

Commodity	Parts per million	Expiration/Revocation Date
Avocado	3.0	1/1/08
Dandelion, leaves	10.0	1/1/07
Papaya	3.0	1/1/08
Pistachio	0.2	1/1/07
Turnip greens	6.0	1/1/07
Watercress	10.0	1/1/07

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301189; FRL-6807-8]

RIN 2070-AC18

Pesticides; Tolerance Exemptions for Minimal Risk Active and Inert Ingredients

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to list in 40 CFR part 180 the pesticide chemicals that are exempted from the requirement of a tolerance based on the Agency's determination that these chemicals are of "minimal risk." The pesticide chemicals to be listed in 40 CFR 180.1001(g) include both active and inert ingredients and will be accomplished in several steps. As a first step, the existing tolerance exemptions for commonly consumed food commodities, animal feed items, and edible fats and oils will be recodified in the newly created paragraph (g) in a different format. Restructuring to this new format will provide greater clarification in defining a minimal risk pesticide chemical as well as increasing the number of substances that are currently considered to be minimal risk. In the future, EPA will propose other minimal risk pesticide chemicals for inclusion in paragraph (g). These regulatory actions are part of the tolerance reassessment requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(q), as amended by the Food Quality Protection Act (FQPA) of 1996. By law, EPA is required to reassess 66% of the tolerances in existence on August 2, 1996, by August 2002, or about 6,400 tolerances. The regulatory actions proposed in this document, the proposed revocation of 39 tolerance exemptions, would be counted toward the August 2002 deadline.

DATES: Comments, identified by docket control number OPP-301189, must be received on or before March 18, 2002.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the

SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-301189 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703-305-6304; fax number: 703-305-0599; e-mail address: boyle.kathryn@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you formulate or market pesticide products. Potentially affected categories and entities may include, but are not limited to:

Cat-egories	NAICS	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 table could also be affected. The North American Industrial Classification System (NAICS) codes are provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. Electronically. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the **Federal Register**—Environmental Documents. You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_180/Title_40/40cfr180_00.html, a beta site currently under development.

2. In person. The Agency has established an official record for this action under docket control number OPP-301189. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is

imperative that you identify docket control number OPP-301189 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPP-301189. Electronic comments may also be filed online at many Federal Depository Libraries.

D. *How Should I Handle CBI that I Want to Submit to the Agency?*

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the proposed rule or collection activity.
7. Make sure to submit your comments by the deadline in this document.
8. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

The Agency is proposing to create a new paragraph (g) in 40 CFR 180.1001, that specifies the pesticide chemicals that are exempt from the requirement of a tolerance under section 408 of Federal Food, Drug, and Cosmetic Act ("FFDCA"). This paragraph will contain a listing of pesticide chemicals that are considered to be of minimal risk. The tolerance exemption in 40 CFR 180.1164(d) (which was established post-FQPA) as well as existing tolerance exemptions in 40 CFR 180.1001(c), (d) and (e) will be recodified in the newly established 40 CFR 180.1001(g), albeit in a different format that will include additional clarification. The effect of these changes will be that all commonly consumed food items (as a reference, there is the Food and Feed Commodity Vocabulary on the Agency's website: see <http://www.epa.gov/pesticides/foodfeed/>), with the exception of the exclusions noted below, will be exempt from the requirement of a tolerance under the newly established 40 CFR 180.1001(g).

The Agency is also proposing to establish in 40 CFR 180.1001(g) an exemption from the requirement of a tolerance for various animal feed items. The Agency is proposing that 40 CFR 180.1001 be amended by deleting the existing exemptions for various feed items, such as pomaces, corn cobs, peanuts shells, and oat hulls in 40 CFR 180.1001(c) and (d). These will be

recodified in 40 CFR 180.1001(g) albeit in a different format that will include additional clarification. All feed items whether or not previously exempted from the requirement of a tolerance with the exception of the exclusions noted below, will be exempt from the requirement of a tolerance under the newly established 40 CFR 180.1001(g).

The Agency is proposing to place expiration dates on seven existing tolerance exemptions for known allergen-containing food commodities. At this time, the Agency cannot consolidate the overlapping and duplicative tolerance exemptions for allergen-containing commodities that currently exist in 40 CFR part 180.

