40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: September 25, 2007.

J.I. Palmer, Jr.,

Regional Administrator, Region 4.

[FR Doc. E7–19513 Filed 10–2–07; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0546; FRL–8151–6]

Thiabendazole; Threshold of Regulation Determination

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to establish by rule that there is no need for a tolerance or tolerance exemption under the Federal Food Drug and Cosmetic Act (FFDCA) for the use of the fungicide thiabendazole as a seed treatment on dry peas. This determination is based on EPA's finding that any residues that remain in food from this use will be both non-detectable and below the level of regulatory concern.

DATES: Comments must be received on or before December 3, 2007.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2007–0546, 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.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2007–0546. 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 e-mail. The regulations.gov website 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 regulations.gov, your e-mail 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 in regulations.gov. 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 website to view the docket index or access available documents. 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: Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5218; fax number: (703) 305–0599; e-mail address: *stanton.susan@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, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

• Crop production (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.

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. *Docket*. EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0546. 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 Office of Pesticide Programs (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.

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. Background

A. What Action is the Agency Taking?

EPA is proposing that the use of the fungicide thiabendazole, 2-(4-thiazolyl) benzimidazole, as a seed treatment on dry peas does not need an FFDCA tolerance or tolerance exemption based on EPA's finding that any residues that remain in food from this use will be both non-detectable and below the level of regulatory concern.

In the **Federal Register** of October 27, 1999 (64 FR 57881), available at *http://www.epa.gov/fedrgstr/EPA-PEST/1999/October/Day-27/p28047.htm*, EPA announced the availability of a policy document titled ''Threshold of Regulation (TOR) Policy – Deciding Whether a Pesticide with a Food Use Pattern Requires a Tolerance.'' This policy document describes:

(a) EPA's authority for determining whether a tolerance or tolerance exemption is, or is not, required for a pesticide use.

(b) Relevant criteria that EPA would consider in determining whether a tolerance is required for a pesticide use in, on, or near food that produces no detected residues in the food.

(c) Data, including toxicology and residue chemistry studies, that EPA would generally consider when deciding whether a tolerance is required.

(d) The procedures that would guide EPA in evaluating whether new or existing pesticide uses fall below the level of regulatory concern.

(e) The procedures that EPA would follow to establish a regulation in title 40 of the Code of Federal Regulations (CFR) for each use found to be below the level of regulatory concern.

You may obtain electronic copies of the TOR policy document from the Office of Pesticide Programs' Home Page at *http://www.epa.gov/pesticides/*. On the Office of Pesticide Programs' Home Page, select ''Science and Policy,'' then select ''Policy and Guidance''and look up the TOR entry under ''TRAC Science Policy Issues and Documents.''

Designation of a pesticide use as below the level of regulatory concern means EPA has determined that no tolerance or exemption is required under section 408. Accordingly, for the purposes of registration of the pesticide use under the Federal Insecticide, Fungicide, and Rodenticide Act (''FIFRA''), 7 U.S.C. 136 et seq., a tolerance or exemption from tolerance would not be deemed necessary under 40 CFR 152.112(g). Designation of a pesticide use as below the level of regulatory concern does not legalize any detectable residues of that pesticide on food.

This proposed decision applies only to the use of the fungicide thiabendazole as a seed treatment on dry peas when applications are made according to the following label directions:

> A single application of thiabendazole may be made as a seed treatment at the rate of 0.075 pounds of active ingredient per 100 pounds of seed (dry pea (including field pea), pigeon pea, chickpea or lentil). Applications will be made as a spray mist or slurry treatment maintained under constant agitation. Vines and hay grown from treated seed may not be fed to livestock.

EPA proposes that there is no need for a tolerance or tolerance exemption for this use under the FFDCA since (a) using a reliable and appropriately sensitive analytical method to measure residues in dry peas, no residues were detected in the commodity under the expected conditions of use; and (b) using reasonably protective criteria, the estimated potential risk of any theoretically possible residues in food is not of concern. The information EPA relied on in proposing this decision is summarized below.

