ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0174; FRL–9343–6]

Sulfuryl Fluoride; Second Request for Comment on Proposed Order Granting Objections to Tolerances and Denying Request for a Stay

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Order; request for comment.

SUMMARY: In this notice, EPA is requesting comment on several issues that were raised in comments on EPA's proposed resolution of objections and a stay request with regard to sulfuryl fluoride and fluoride tolerances promulgated in 2004 and 2005 under section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA). EPA is requesting that interested parties address various legal issues that were raised by several commenters as well as provide further documentation for submissions regarding the impacts of the withdrawal of the sulfuryl fluoride and fluoride tolerances.

DATES: Comments must be received on or before July 30, 2012.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2005–0174, 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 Facility'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.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2005–0174. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line 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 regulations.gov or email. The 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 email comment directly to EPA without going through regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the 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 docket index available at *http://www.regulations.gov.* 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, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either 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 hours of operation of this Docket Facility are 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: Meredith Laws, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–7038; email address: *laws.meredith@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, pesticide manufacturer, or consumer. Potentially affected entities may include, but are not limited to:

- Food manufacturing (NAICS code 311), e.g., grain and oilseed milling; animal food manufacturing; flour milling; bread and bakery product manufacturing; cookie, cracker, and pasta manufacturing; snack food manufacturing.
- Pesticide manufacturing (NAICS code 32532), *e.g.,* pesticide manufacturers; commercial applicators.
- Community Food Services (NAICS code 624210), *e.g.,* food banks.
- 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 provides 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 North American Industrial Classification System (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. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Request for Additional Comment

A. What action is the agency taking?

In this notice, EPA is requesting additional comment on several issues that were raised in comments on EPA's proposed resolution of objections and a stay request with regard to sulfuryl fluoride and fluoride tolerances promulgated in 2004 and 2005 under section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA). (January 19, 2011, 76 FR 3422). In that notice, EPA proposed to grant the objections to the tolerances based on a conclusion that aggregate exposure to fluoride (from all sources including drinking water, dental products, and food) does not meet the safety standard in FFDCA section 408, although EPA notes that fluoride exposure that occurs as a result of sulfuryl fluoride use accounts for a relatively small portion of overall aggregate exposure (approximately 3 to 4 percent of total fluoride exposure). In the notice, EPA proposed to withdraw the sulfuryl fluoride and fluoride tolerances under an implementation schedule that would provide time for sulfuryl fluoride users to transition to new pest control alternatives. The notice also specified that the proposed tolerance withdrawal, if finalized, would become effective 60 days from the date of the final order, and would follow the implementation schedule detailed in the final order. EPA notes that during the pendency of the Agency's consideration of the objections to the sulfuryl fluoride and fluoride tolerances, the tolerances remain in effect. Neither the January 2011 proposed order nor this notice constitute final agency action.

B. What is the agency's authority for taking this action?

The procedure for filing objections to tolerance actions and EPA's authority for acting on such objections is contained in section 408(g) of FFDCA (21 U.S.C. 346a(g) and regulations at 40 CFR part 178. That same authority governs hearing and stay requests.

C. On what matters is EPA requesting additional comment?

EPA is seeking additional comment in two general areas. First, several commenters argued that, as a legal matter, EPA had a greater degree of discretion in how to interpret the standard in section 408(b) than indicated by EPA's proposal. EPA believes a fuller discussion of these arguments would aid its decision-making. Second, EPA has been contacted by several organizations regarding their comments bearing on the availability of alternatives to sulfuryl fluoride and the impacts of removal of the sulfuryl fluoride and fluoride tolerances. In discussions with these organizations, EPA noted that additional documentation was needed to support assertions made in the comments in question. In light of this, as well as due to the importance of this action, EPA has surveyed the comments and identified several issues related to availability of alternatives and impacts from withdrawal of the sulfuryl fluoride and fluoride tolerances that were raised by one or more commenters but were not always sufficiently documented. EPA is reopening the comment period to allow all commenters or others to provide additional information on the following issues.