This proposed rule begins the process of harmonizing the regulation of certain pesticide chemicals whether used as inert or active ingredients. At the completion of this process there will be a single consistent approach for all food and feed commodities used as pesticide chemicals.

III. What is the Agency's Authority for Taking these Actions?

This proposed rule is issued under section 408 of FFDCA, 21 U.S.C. 346a, as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170). Section 408(e) of FFDCA authorizes EPA to establish, modify, or revoke tolerances, or exemptions from the requirement of a tolerance for residues of pesticide chemicals in or on raw agricultural commodities and processed foods.

IV. Why is the Agency Proposing These Actions?

A. Why is a "Minimal Risk" Paragraph Being Created?

The term "minimal risk" has been used by EPA for over 10 years, and has generally meant List 4A inert ingredient chemicals. On April 22, 1987 (52 FR 13305), EPA created a series of four lists as part of an initiative to address the risks potentially posed by inert ingredients in pesticides. List 1 inert ingredients are "inerts of toxicological concern". List 1 inert ingredients are classified on the basis of peer reviewed studies which demonstrated carcinogenicity, adverse reproductive effects, neurotoxicity or other chronic effects, developmental toxicity (birth defects), ecological effects and the potential for bioaccumulation. List 2 inert ingredients are "potentially toxic inerts/high priority for testing." Many of these inert ingredients are structurally similar to chemicals known to be toxic; some have data suggesting a concern. List 3 inert ingredients are "unknown

toxicity." An inert ingredient was placed on List 3 if there was no basis for listing it on any of the other lists. At that time all List 4 inert ingredients were classified as "inerts of minimal concern".

The 4A Inert Ingredient List was created on November 22, 1989 (54 FR 48314) by subdividing List 4 into Lists 4A and 4B. List 4B inert ingredients are "inerts for which EPA has sufficient information to reasonably conclude that the current use pattern in pesticide products will not adversely affect public health or the environment." List 4A inert ingredients are "minimal risk inert ingredients." Examples of List 4A inert ingredients are salt, and sugar.

The September 28, 1994, **Federal Register** Notice (FRL 4872-5) was the last time that the Agency added new substances to and issued the 4A List. Classification as a List 4A inert ingredient is critical to those products that are exempted from Federal regulation under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) section 25(b). The substances on List 4A are the only inert ingredients that can be used in 25(b) deregulated products (see 40 CFR 152.25(g)(2)).

Minimal risk does not imply no risk under any circumstances. Every substance, even for example water, presents some risk in certain circumstances. Minimal risk is used to indicate a substance for which there is no information to indicate that there is a basis for concern. Minimal risk or List 4A substances are mostly naturally occurring substances to which some refinement has occurred, such as beeswax, salt, sugar, limestone, and red cedar chips. The determination that a chemical is minimal risk would be based on a recognition of the overall safety of the chemical (such as very low toxicity or practically non-toxic) considering the widely available information on the chemical's known properties, and a history of safe use under reasonable circumstances. Minimal risk (List 4A) substances are recognized as safe for use in all pesticide products subject only to good agricultural practices or good manufacturing practices. Classification as a List 4A, minimal risk, substance is a high standard to meet. As an example, substances of high acute toxicity are usually not considered for classification to List 4A. The critical distinction between List 4A minimal risk substances and other substances, is that the Agency does not define how, where, when or in what manner the substance can be used. Any reasonably foreseeable use of these substances is not expected to present a risk to humans.

Accordingly, there should not be any unreasonable adverse effects from the inclusion of a List 4A substance in a pesticide product to the person applying a pesticide product in and around their home, to a child in a day-care center, or when ingesting a food commodity that has been treated. A List 4A substance used as an inert ingredient, incorporated into a 25(b) product (meeting all the appropriate exemption criteria) is subject to no Federal regulation. Therefore, unless a substance can meet and continues to meet this high standard, it will not be classified as minimal risk.