1. *Toxicology considerations*—i. *Toxicological profile.* EPA has evaluated the available toxicity data for thiabendazole and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. EPA has concluded that there are sufficient data to characterize the hazard posed by any potential exposures to thiabendazole. Specific information on the toxicity of thiabendazole is available in the Reregistration Eligibility Decision (RED) document, issued by the Agency in October 2002, and available electronically on the Office of Pesticide Programs' Home Page at http://www.epa.gov/pesticides/. On the Office of Pesticide Programs' Home Page, under ''Featured Sites'' select ''REDs & Pesticide Reregistration Status;'' then look up the RED for Thiabendazole and its salts in the alphabetical listing.

ii. *Toxicological endpoints.* For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic risks by comparing exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

The toxicological endpoints used in making the TOR determination for the proposed use of thiabendazole as a seed treatment on dry peas are discussed below and summarized in Table 1 of this unit.

a. *Acute dietary endpoint.* At the time of the thiabendazole RED, EPA had selected acute dietary endpoints for the

general population and females, 13 years and older, based on reduced fetal weights and decreased maternal body weights seen in the rat developmental toxicity study. EPA has reconsidered these endpoints and concluded that reduced fetal weights and decreased maternal body weights are not effects that are likely to occur after a single dose of a pesticide and are, therefore, not appropriate for use in assessing acute risks. EPA has reviewed the toxicology database to determine if there are other endpoints that would be appropriate for acute assessment, giving careful consideration to the reproductive and developmental effects noted in the database and in literature citations. Since those effects were only observed at very high doses, they were determined to be inappropriate for risk assessment at the exposures expected for thiabendazole. EPA has concluded that there is no appropriate endpoint in the toxicology database that is attributable to a single dose of thiabendazole and that an acute risk assessment is not required for this chemical.

b. *Chronic dietary endpoint.* The chronic dietary endpoint (NOAEL of 10 mg/kg/day) is based on decreased body weight gains and liver hypertrophy seen at the LOAEL of 30 mg/kg/day in the 2–year chronic feeding/carcinogenicity study in the rat.

c. *Cancer.* The Agency has classified thiabendazole as ''likely to be carcinogenic at doses high enough to cause a disturbance of the thyroid hormone balance. It is not likely to be carcinogenic at doses lower than those which could cause a disturbance of this hormonal balance.'' A mode of action was established in which these tumors were attributed to interference with thyroid-pituitary homeostasis. EPA is currently regulating chronic dietary risk using a cPAD that reflects a dose level below levels at which thyroid hormone balance is impacted; therefore, the chronic risk assessment is protective of potential carcinogenic effects. A separate risk assessment for cancer is not required.

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR THIABENDAZOLE USED IN THE TOR HUMAN RISK ASSESSMENT

Exposure/Scenario	Dose Used in Risk Assessment, Interspecies and Intraspecies and any Traditional FQPA, SF	FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13–50 years of age)	Not Applicable (N/A)	N/A	No effect attributable to a single dose identified in the database.
Acute dietary (General population including infants and children)	N/A	N/A	No effect attributable to a single dose identified in the database.
Chronic dietary (All populations)	NOAEL= 10 mg/kg/day SF = 100 Chronic RfD = 0.1 mg/kg/day	FQPA SF = 1 cPAD = chronic RfD ÷ FQPA SF = 0.1 mg/kg/day	2–Year Feeding/Chronic Carcinogenicity Study in the Rat. LOAEL = 30 mg/kg/day based on decreased body weight gains and liver hypertrophy.
Cancer (Oral, dermal, inhalation)	NA	NA	Classified as ''not likely to be carcinogenic to humans at doses that do not alter rat thyroid hormone homeostasis.

2. *Safety Factor for Infants and Children.* Section 408 of FFDCA provides that EPA shall apply an additional (''10X'') tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional uncertainty (UFs) and/or considerations specifically raised in the FQPA, as appropriate.

EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor for thiabendazole to 1X. That decision is based on the following findings:

i. The toxicity database for thiabendazole is complete.

ii. There is no indication that thiabendazole is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that thiabendazole results in increased susceptibility in *in utero* rats, rabbits or mice in the prenatal developmental studies or in young rats in the 2–generation reproduction study. In the prenatal developmental toxicity studies in rats, rabbits, and mice and in the 2–generation reproduction study in rats, developmental effects in the fetuses or neonates occurred at or above doses that caused maternal or parental toxicity.

iv. There are no residual uncertainties identified in the exposure databases. The dietary exposure assessment of the TOR use, discussed below in Unit II.A.3., was performed assuming 100% crop treated and a conservative residue estimate. The assessment will not underestimate the exposure and risks posed by the use of thiabendazole as a seed treatment on dry peas.