1. *Legal issues.* There are three legal issues that EPA believes warrant comment: whether the *de minimis* doctrine is applicable here given the limited fluoride exposure from pesticidal sources; whether EPA's aggregation of exposure to a pesticide and other related substances can include non-pesticidal substances, especially where pesticidal exposure is proportionally small compared to exposure to related substances; and whether EPA's obligations under other statutory authority should be considered in implementing FFDCA section 408.

i. *De minimis doctrine.* Several commenters have asserted that EPA's proposed action would lead to absurd and undesirable consequences because removing the sulfuryl fluoride and fluoride tolerances will result in no greater than a minimal reduction in fluoride exposure but could have major impacts with regard to pest control for various stored commodities as well as complicating compliance by the United States with its obligations under the Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol) and Title VI of the Clean Air Act (CAA) addressing Stratospheric Ozone Protection. In fact, Dow AgroSciences LLC argues that ''if sulfuryl fluoride were not in use as a fumigant, there would be no change in the number of children in the U.S. currently exposed to excessive levels of fluoride * * *.'' (EPA–HQ–OPP–2005–0174–0228).

In brief, these commenters are objecting to the fluoride exposures EPA has taken into account in assessing fluoride risk under FFDCA section 408. Under that provision, 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)). ''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)). Other provisions in section 408 enlarge on the obligation to aggregate and cumulate exposures to the pesticide as well as other related substances. See 21 U.S.C. 346a(b)(2)(C)(i)(III) (requiring assessment of risk to infants and children based on cumulative effects of the pesticide and other substances that have a common mechanism of toxicity), 346a(b)(2)(D)(v) (requiring consideration of cumulative effects of the pesticide and other substances that have a common mechanism of toxicity), 346a(b)(2)(D)(vi) (requiring consideration of aggregate exposure to the pesticide and other related substances). In implementing this safety standard for the sulfuryl fluoride and fluoride tolerances, EPA has summed fluoride exposures from all sources, not just pesticidal sources, in evaluating the safety of the tolerances. The commenters have challenged this approach arguing that the *de minimis* doctrine would allow EPA to soften its approach to the aggregation of fluoride exposures and thus avoid potentially absurd consequences. As to absurd results, Dow AgroSciences LLC notes the ''insignificant exposure profile [of sulfuryl fluoride], the adverse impacts on public health that would follow its elimination, and the *de minimis* treatment that EPA has afforded sources of similar amounts of fluoride exposure.''

Under the *de minimis* doctrine, an agency need not apply the language of the statute in a literal manner if this leads to ''patently absurd results that will undermine Congress' broader purposes,'' *Public Citizen* v. *FTC,* 869

F.2d 1541, 1557 n. 33 (D.C. Cir. 1989), and the covered matter can ''fairly be considered *de minimis,'' Alabama Power Co.* v. *Costle,* 636 F.2d 323, 360 (D.C. Cir. 1979). Essential to exercise of a *de minimis* exception is that Congress cannot have been ''extraordinarily rigid,'' *Alabama Power Co.* v. *Costle,* 636 F.2d at 360; the exception cannot ''thwart a statutory command; it must be interpreted with a view to 'implementing the legislative design;' '' *Public Citizen* v. *Young,* 831 F.2d 1108, 1113 (D.C. Cir. 1987) (quoting *Alabama Power Co.* v. *Costle,* 636 F.2d at 360–61); and regulation under the terms of the statute must ''yield a gain of trivial or no value,'' *Alabama Power Co.* v. *Costle,* 636 F.2d at 360–61. See *EDF* v. *EPA,* 82 F.3d 451, 466–467 (D.C. Cir. 1996); *Ohio* v. *EPA,* 997 F.2d 1520, 1534–35 (D.C. Cir. 1993).

EPA seeks comment on how, if at all, the three elements of the *de minimis* doctrine would apply in the context of EPA's proposal to withdraw the sulfuryl fluoride and fluoride tolerances. First, has Congress imposed the aggregation requirement with extraordinary rigidity? In responding to this question it would be helpful if commenters would address the numerous references in FFDCA section 408 to the aggregation and cumulation of exposures, including the multiple references to the aggregation and cumulation of exposures to pesticides and other substances. See 21 U.S.C. 346a(b)(2)(C)(i)(III), 346a(b)(2)(D)(v), and 346a(b)(2)(D)(vi). Second, does not aggregating fluoride from pesticidal and non-pesticidal sources thwart or implement the statutory design? In other words, is the withdrawal of the sulfuryl fluoride and fluoride tolerances a ''patently absurd result[]'' that would thwart purposes of FFDCA section 408 or does it implement the statutory design? Finally, does fluoride exposure from pesticides truly amount to no greater than a *de minimis* risk? In approaching this question, it should be considered that EPA's risk assessments show that for the most highly exposed communities, total pesticidal fluoride amounts are approximately 3 to 4 percent of total fluoride exposure and 2 to 8 percent of the fluoride reference dose (RfD), depending on the age groups considered. See *Kentucky Waterways Alliance* v. *Johnson,* 540 F.3d 466, 492 (6th Cir. 2008). More broadly, any decision regarding whether fluoride exposure from pesticides is *de minimis* would potentially be precedential regarding other pesticides, and thus EPA requests comment generally on what factors should be considered in determining whether a pesticide's contribution to aggregate exposure is *de minimis.*