B. Why Are Uses as Both an Inert or Active Ingredient Being Included?

Active ingredients are defined in 40 CFR 153.125 as having the capability at the proposed use dilution to function as a pesticide, that is to kill, repel, or mitigate the pest. Inert ingredients are defined as all ingredients that are not active ingredients. However, it is possible for a chemical to be an active ingredient in one pesticide product and an inert ingredient in another pesticide product. Determining whether an ingredient in a pesticide product is inert or active requires information on the purpose of the ingredient in the formulation. As an example, citric acid can be used as a disinfectant, sanitizer, and fungicide (an active ingredient). However, citric acid can also perform as a sequestration agent or to lower the pH, thus functioning as an inert ingredient. To determine whether an ingredient is inert or active requires an understanding of the purpose of the ingredient in the formulation.

Thus, the toxicity of a chemical does not depend on whether it is used as either an inert ingredient or active ingredient, but on its impact to human health and the environment. Establishment of a tolerance exemption under 40 CFR 180.1001(g) indicates that the substance may be used as either an inert or an active ingredient (as appropriate, based on its use in the formulation) in pesticide formulations applied to food crops.

C. Why Are Commonly Consumed Foods Being Included in this New Paragraph?

It is unlikely that a commonly consumed food commodity could be used to control a pest via a toxic mode of action. Generally, when used as an active ingredient, food commodities have been used to either attract or repel pests. Canola oil is a refined vegetable oil that can be used as an active ingredient to control insects in a wide variety of crops. Scientists believe that

canola oil repels insects by altering the outer layer of the leaf surface or by acting as an insect irritant. Oils such as canola, however, can also be used as a surfactant in pesticide formulations. Surfactants are used to modify the nature of a surface, such as reducing the surface tension of water. Surfactants can be used as wetting agents, detergents, penetrants, and emulsifiers. When used in this capacity, canola oil would be an inert, rather than an active, ingredient. Other food commodities also are used as inert ingredients. For example, oats can be used as a carrier, i.e., the active ingredient is coated onto the oats, which is then consumed by the pest.

In the September 28, 1994, **Federal Register** Notice titled "Inert Ingredients in Pesticide Products; List of Minimal Risk Inerts" the Agency established a policy of considering all commonly consumed foods as acceptable for use in all pesticide products. The Notice specifically stated that a specific exemption from tolerance would not be required for foods used as inert ingredients because foods were generally recognized as safe (GRAS). However, the above GRAS determination was superceded, on December 4, 1998, in the **Federal Register** (63 FR 37307) (FRL 6039-5) by EPA's establishment of a tolerance exemption for all edible food commodities. That exemption excepted certain foods known to have allergenic properties.

D. Why Are the Tolerance Exemptions for Known Food Allergens Being Time-Limited?

As noted above, EPA has previously established an exemption from tolerance for all edible food commodities with the exception of peanuts, tree nuts, milk, soybeans, eggs, fish, crustacea, and wheat due to the allergenic properties of these foods. (40 CFR 180.1164(d)). The comment received by EPA in this 1998 rulemaking proceeding indicated a concern that the proposed exclusions for allergen-containing food commodities were not sufficient, given that tolerance exemptions existed for some of the same commodities when used as inert ingredients.

The following tolerance exemptions are currently listed in 40 CFR 180.1071 and 40 CFR 180.1001(c), (d), and (e), for the eight known allergen food or food groups and their processed commodities:

40 CFR	Tolerance Exemption
180.1001(c)	casein
180.1001(c)	fish meal
180.1001(c)	soy protein, isolated

40 CFR	Tolerance Exemption
180.1001(c)	soybean flour
180.1001(c)	starch (potato, tapioca, wheat)
180.1001(c)	wheat bran
180.1001(d)	sodium caseinate
180.1001(d)	wheat
180.1001(d)	wheat flour
180.1001(e)	soy protein, isolated
180.1001(e)	wheat shorts
180.1071	egg solids (whole)

The Agency has investigated the post-harvest uses of these eight allergen food or food groups, and has determined that such uses do exist. An example would be a formulation, that contains wheat as a carrier, which is then applied to stored grain other than wheat. Thus, some of the above tolerance exemptions are necessary to cover the use of these existing products. The 12 tolerance exemptions overlap to some degree and therefore EPA is proposing to amend them to reduce duplication. The result will be that the 12 tolerances will be reduced to 8.