3. *Residue data and analytical method considerations.* For a use to be below the level of regulatory concern it is important for it not to result in detectable residues under a reasonably sensitive analytical method and for any theoretical residues that are present to pose essentially a zero risk. Considering the range of sensitivities of tolerance analytical methods, EPA believes that a reasonably sensitive method should have a limit of quantitation (LOQ) in the range of 0.01 parts per million (ppm). However, the sensitivity of the method is not chosen in a vacuum and consideration should be given to how the sensitivity of the method affects any

estimation of risk. Accordingly, on a case-specific basis, EPA may accept a higher or lower LOQ if an appropriate rationale, including a consideration of risks estimated based on exposure as measured by that LOQ, supports such a decision.

Interregional Research Project No. 4 (IR–4), 500 College Road East, Suite 201 W, Princeton, NJ 08540, submitted field trial data for thiabendazole on dry pea. A total of five field trials were conducted in Zone 11 (2 trials in Idaho and 3 trials in Washington) during the 1996 growing season. Thiabendazole (30% flowable concentrate formulation) was formulated with water and seed dye and applied to dry pea seed at a seed treatment facility, at a nominal rate of 0.075 pounds of active ingredient per 100 pounds of seed. Treated seed was planted within 10 days of seed treatment, and samples of dry pea were collected from the field trial sites at maturity, 83–90 days after planting.

Samples of dry pea were analyzed for residues of thiabendazole *per se* using a High Pressure Liquid Chromatography/ Fluorescence Detector (HPLC/FLD) method with a lower limit of the method validation (LLMV) of 0.05 ppm. The method (MRID# 45428201) is a modification of the method *Ion-Pairing Liquid Chromatographic Determination of Benzimidazole Fungicides in Foods*, Gilvydis and Walters, JAOAC, vol. 73, no. 5, 1990. The mobile phase hold times were increased to obtain adequate separations. Duplicate samples were analyzed for residues of thiabendazole at each of the five field trial locations. Residues of thiabendazole were less than the method limit of detection (LOD) of 0.02 ppm in all 10 field trial samples.

No data were provided on residues of benzimidazole, a regulated metabolite of thiabendazole in or on dry pea grown from treated seed. However, based on residue studies in three diverse crops (wheat, soybean and sugar beets) in which residues of benzimidazole were consistently lower than residues of the parent compound, thiabendazole, EPA does not expect detectable residues of benzamidazole in dried peas grown from thiabendazole treated seed.

The analytical method used to measure thiabendazole residues appeared in the JAOAC, The Journal of the Association of Official Analytical Chemists, a peer reviewed publication. Further, adequate method validation data were provided in both the journal article and in conjunction with the submitted residue data. EPA concludes that the method would be suitable for enforcement purposes. The analytical method's reported LLMV of 0.05 ppm is higher than the 0.01 ppm value that has been identified as a target LOQ by the policy document on identifying uses below the threshold of regulatory concern. Nevertheless, EPA has concluded that the analytical method used to generate the residue data is sufficiently sensitive to support the threshold of regulation determination based on the following supporting information.

i. The LLMV is an artifact of the concentrations chosen for the study validation, and the actual analytical limits of quantitation (LOQ) and limits of detection (LOD) may be significantly below that value. EPA carefully examined the method chromatograms. Based on peak heights relative to concentration, peak shape and signal to noise ratio, the method's LOD was determined to be no greater than 0.02 ppm.

ii. EPA also considered data on the nature of the residue in soybeans submitted by Gustafson, Inc. The study was entitled ''Total ^{14}C Thiabendazole Residues in Soybeans from Treated Seed Grown Under Field Conditions'' (1998, MRID 45200301). In this study, soybean seeds were treated with 38 ppm ^{14}C Thiabendazole (0.00382 lb. a.i./100 lbs. seed). The treated seeds were then planted in the field and samples were taken of mature dry bean (82 days after treatment). Samples were assayed by combustion and analysis of $^{14}CO_2$ by liquid scintillation spectrometry. The total radioactive residue (TRR) in soybean seed was <0.001 ppm (<1 ppb). EPA considers soybeans to be an appropriate surrogate for dry pea. Taking into account the higher application rate currently requested for dry peas, the study supports the conclusion reached in the field trial data that residues will not exceed the estimated LOD of 0.02 ppm in dry pea grown from treated seed at the currently requested use rate, and may be lower than 0.02 ppm.

iii. Statistical data on the thiabendazole analytical method submitted by IR–4 further support the conclusion that the actual LOD is likely below the conservatively estimated value of 0.02 pm and indicates that the statistical LOD is much closer to 0.01 ppm.

iv. Finally, EPA's risk assessment of the proposed use assumed theoretical residues in dry peas equal to one-half the estimated LOD, which is 0.01 ppm. The resulting risk estimates were essentially zero, indicating that the method is sensitive enough to demonstrate that any potential residues in food are not of concern. The risk assessment is discussed in detail in the next section.