ii. *Exposure to other related substances.* FIFRA section 408(b)(1)(A)(ii) defines the safety finding for the establishment of tolerances as requiring a determination 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.'' FIFRA section 408(b)(2)(D)(vi) requires EPA in establishing tolerances to ''consider, among other relevant factors * * * available information concerning the aggregate exposure of consumers (and major identifiable subgroups of consumers) to the pesticide chemical and to other related substances * * *.'' Dow AgroSciences LLC argues (1) that the ''other related substances'' referenced in FIFRA section 408(b)(2)(D)(vi) are only other related pesticidal substances; and (2) that, even if the term ''other related substances'' includes non-pesticidal substances, aggregation of pesticide alone must have a ''meaningful impact on the end point of concern.'' EPA requests comment on whether such an interpretation is consistent with the language of these two provisions, as well as the other provisions of the statute that discuss aggregation and cumulation of pesticides and other related substances. See 21 U.S.C. 346a(b)(2)(C)(i)(III), 346a(b)(2)(D)(v).

iii. *Reconciling all environmental statutes and treaty obligations.* The Natural Resources Defense Council (NRDC) argues in its comments that EPA has an obligation to reconcile its action on sulfuryl fluoride under FFDCA section 408 with its duties under the Clean Air Act and the Montreal Protocol relating to the phase-out of methyl bromide. (EPA–HQ–OPP–2005–0174–0150). Specifically, NRDC asserts that EPA must consider the ''full range of the health consequences of its actions'' under FFDCA section 408. EPA requests comment on whether the presence of other statutory duties would allow EPA to approve a pesticide tolerance that was otherwise unsafe under FFDCA section 408, if failing to approve the tolerance would lead to greater net damages to the environment. In responding to this question, commenters should address FFDCA section 408(b)(2)(B) that describes the circumstances under which EPA may take such health-health tradeoffs into account. Also, EPA requests comment on the question of what are the ''full range of the health consequences'' of withdrawing the sulfuryl fluoride and fluoride tolerances. If EPA were to accept NRDC's legal premise, the facts surrounding the ''range of health consequences'' would be important to any EPA decision.

2. *Alternatives and impacts.* EPA has identified several issues related to availability of alternatives and impacts from withdrawal of the sulfuryl fluoride and fluoride tolerances that were raised by one or more commenters but were not always sufficiently documented. EPA would recommend commenters consider the following descriptions of the types of documentation that would aid EPA in compiling adequate record materials on the issues in question:

i. Please provide complete and accurate references (i.e., peer-reviewed articles, personal contacts, consultants, other) for any and all data and information included, mentioned, referred to, and/or cited in comments. For example, provide sources of information for costs of heat treatment, costs of construction, phosphine resistance, phosphine corrosion, efficacy of alternatives, etc. Any information relied on to make any inference, reach a conclusion, or derive a quantitative estimate should be accompanied by a complete and accurate reference. Some of the commenters already provided references for their information; others did not. Please note that without accurate references, the Agency may not be able to locate the information to update and/or revise impacts where appropriate.

ii. If cost estimates for warehouse construction, fumigation chamber construction, or other types of construction were included in a comment, please provide the full details of the calculations and all assumptions used to derive the estimates, and please provide a contact name and number for the person or company that created the estimates, in case the Agency has further questions.

iii. Regarding the corrosive effects of phosphine to equipment, what types of machines are damaged by phosphine, what is the nature of the damage, how many phosphine treatments does it take to damage them, how much does the equipment cost, and, if possible, how could the equipment be moved or retrofitted so that the damage does not occur?

iv. Please provide complete and accurate references to any law or regulation on food safety cited in a comment. For example, some comments mentioned mandatory fumigation, pasteurization, etc. of food products. Please provide specific references to any

and all statutes and/or regulations that require such treatments.

v. Several applicators mentioned that sulfuryl fluoride was safer than phosphine for applicators. Please explain why sulfuryl fluoride application is safer, using specific examples where possible.