More importantly, the Agency is proposing to place 3-year expiration dates on the eight tolerance exemptions that will remain. This will give the Agency a period of 3 years to continue its examination of the uses of these food commodities, and discuss product reformulation with affected registrants. The Agency recognizes that various factors such as restrictions on post-harvest applications or information on the environmental degradation/metabolism of the allergen may enable the Agency, at a future date, to (1) make a determination of safety, (2) reassess these tolerances, and (3) establish tolerance exemptions with limitations on the use pattern, that would not be time-limited.

E. Why Are Animal Feed Exemptions Being Included in this New Paragraph?

Like commonly-consumed human food, animal feed items are of minimal risk to humans who consume animal products (such as meat, milk, poultry or eggs), or to the animals. They are therefore being included in proposed 40 CFR 180.1001(g). Feed items are occasionally used as pesticides. For example, a feed item, such as corn cobs, can be used as a carrier. For such a use, the corn cobs would be ground, and then an active ingredient coated onto the ground feed item, is then consumed by the pest. Or a feed item could be used as a carrier for a lawn and garden product, with the added advantage of degrading over a period of time in the natural environment. Again, there is a long history of safe use of animals consuming these feed items, and then

producing meat, milk, poultry, and eggs that are in turn consumed by humans.

Feed items can also include items derived from known allergen-containing foods, such as almond hulls and peanut shells. These by-products of allergen-containing foods are not likely to cause an allergic reaction due to the separation of the hull or shell from the protein allergen.

There are a large variety of feed items. Most agricultural crops and their corresponding raw agricultural and processed commodities can be, and are, fed to livestock. Due to differences in their metabolisms, animals can obtain nutrition from parts of plants that are not digested by humans such as hays, forages, seeds, leaves, hulls and shells, and stovers. Animals also consume plants, such as sorghum, that are not consumed by humans. As a reference, the significant feed items consumed by animals are contained in Table 1 ("Raw Agricultural and Processed Commodities and Feedstuffs Derived From Crops"), OPPTS Test Guidelines, *Residue Chemistry*, Guideline 860.1000, Background. (see <http://www.epa.gov/docs/OPPTS-Harmonized/860-Residue-Chemistry-Test-Guidelines/Series/>). There are also other feed items not listed in Table 1 such as pineapple forage and fodder, or sugarcane forage and fodder that are consumed by animals, but not in amounts considered to be significant feed items on a national basis.

F. Why Are Edible Fats and Oils Being Included in the New Paragraph?

As previously explained on December 4, 1998, EPA established an exemption from tolerance for all edible food commodities with the exception of peanuts, tree nuts, milk, soybeans, eggs, fish, crustacea, and wheat due to the allergenic properties of these foods. (40 CFR 180.1164(d)) The exception included all processed forms of the allergen-containing food commodities including oils. EPA is proposing to no longer exclude highly refined edible oils derived from peanuts, tree nuts, soybeans, fish, crustacea, and wheat. Most oils are highly refined. The information available to the Agency does not indicate the presence of the protein allergens in the oils. The production process is generally believed to remove or destroy the allergen, which would cause the allergic reaction.

G. Why is Lactose Being Included?

It is also proposed to include lactose (milk sugar) in the to-be-established 40 CFR 180.1001(g) tolerance exemptions. Lactose intolerance occurs when the body does not produce a sufficient

amount of lactase, the enzyme that digests lactose. The presence of undigested lactose in the large intestine can cause gas or diarrhea; however, this is not life-threatening, as allergic reactions can be. Many lactose-intolerant individuals are capable of consuming small amounts of lactose with few or no symptoms. EPA can only regulate the use of lactose in pesticide formulations. Given the wide-spread nature of lactose in the food supply, the amount of lactose that can be applied to food as a result of its use in a pesticide product should not significantly increase the existing amounts in the food supply. Additionally, given the nature of plant metabolism it is unlikely that lactose would be directly absorbed or actually present in plant tissues. Lactose can be hydrolyzed to glucose, which is a natural plant compound and is, in fact, the sugar produced by photosynthesis. In plants, glucose is converted into starch or sucrose.

H. Conclusions

All of the substances considered in this proposed rule for inclusion in 40 CFR 180.1001(g) can be grouped into and included in three major categories. These are: (1) Commonly consumed food commodities; (2) animal feed items; and (3) edible fats and oils. All of the revoked tolerances will be recodified in 40 CFR 180.1001(g), albeit in a different format. In fact, the amendments and revisions to the tolerance exemptions will be beneficial to the regulated community by increasing the number of minimal risk inert ingredients for use in pesticide formulations.