Taking all of these factors into consideration, EPA concludes that the analytical method used to generate the residue data is sufficiently sensitive to support a conclusion that the use will not result in detectable residues in food using a reasonably sensitive method. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

4. *Dietary risk assessment*. For a use to be below the level of regulatory concern, any theoretical residues present from the use should pose essentially zero dietary risk. As a starting point for analysis of this question, EPA's policy document has recommended that essentially zero dietary risk is evidenced by a showing that incremental risk from exposure to potential residues in food resulting from use of a pesticide should generally be less than 1/1000 of the acceptable risk. For a pesticide such as thiabendazole that exerts ''threshold'' effects, this means that incremental acute or chronic potential exposure from the use should occupy less than 0.1% of the acute or chronic population-adjusted dose (aPAD or cPAD) for the pesticide. EPA assessed dietary exposure to thiabendazole from its use as a seed treatment on dry peas as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1–day or single exposure. No such effects were identified in the toxicological studies for thiabendazole; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 Continuing Surveys of Food Intakes by Individuals (CSFII). EPA assumed residues of thiabendazole would be present in dry peas at one-half the LOD, equal to 0.01 ppm. Only dry peas were included in the dietary assessment, and 100% of dry peas were assumed to be treated with thiabendazole.

Using these assumptions, EPA has concluded that chronic dietary exposure to thiabendazole from residues theoretically present in dry peas will not exceed 0.01% of the cPAD for the U.S. population or any population subgroup, including infants and children. The estimated chronic risk for

the U.S. population and all subpopulations of concern is significantly below the level recommended in EPA's policy as showing essentially zero risk (0.1% of the cPAD).

iii. *Cancer.* Thiabendazole has been classified as ''not likely to be carcinogenic to humans at doses that do not alter rat thyroid hormone homeostasis.'' The Office of Pesticide Programs' Health Effects Division is currently regulating chronic dietary risk with a chronic cPAD that reflects a dose level below dose levels at which thyroid hormone balance is impacted and, consequently, is also being protective of potential carcinogenic effects. Therefore, a cancer dietary assessment is unnecessary. Based on the results of the chronic dietary assessment, the use of thiabendazole on dry peas is not expected to pose a cancer risk.

5. *Threshold of regulation determination.* Based on the information discussed above, EPA has concluded that:

i. Reliable residue data developed using an analytical method with appropriate sensitivity show that no thiabendazole residues resulting from the use of the pesticide as a seed treatment on dry peas are detected in dry peas grown from treated seed when they enter interstate commerce.

ii. There are sufficient data to characterize the hazard posed by any potential exposures to thiabendazole.

iii. Risk estimates show that any thiabendazole residues theoretically present in dry peas as a result of this use pose an ''essentially zero'' dietary risk.

Therefore, EPA proposes to designate the use of thiabendazole as a seed treatment on dry peas as below the threshold of regulatory concern and thus as not requiring a tolerance or a tolerance exemption under FFDCA. EPA proposes to identify the use as such under 40 CFR part 180.2010 (Threshold of regulation determinations).

B. What is the Agency's Authority for Taking this Action?

The Federal Food, Drug and Cosmetic Act (FFDCA) section 408(e)(1)(C) authorizes the Agency to establish general procedures and requirements to implement FFDCA section 408. FFDCA section 701(a) authorizes the Agency to establish rules implementing the various provisions of FFDCA, as follows: ''The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.'' The term ''Secretary'' means ''Administrator'' with respect to those provisions of FFDCA for which the Administrator of EPA, rather than the Secretary of Health and Human Services, has responsibility. These provisions grant EPA the authority to identify by regulation pesticide uses that do not need tolerances or exemptions from tolerances under section 408 of FFDCA.

III. Statutory and Executive Order Reviews

The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993, as amended by Executive Order 13422, 72 FR 2763, January 18, 2007). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use* (66 FR 28355), May 22, 2001 or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks or Safety Risks* (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

In addition, pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), the Agency hereby certifies that this action will not have a significant adverse economic impact on a substantial number of small entities because this action does not have any adverse economic impacts.