vi. Several comments mentioned the inability of heat to penetrate finished product. Please contrast this with the ability for fumigant gas to penetrate the products.

vii. If any specific customer requests for fumigation to address a particular pest infestation are mentioned in a comment, please provide examples of those requests.

viii. If any claims are made that sulfuryl fluoride is needed so that food can meet phytosanitary conditions in foreign markets, please provide examples of those requirements (e.g., import requirements of other countries), please explain why quarantine methyl bromide cannot be used to meet the requirements, and please provide details on the pounds of product fumigated with sulfuryl fluoride for export each year to countries with these requirements.

ix. Many comments from groups that process and store commodities, such as nuts and dried fruit, noted that there was a need for fast turnaround times in fumigation to meet market demand. If the industry never requested a methyl bromide critical use exemption, please explain how fast fumigation was conducted prior to the introduction of sulfuryl fluoride, why the transition to sulfuryl fluoride occurred, and why it would now not be possible to switch back to previous methods. Several comments indicated that there would be human health concerns from lack of an effective fumigant. If available, please provide specific examples (with complete and accurate references) of public health issues caused by lack of fumigants.

x. As to claims that there are commercially viable, chemical or non-chemical, alternatives for commodities and/or structures, please provide literature citations and/or personal contacts for the efficacy of these alternatives and the costs and technical feasibility of transition. In addition, please provide any available information on how using the alternatives is expected to affect the cost of the end product.

xi. As to claims that pest problems for which U.S. industries currently employ sulfuryl fluoride are successfully controlled in countries where neither sulfuryl fluoride nor methyl bromide is used, please provide data, literature citations and/or personal contacts for the efficacy and costs of these chemical or non-chemical alternatives.

xii. As to claims of economic or other types of impacts as a result of EPA's proposed order, recognizing that EPA has not yet issued a final order or taken final agency action, please provide specific information, data, and/or personal contacts to substantiate these claims.

X. Regulatory Assessment Requirements

This notice seeks additional comment on the Agency's proposed order regarding objections filed under section 408 of FFDCA. The proposed order is part of an adjudication and not a rule. The regulatory assessment requirements imposed on rulemaking do not, therefore, apply to this notice.

XI. 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 to this notice because this is not a rule for purposes of 5 U.S.C. 804(3).

List of Subjects in 40 CFR Part 180

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

Dated: April 24, 2012.

Steven Bradbury,

Director, Office of Pesticide Programs.

[FR Doc. 2012–10493 Filed 4–30–12; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R6–ES–2011–0039; 92220–1113–0000–C6]

RIN 1018–AX94

Endangered and Threatened Wildlife and Plants; Removal of the Gray Wolf in Wyoming From the Federal List of Endangered and Threatened Wildlife and Removal of the Wyoming Wolf Population's Status as an Experimental Population

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the reopening of the public comment period on our October 5, 2011, proposal to remove the gray wolf (*Canis lupus*) in Wyoming from the List of Endangered and Threatened Wildlife. This proposal relied heavily on Wyoming's wolf management plan and noted that conforming changes to State law and regulation would be required to allow Wyoming's plan to be implemented as written. Wyoming recently completed four documents that clarify Wyoming's approach to wolf management should we delist the gray wolf in Wyoming, including revised State statutes, revised gray wolf management regulations (chapter 21), revised gray wolf hunting season regulations (chapter 47), and an Addendum to the Wyoming Gray Wolf Management Plan. We are reopening the comment period for the proposal to allow all interested parties an additional opportunity to comment on the proposed rule in light of these documents. If you submitted comments previously, you do not need to resubmit them because we have already incorporated them into the public record and will fully consider them in preparation of the final rule.

DATES: We will consider all comments received or postmarked on or before May 16, 2012. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES** section, below) must be received by 11:59 p.m. Eastern Time on the closing date.

ADDRESSES: You may submit comments by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov*. Search for FWS–R6–ES–2011–0039, which is the docket number for this rulemaking. On the search results page, under the Comment Period heading in the menu on the left side of your screen, check the box next to ''Open'' to locate this document. Please ensure you have found the correct document before submitting your comments. If your comments will fit in the provided comment box, please use this feature of *http://www.regulations.gov,* as it is most compatible with our comment review procedures. If you attach your comments as a separate document, our preferred file format is Microsoft Word. If you attach multiple comments (such as form letters), our preferred format is a spreadsheet in Microsoft Excel.

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R6–ES–2011–0039; Division of Policy and Directives