EPA believes that the proposed tolerance exemptions in 40 CFR 180.1001(g) will be safe for humans including infants and children. EPA also is not aware of any data submitted pursuant to Section 6(a)2 of FIFRA showing significant adverse effects to humans from use of commonly consumed food commodities, animal feed items, or fats and oils. Because of the above, EPA has not assessed the risk of these substances using a safety factor approach. Accordingly, application of an additional 10X safety factor analysis or quantitative risk assessment is not necessary to protect infants and children.

V. What is the Contribution to Tolerance Reassessment

By law, EPA is required to reassess 66% or about 6,400 of the tolerances in existence on August 2, 1996, by August 2002. This proposed rule proposes to revoke 39 tolerance exemptions which will be counted toward the August 2002

review deadline of FFDCA section 408(q), as amended by FQPA in 1996.

VI. Future Issues

As previously stated, this proposed rule only considers commonly consumed foods, animal feed commodities, and refined, edible oils and fats. The Agency intends (in future proposed and final rules) to expand beyond these three categories and propose additional minimal risk chemicals for inclusion in 40 CFR 180.1001(g). Possible categories could include naturally occurring organic chemicals (such as fatty acids), common substances derived from weathered rocks and minerals, or some animal feed components.

The eight allergen food or food groups tolerance exemptions mentioned earlier in this preamble cannot be reassessed at this time. The Agency will examine the use patterns of these eight and determine the appropriate actions that would allow the Agency to make the safety finding. As explained earlier, restrictions on post-harvest applications or information on the environmental degradation/metabolism of the allergen could enable the Agency, at a future date, to make a determination of safety. Since use restrictions will be necessary, these allergens will no longer meet the criteria of List 4A classification and therefore these eight food or food groups will be transferred from the Agency's 4A list to the 4B list.

VII. Regulatory Assessment Requirements

The Agency is acting on its own initiative under FFDCA section 408(e) in establishing new tolerance exemptions that will consolidate the existing, overlapping and duplicative tolerance exemptions. Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" subject to review by the Office of Management and Budget (OMB). Because the proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001).

This proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any 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).

Nor does it require any special considerations as required by Executive Order 12898 entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994) or require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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).

This proposed rule would establish a new paragraph in 40 CFR 180.1001. Creating a new paragraph does not have a substantive effect and hence causes no impact. This proposed rule would place expiration dates on seven existing tolerance exemptions for various known allergen-containing food commodities. Currently, the Agency's regulatory approach as written in various CFR paragraphs and sections is inconsistent. This 3-year transition period will allow sufficient time to examine the uses of these food commodities, and discuss product re-formulation with affected registrants. At the completion of this process there will be a single consistent approach for all food commodities used as pesticide chemicals.

This proposed rule would also revoke 39 tolerance exemptions, thus (1) revoking duplicative and overlapping tolerance exemptions for commonly consumed (non-allergen) food commodities, (2) revoking and consolidating the existing tolerance exemptions for animal feed items and allowing additional minimal risk animal feed items not previously exempted for use in pesticide products, and (3) establishing the use of edible oils derived from allergens since the available information indicates that the use of these oils is not of concern.

Pursuant to the section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), the Agency hereby certifies that these proposed actions will not have significant negative economic impact on a substantial number of small entities. By contrast, the amendments and revisions to the tolerance exemptions will be beneficial to the regulated community by increasing the number of minimal risk inert ingredients for use in pesticide formulations.

Pursuant to the RFA the Agency previously assessed whether revocations of tolerances or tolerance exemptions might significantly impact a substantial number of small entities and concluded that, as a general matter, these actions do impose a significant economic impact on a substantial number of small entities. This analysis was published on December 17, 1997 (62 FR 66020) (FRL-5753-1), and was provided to the Chief Counsel for Advocacy of the Small Business Administration. Taking into account this analysis, the available information concerning the pesticide chemicals listed in this rule, the transition time for the known allergen containing commodities and considering that all of the to-be-revoked tolerance exemptions will be covered in the to-be-established 40 CFR 180.1001(g), the Agency knows of no extraordinary circumstances that exist as to the present revocation that would change EPA's previous analysis.