This action directly regulates growers, food processors, food handlers and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (59 FR 22951, November 6, 2000) do not apply to this action. In addition, this action does not impose an enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

List of Subjects in 40 CFR Part 180

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

Dated: September 26, 2007.

Debra Edwards,

Director, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.2010 is amended by adding text to read as follows:

§ 180.2010 Threshold of regulation determinations.

The following pesticide chemical uses do not need a tolerance or exemption from the requirement of a tolerance based on EPA's determination that the uses are below the threshold of regulation.

Pesticide Chemical	CAS Reg. No.	Use/Limits	Analytical Method
Thiabendazole	148–79–8	As a seed treatment for dry pea (including field pea), pigeon pea, chickpea or lentil, using a maximum application rate of 0.075 pounds of active ingredient per 100 pounds of seed. Vines or hay grown from treated seed may not be fed to livestock.	High Performance Liquid Chromatography/Florescence Detector method[1]; *Modification of Ion-Pairing Liquid Chromatographic Determination of Benzimidazole Fungicides in Foods*, Gilvydis and Walters, JAOAC, vol. 73, no. 5, 1990.

[1] Available from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: *residuemethods@epa.gov*.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

RIN 0648–AU89

Atlantic Highly Migratory Species; Atlantic Shark Management Measures; Amendment 2 to the Consolidated Highly Migratory Species Fishery Management Plan

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; extension of comment period.

SUMMARY: Due to public, Regional Fishery Management Council, and Atlantic States Marine Fisheries Commission requests, NMFS is extending the comment period to provide additional opportunity for public comment on the draft Amendment 2 to the Consolidated Highly Migratory Species (HMS) Fishery Management Plan (FMP) and its proposed rule. NMFS is extending the comment period until November 2, 2007. The original comment period was scheduled to conclude on October 10, 2007. The draft Amendment 2 to the Consolidated HMS FMP and its proposed rule describe a range of management measures that could impact fishermen and dealers for HMS fisheries.

DATES: The deadline for receiving written comments on the July 27, 2007 (72 FR 41392), proposed rule and the draft Amendment 2 to the Consolidated HMS FMP is extended from October 10, 2007, to 5 p.m. on November 2, 2007.

ADDRESSES: You may submit comments, identified by 0648–AU89, by any one of the following methods:

• Electronic Submissions: Submit all electronic public comments via the Federal eRulemaking Portal *http://www.regulations.gov* or by email to *ShkA2@noaa.gov*. Please write in the subject line ''Comment on Amendment 2.''

• Fax: 301–713–1917, Attn: Michael Clark

• Mail: Attn: Michael Clark, 1315 East-West Highway, Silver Spring, MD 20910. Please mark the outside of the envelope ''Comment on Amendment 2.''

INSTRUCTIONS: All comments received are part of the public record and will generally be posted to *http://www.regulations.gov* without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments. Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

Copies of the draft Amendment 2 to the Consolidated HMS FMP and other relevant documents are available on the HMS Management Division's website at *www.nmfs.noaa.gov/sfa/hms* or by contacting HMS at 301–713–2347.

FOR FURTHER INFORMATION CONTACT: For more information concerning the draft Amendment 2 to the Consolidated HMS FMP and its proposed rule, contact: Michael Clark at 301–713–2347 or fax 301–713–1917; or Jackie Wilson at 240–338–3936 or fax 404–806–9188.

SUPPLEMENTARY INFORMATION: The Atlantic HMS fisheries are managed under the dual authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) and the Atlantic Tunas Convention Act (ATCA). The Consolidated HMS FMP, finalized in 2006, and amendments to that FMP are implemented by regulations at 50 CFR part 635.

On July 27, 2007 (72 FR 41392), NMFS published a proposed rule that requested comments on the draft Amendment 2 to the Consolidated HMS FMP, and scheduled 10 public hearings throughout August and September 2007 to receive comments from fishery participants and other members of the public regarding the proposed rule and draft Amendment 2 to the Consolidated HMS FMP. NMFS has since received many requests to extend the comment period in order to allow for more adequate comment submissions. In order to accommodate these requests and to provide additional opportunities for public comment by constituents, NMFS is extending the public comment period on the proposed rule and draft Amendment 2 to the Consolidated HMS FMP to 5 p.m., November 2, 2007.

Authority: 5 U.S.C. 561 and 16 U.S.C. 1801 *et seq.*

Dated: September 28, 2007.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

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