to determine that the cumulative effects

from exposure to all NMC residues, including carbaryl, was safe, the carbaryl RED relied upon the revised assessments and the mitigation that had already been implemented (e.g., cancellation of pet uses except for collars). In addition, the RED included additional mitigation with respect to granular turf products for residential use; namely, that product labels direct users to water the product immediately after application. Subsequently, on August 25, 2008, EPA completed an addendum to the Carbaryl RED, incorporating the results of a revised occupational risk assessment and modified mitigation measures for the protection of workers (Ref. 8).

Subsequent to the completion of the carbaryl RED addendum, EPA completed a revised master label table for carbaryl and a list of carbaryl uses eligible for reregistration. These materials, which summarized the changes necessary to implement the carbaryl RED and addendum, were sent to all carbaryl end-use registrants on March 25, 2009. (See docket entry: EPA-HQ-OPP-2007-0941-0088.) All carbaryl end-use registrants were required to submit revised labels to EPA by April 30, 2009. EPA has completed its review of these amended labels, and all acceptable carbaryl products are now reregistered. Once again, some registrants chose to cancel their carbaryl product registrations rather than submit revised labels that incorporate the final RED mitigation. EPA has received voluntary cancellation requests for 19 additional carbaryl product registrations, and 7 Special Local Need registrations, from 8 registrants, including the last remaining carbaryl products registered for use on pets – carbaryl-treated dog and cat collars. The Agency has published Notice of Receipt of Requests for Cancellation and/or Cancellation Notice for all 26 carbaryl product registrations as per sec. 6(f) of FIFRA. The two carbaryl pet collar product registrations, specifically, will be canceled effective September 30, 2010, with a reduced existing stock provision of 3 months (74 FR 66642).

Finally, EPA completed a response to NRDC's January 10, 2005 petition to cancel all uses of carbaryl in a letter dated September 30, 2008 (Ref. 9). The Agency's response to NRDC's petition to revoke carbaryl tolerances is in an Order also dated September 30, 2008 (Ref. 10). This Order Denying NRDC's Petition to Revoke Tolerances was published in the **Federal Register** on October 29, 2008 (73 FR 64229).

B. FFDCA Tolerance Reassessment and FIFRA Pesticide Reregistration

As required by the Food Quality Protection Act of 1996, EPA reassessed the safety of the carbaryl tolerances under the safety standard established in the FQPA. In the September 2007 RED for carbaryl, EPA evaluated the human health risks associated with all currently registered uses of carbaryl and determined that there is a reasonable certainty that no harm will result from aggregate, non-occupational exposure to the pesticide chemical residue. In making this determination, EPA considered dietary exposure from food and drinking water and all other non-occupational sources of pesticide exposure for which there is reliable information. (Ref. 7). The Agency has concluded that with the adoption of the risk mitigation measures identified in the NMC cumulative risk assessment, all of the tolerances for carbaryl meet the safety standard as set forth in section 408(b)(2)(D) of the FFDCA. Therefore, the tolerances established for residues of carbaryl in or on raw agricultural commodities were considered reassessed as safe under section 408(q) of FFDCA, as amended by FQPA, in September 2007. These findings satisfied EPA's obligation to review the carbaryl tolerances under the FQPA safety standard.

To implement the carbaryl tolerance reassessment, EPA commenced with rulemaking in 2008. The Agency published a Notice of proposed tolerance actions in the May 21, 2008 **Federal Register** (73 FR 29456). This proposed rule provided for a 60-day public comment period. No comments relevant to carbaryl tolerances were received and EPA published a Notice of final tolerance actions in the September 10, 2008 **Federal Register** (73 FR 52607). This carbaryl tolerance rule is codified in 40 CFR 180.169.

V. The Petition to Revoke Tolerances

WTC filed a petition on January 10, 2005, requesting, among other things, that EPA cancel all carbaryl registrations and revoke all carbaryl tolerances. This January 10, 2005 submission is in the form of comments on and requests for changes to the Carbaryl IRED published in the **Federal Register** on October 27, 2004. (70 FR 62663) (Ref. 1). Nevertheless, in the introduction to the comments, WTC included a statement that it is also petitioning the Agency to revoke all carbaryl tolerances. It should be noted that the WTC petition primarily raises a subset of identical issues raised by a petition submitted by NRDC, which is also dated January 10,

2005. Indeed, to the extent they address the same issues, most of the WTC's petition is virtually a word-for-word copy of the NRDC petition. The primary difference is that the WTC petition does not address any of the tolerance-related issues raised in the NRDC petition. Nonetheless, to the extent that anything in the WTC Petition could be construed as raising a tolerance-related issue, EPA is relying on its response to the NRDC petition to revoke all carbaryl tolerances in denying the WTC Petition to revoke all carbaryl tolerances.