In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This proposed rule does not affect States directly, but does directly regulate growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of

regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practices and

procedures, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 21, 2001.

James Jones,

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 would continue to read as follows:

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

§ 180.1001 [Amended]

2. Section 180.1001 is amended as follows:

A. In paragraph (c) remove the entries for: almond shells; apple pomace; citrus meal; cocoa shells; coconut oil; corn cobs; corn meal; corn oil; cornstarch; corn syrup; cottonseed oil; dextrose; fish oil; grape pomace, dried; lactose; lard;

molasses; oatmeal; oats; orange pomace; peanut shells; rice bran; soybean oil; starch (potato, tapioca, wheat); and sucrose.

B. In paragraph (d) remove the entries for: cinnamon; clove; coffee; corn; corn gluten meal, hydrolyzed; fenugreek; low erucic acid rapeseed oil, conforming to 21 CFR 184.1555(c) (CAS Reg. No. none); oat hulls; wheat; and wheat flour.

C. In paragraph (e) remove the entries for: corn syrup; dextrose; and sucrose.

3. Section 180.1001 is further amended by revising the following entries in the tables to paragraphs (c), (d), and (e), by adding the entry "wheat, including flour, bran, and starch" to the table in paragraph (c), by adding and reserving paragraph (f) and by adding paragraph (g) to read as follows.

§ 180.1001 Exemptions from the requirement of a tolerance.

(c) * * *

Inert ingredients	Limits	Uses
Casein	* * * * * *	*
	expires [insert date 3 years from date of publication of the final rule in the FEDERAL REGISTER]. * * * * *	Surfactant, emulsifier, wetting agent
Fish meal	* * * * *	*
	expires [insert date 3 years from date of publication of the final rule in the FEDERAL REGISTER]. * * * * *	Solid diluent, carrier
Soy protein, isolated	* * * * *	*
	expires [insert date 3 years from date of publication of the final rule in the FEDERAL REGISTER]. * * * * *	Adhesive
Soybean flour	* * * * *	*
	expires [insert date 3 years from date of publication of the final rule in the FEDERAL REGISTER]. * * * * *	Surfactant
Wheat, including flour, bran, and starch.	* * * * *	*
	expires [insert date 3 years from date of publication of the final rule in the FEDERAL REGISTER]. * * * * *	Solid diluent, carrier, attractant

(d) * * *

Inert ingredients	Limits	Uses
Sodium caseinate	* * * * * *	*
	expires [insert date 3 years from date of publication of the final rule in the FEDERAL REGISTER]. * * * * *	Suspending agent and binder

(e) * * *

Inert ingredients	Limits	Uses
Soy protein, isolated	* * * * * *	*
	expires [insert date 3 years from date of publication of the final rule in the FEDERAL REGISTER]. * * * * *	Adhesive
Wheat shorts	* * * * *	*
	expires [insert date 3 years from date of publication of the final rule in the FEDERAL REGISTER]. * * * * *	Solid diluent

(f) [Reserved]

(g) *Minimal risk substances.* Unless specifically excluded, residues resulting

from the use of the following substances as either an inert or an active ingredient in a pesticide chemical formulation,

including antimicrobial pesticide chemicals, are exempted from the requirement of a tolerance under section

408 of the FFDCA if such use is in accordance with good agricultural or manufacturing practices.

(1) *Commonly-consumed food commodities.* "Commonly-consumed food commodities" means foods that are commonly consumed for their nutrient properties. The term "commonly-consumed food commodities" shall only apply to food commodities, whether a raw agricultural commodity or a processed commodity, in the form the commodity is sold or distributed to the public for consumption.

(i) Included within the term "commonly-consumed food commodities" are:

(A) Sugars such as sucrose, lactose, dextrose and fructose, and invert sugar and syrup.

(B) Spices such as cinnamon, cloves, and red pepper.

(C) Herbs such as basil, anise, or fenugreek.

(ii) Excluded from the term "commonly-consumed food commodities" are:

(A) Any food commodity that is adulterated under 21 U.S.C. 342.

(B) Both the raw and processed forms of peanuts, tree nuts, milk, soybeans, eggs, fish, crustacea, and wheat.

(C) Alcoholic beverages.

(D) Dietary supplements.

(2) *Animal feed items.* "Animal feed items" means all items derived from field crops that are fed to livestock, and meat meal. Meat meal is an animal feed composed of dried animal fat and protein that has been sterilized. Other than meat meal, the term "animal feed item" does not extend to any item designed to be fed to animals that contains, to any extent, components of animals.

(i) Included within the term "animal feed items" are:

(A) The hulls and shells of the commodities specified in paragraph (g)(1)(ii)(B) of this section, and cocoa beans.

(B) Bird feed such as canary seed.

(C) Any feed component of a medicated feed meeting the definition of an animal feed item.

(ii) Excluded from the term animal feed item are both the raw and processed forms of peanuts, tree nuts, milk, soybeans, eggs, fish, crustacea, and wheat.

(3) *Edible fats and oils.* Edible fats and oils means all edible (food or feed) fats and oils, derived from either plants or animals, whether or not commonly consumed, including products derived from hydrogenating (food or feed) oils, or liquefying (food or feed) fats.

Excluded from the term edible fats and oils are plant oils used in the pesticide

chemical formulation for their characteristic smell and/or taste and oils derived from the commodities specified in paragraph (g)(1)(ii)(B) of this section except to the extent such oils are highly refined.

4. Section 180.1071 is revised to read as follows:

§ 180.1071 Egg solids (whole); exemption from the requirement of a tolerance.

A time-limited tolerance exemption expiring [insert date 3 years from date of publication of the final rule in the **Federal Register**] is established for residues of whole egg solids (of at least feed grade quality) when used as an animal repellent in or on almonds and applied to the growing crop in accordance with good agricultural practices.

§ 180.1164 [Removed]

5. Section 180.1164 is removed.

§ 180.1194 [Removed]

6. Section 180.1194 is removed.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL-7127-6]

Washington: Proposed Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Washington has applied to EPA for final authorization of changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA has reviewed Washington's application and made the preliminary decision that these changes satisfy all requirements needed to qualify for final authorization, and is proposing to authorize the State's changes.

DATES: EPA will accept written comments on the Agency's preliminary decision to authorize changes to the State of Washington's hazardous waste management program which are received at the address below on or before February 14, 2002.

ADDRESSES: Send written comments to Nina Kocourek, U.S. EPA, Region 10, Office of Waste and Chemicals Management, 1200 Sixth Avenue, Mail Stop WCM-122, Seattle, WA 98101, phone, (206) 553-6502. You can

examine copies of the materials submitted by Washington during normal business hours at the following locations: EPA Region 10 Library, 1200 Sixth Avenue, Seattle WA 98101, phone, (206) 553-1289; and at the Washington Department of Ecology, 300 Desmond Drive, WA 98503; Ecology contact is Patricia Hervieux at (360) 407-6756.

FOR FURTHER INFORMATION CONTACT:

Nina Kocourek, U.S. EPA Region 10, Office of Waste and Chemicals Management, 1200 Sixth Avenue, Mail Stop WCM-122, Seattle, WA, 98101; (206) 553-6502. For general information available on the authorization process, see EPA's website at: <http://www.epa.gov/epaoswer/hazwaste/state/rcra>.

SUPPLEMENTARY INFORMATION:

A. Why Are Revisions to State Programs Necessary?

States which have received final authorization from EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to and consistent with the Federal program. States are required to have enforcement authority which is adequate to enforce compliance with the requirements of the hazardous waste program. Under RCRA section 3009, States are not allowed to impose any requirements which are less stringent than the Federal program. As the Federal program changes, States must change their programs and ask EPA to authorize the changes. Changes to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to EPA's regulations in Title 40 of the Code of Federal Regulations (CFR) parts 124, 260 through 266, 268, 270, 273 and 279.

B. What Decisions Have We Made in This Rule?

EPA has made the preliminary determination that Washington's program, as revised, meets the statutory and regulatory requirements established by RCRA. Therefore, we are proposing to grant Washington final authorization to operate its hazardous waste program with the changes described in the authorization application and as described in this proposed rule. Regulatory revisions which are less stringent than Federal program requirements and those regulatory revisions which are broader in scope than Federal program requirements will not be authorized.