The issues raised by the WTC Petition center around the ecological risk assessment that supported the 2004 IRED decision. Again, most of these issues are identical to those raised by NRDC and have been addressed in a response denying the NRDC petition to cancel all carbaryl registrations, dated September 30, 2008. The ecological risk assessment issues that are unique to the WTC Petition are addressed in a separate response, dated June 18, 2010. EPA hereby announces the availability of this response in the public docket EPA-HQ-OPP-2006-0801.

VI. Public Comment

In response to the statement that the WTC Petition sought the revocation of the carbaryl tolerances, EPA published notice of the WTC Petition for comment on October 13, 2006 (71 FR 60511). EPA received 28 comments in response to the notice of availability for the WTC Petition. These comments may be found in their entirety in docket EPA-HQ-OPP-2006-0801. A number of commenters from land grant universities mentioned the importance of carbaryl in agriculture, especially in the production of grapes, small fruit, and pecans. Several commenters from the U.S. Forest Service and state departments of forestry commented on the importance of carbaryl in controlling bark beetle. In addition, the carbaryl registrant, Bayer CropScience, submitted comments opposing the claim by the WTC that carbaryl poses unreasonable risks to non-target organisms. In general, these comments focus on the importance and benefits of carbaryl, and are not specific to carbaryl tolerances and, therefore, are not relevant to the requested revocation of pesticide tolerances. EPA is responding to the WTC Petition insofar as it seeks cancellation of all carbaryl products separately, and, therefore, these comments are not directly relevant here.

In addition, one comment from a private citizen supported WTC's petition, asserting that all carbaryl tolerances should be revoked (but without, however, providing sufficient

details to substantiate this position). Another commenter, Northwest Horticultural Council, submitted comments stating that WTC's claims are often based on outdated information, such as carbaryl residue levels on apples and pears reported in a 1967 monograph of the Food and Agricultural Organization (FAO) of the United Nations World Health Organization. The Northwest Horticultural Council states that the FAO Monograph is superseded by 2004 residue monitoring data from USDA's Pesticide Data Program (PDP), which shows less than 10% of samples with detection, where carbaryl residues ranged from 0.0005 to 0.49 ppm. In any event, the comments as a whole (including these particular comments) did not add any new information pertaining to whether the tolerances were in compliance with the FFDCA.

VII. Ruling on Petition

This Order responds to the WTC Petition to revoke carbaryl tolerances. As noted above, this request was included as part of WTC's comments on the carbaryl IRED. The WTC Petition contains a number of comments that do not provide a basis upon which to either cancel all carbaryl registrations or revoke all carbaryl tolerances. Moreover, the WTC Petition focuses solely on ecological issues. EPA is responding to WTC's comments regarding the ecological assessment supporting the carbaryl RED in a separate response, which is available in docket EPA-HQ-2006-0801. However, EPA has not attempted to respond to every comment or suggestion for improvement made in the comments provided by the WTC.

EPA hereby denies the WTC Petition to revoke all carbaryl tolerances. The WTC Petition has not demonstrated that carbaryl tolerances are unsafe. Again, the WTC Petition primarily raises a subset of identical issues that were raised in the NRDC petition, and does not provide any factual support for the proposition that the carbaryl tolerances do not meet the FFDCA safety standard. To the extent that the WTC Petition can be construed as raising any tolerance-related issues, in denying the WTC Petition, EPA is relying on and hereby incorporates its response to the NRDC petition. (See 73 FR 64229).

VIII. Regulatory Assessment Requirements

As indicated previously, this action announces the Agency's order denying a petition filed, in part, 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.

IX. 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).

X. References

1. Washington Toxics Coalition Comments to Carbaryl IRED and petition to cancel registrations. January 10, 2005.
2. National Resources Defense Council (NRDC) Comments to Carbaryl IRED and petition to cancel registrations. January 10, 2005.
3. U.S. EPA. Office of Pesticide Programs. 2003. Interim Reregistration Eligibility Decision for Carbaryl. June 30, 2003.
4. U.S. EPA. Office of Pesticide Programs. 2004. Amended Interim Reregistration Eligibility Decision for Carbaryl. October 22, 2004.
5. U.S. EPA. Office of Pesticide Programs. 2005. Letter to Peg Cherney, Bayer CropScience, Final Cancellation Order for Carbaryl Liquid Broadcast Application to Lawns/Turf; EPA Registration Numbers 264–324, 264–325, and 264–328. March 9, 2005.
6. U.S. EPA Office of Pesticide Programs. 2007. Revised N-methyl Carbamate Cumulative Risk Assessment. September 24, 2007. Docket EPA–HQ–OPP–2007–0935–0003.
7. U.S. EPA. Office of Pesticide Programs. Reregistration Eligibility Decision (RED) for Carbaryl. September 24, 2007.
8. U.S. EPA. Office of Pesticide Programs. 2008. Amended Reregistration Eligibility Decision (RED) for Carbaryl. Revised August 24, 2008.
9. U.S. EPA. Office of Pesticide Programs. 2008. Letter to Jennifer Sass, Natural Resources Defense Council, Re: NRDC's comments on the Carbaryl IRED and petition to cancel registrations dated January 10, 2005 as well as petition to cancel carbaryl registrations dated November 26, 2007 and submitted as part of NRDC's comments to N-methyl carbamate cumulative. September 30, 2008.
10. U.S. EPA. Office of Pesticide Programs. Carbaryl: Order Denying NRDC's Petition to Revoke Tolerances. September 20, 2008. Docket EPA–HQ–OPP–2007–0941–0031.

List of Subjects in 40 CFR Part 180

Environmental protection, Carbaryl, Pesticides and pests.

Dated: June 18, 2010.

Steven Bradbury,

Director, Office of Pesticide Programs.

[FR Doc. 2010–15751 Filed 7–1–2010; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket OST–2008–0088]

RIN OST 2105–AD84

Procedures for Transportation Workplace Drug and Alcohol Testing Programs

AGENCY: Office of the Secretary, DOT.

ACTION: Final rule.

SUMMARY: The Department of Transportation published a final rule authorizing the use of an updated Alcohol Testing Form with a mandatory start date of August 1, 2010. The Department subsequently learned the industry might not use all the forms by that mandatory use date. To avoid wasting the forms, the Department is extending the mandatory use date to January 1, 2011.

DATES: This rule is effective July 2, 2010.

FOR FURTHER INFORMATION CONTACT: For program issues, Bohdan Baczara, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Avenue, SE., Washington, DC 20590; (202) 366–3784 (voice), (202) 366–3897 (fax), or bohdan.baczara@dot.gov (e-mail).

SUPPLEMENTARY INFORMATION:

Background and Purpose

On February 25, 2010, the Department published a final rule [75 FR 8528] updating the Alcohol Testing Form (ATF). The Department anticipated that employers and alcohol testing technicians could have a supply of old ATFs and, to avoid unnecessarily wasting these forms, the Department permitted the use of the old ATF until August 1, 2010. Employers were authorized to begin using the updated ATF immediately.

Since the final rule was published, the Department became aware that some vendors of the ATF might not be able to deplete their current supply of the ATFs before the August 1, 2010 implementation date. In light of this new information and to avoid wasting already printed forms, on May 11, 2010, the Department published a notice of proposed rulemaking [75 FR 26183] to

propose to extend the implementation date to January 1, 2011.

Discussion of Comments to the Docket

There were fifteen commenters, including alcohol testing device manufacturers and suppliers, third party administrators, a medical facility, individuals and a trade association. The commenters unanimously agreed to extend the mandatory use date to January 1, 2011, citing that the extra time to use the old form will enable them to reduce their inventory of alcohol testing forms and give them the necessary time to design, print and distribute the new form. The commenters also appreciated the Department's sensitivity to minimizing the unnecessary waste of paper and expense that would have been caused by throwing away forms that could no longer be used. One commenter suggested for the Department to permit the use of the old ATF past the proposed mandatory use date of January 1, 2011. Two commenters asked for guidance on what would happen if an old ATF was used past the January 1, 2011 mandatory use date.

The Department agrees with the commenters that extending the mandatory use date from August 1, 2010 to January 1, 2011 will enable regulated employers and their service agents to reduce their inventory of old alcohol testing forms and give them sufficient time to design, print, and distribute the new ATF. As such, the final rule will reflect this new date. Regarding the use of the old ATF past the January 1, 2011 date, the Department expects that the ten month transition period from using the old ATF to the new ATF will be sufficient time for employers and TPAs to ensure the breath alcohol technicians (BATs) that service them are aware of the new form and have the new form for use by the January 1, 2011 date. The Department does not see the need to make a provision for use of the old ATF past the January 1, 2011.

Regulatory Analyses and Notices

The statutory authority for this proposed rule derives from the Omnibus Transportation Employee Testing Act of 1991 (49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 45101 *et seq.*) and the Department of Transportation Act (49 U.S.C. 322).

This proposed rule is a non-significant rule both for purposes of Executive Order 12886 and the Department of Transportation's Regulatory Policies and Procedures. The Department certifies that it will not have a significant economic effect on a substantial number of small entities, for