(i) *Location.* All waters of Steilacoom Bay, from surface to bottom, extending out to a 1300 foot radius from the launch site at 47°10′24″ N, 122°36′12″ W.

(ii) *Effective time and date.* 8 p.m. to 10:30 p.m. on July 4, 2007.

(9) *4th of July Fireworks Show Safety Zone, Everett, WA:*

(i) *Location.* All waters of Possession Sound, from surface to bottom, extending out to a 1000 foot radius from the launch site at 47°59′00″ N, 122°14′35″ W.

(ii) *Effective time and date.* 10 p.m. to 11 p.m. on July 4, 2007.

(10) *Everett 4th of July Celebration Fireworks Safety Zone, Everett, WA:*

(i) *Location.* All waters of Port Gardner, from surface to bottom, extending out to a 1300 foot radius from the launch site at 47°59′56″ N, 122°14′22″ W.

(ii) *Effective time and date.* 10 p.m. to 11 p.m. on July 4, 2007.

(11) *Henderson Bay Fireworks Display Safety Zone, Gig Harbor, WA:*

(i) *Location.* All waters of Carr Inlet, from surface to bottom, extending out to a 700 foot radius from the launch site at 47°21′48″ N, 122°38′22″ W.

(ii) *Effective time and date.* 10 p.m. to 11 p.m. on July 4, 2007.

(12) *Vashon Island, Quartermaster Harbor Fireworks Safety Zone, WA:*

(i) *Location.* All waters of Quartermaster Harbor, from surface to bottom, extending out to a 1300 foot radius from the launch site at 47°24′00″ N, 122°27′00″ W.

(ii) *Effective time and date.* 10 p.m. to 11 p.m. on July 4, 2007.

(13) *Renton 4th of July Display Fireworks Safety Zone, Renton, WA:*

(i) *Location.* All waters of Lake Washington, from surface to bottom, extending out to a 400 foot radius from the launch site at 47°30′25″ N, 122°12′25″ W.

(ii) *Effective time and date.* 10 p.m. to 11 p.m. on July 4, 2007.

(14) *Three Tree Point Fireworks Safety Zone, Burien, WA:*

(i) *Location.* All waters of East Passage, from surface to bottom, extending out to a 400 foot radius from the launch site at 47°27′02″ N, 122°23′07″ W.

(ii) *Effective time and date.* 10 p.m. to 11 p.m. on July 4, 2007.

(15) *Yarrow Point 4th of July Fireworks Safety Zone, Yarrow Point, WA:*

(i) *Location.* All waters of Lake Washington, from surface to bottom, extending out to a 400 foot radius from the launch site at 47°39′45″ N, 122°13′30″ W.

(ii) *Effective time and date.* 10 p.m. to 11 p.m. on July 4, 2007.

(16) *WAMU Family 4th Fireworks Safety Zone, Seattle, WA:*

(i) *Location.* All waters of Lake Union, from surface to bottom, extending out to a 1000 foot radius from the launch site at 47°38′24″ N, 122°20′05″ W.

(ii) *Effective time and date.* 10 p.m. to 11 p.m. on July 4, 2007.

(17) *Haggens 4th July Blast Over Bellingham Bay Fireworks Safety Zone, Bellingham, WA:*

(i) *Location.* All waters of Bellingham Bay, from surface to bottom, extending out to a 1300 foot radius from the launch site at 48°44′58″ N, 122°29′34″ W.

(ii) *Effective time and date.* 10 p.m. to 11 p.m. on July 4, 2007.

(18) *Port Orchard 4th of July Fireworks Safety Zone, Port Orchard, WA:*

(i) *Location.* All waters of Port Orchard, from surface to bottom, extending out to a 1000 foot radius from the launch site at 48°32′53″ N, 122°37′55″ W.

(ii) *Effective time and date.* 9 p.m. to 11 p.m. on July 4, 2007.

(19) *Kirkland 4th of July Fireworks Safety Zone, Kirkland, WA:*

(i) *Location.* All waters of Lake Washington, from surface to bottom, extending out to a 700 foot radius from the launch site at 47°40′19″ N, 122°12′47″ W.

(ii) *Effective time and date.* 10 p.m. to 11 p.m. on July 4, 2007.

(20) *Lake Forest Park July 4th Fireworks Safety Zone, Lake Forest, WA:*

(i) *Location.* All waters of Lake Washington, from surface to bottom, extending out to a 400 foot radius from the launch site at 47°45′07″ N, 122°16′22″ W.

(ii) *Effective time and date.* 10 p.m. to 11 p.m. on July 4, 2007.

(21) *Mercer Island Summer Celebration Fireworks Safety Zone, Mercer Island, WA:*

(i) *Location.* All waters of Lake Washington, from surface to bottom, extending out to a 700 foot radius from the launch site at 47°35′31″ N, 122°13′14″ W.

(ii) *Effective time and date.* 10 p.m. to 11 p.m. on July 14, 2007.

(22) *Whaling Days Fireworks Safety Zone, Silverdale, WA:*

(i) *Location.* All waters of Dyes Inlet, from surface to bottom, extending out to a 800 foot radius from the launch site at 47°38′36″ N, 122°41′18″ W.

(ii) *Effective time and date.* 9 p.m. to 11 p.m. on July 27, 2007.

(23) *Barghausens Annual Fireworks Display Safety Zone, Olympia, WA:*

(i) *Location.* All waters of Case Inlet, from surface to bottom, extending out to a 1300 foot radius from the launch site at 47°11′20″ N, 122°50′00″ W.

(ii) *Effective time and date.* 9 p.m. to 11 p.m. on August 3, 2007.

(24) *Medina Days Fireworks Safety Zone, Medina, WA:*

(i) *Location.* All waters of Lake Washington, from surface to bottom, extending out to a 400 foot radius from the launch site at 47°36′53″ N, 122°14′93″ W.

(ii) *Effective time and date.* 10 p.m. to 11 p.m. on August 11, 2007.

(25) *ESAM Surprise Party Fireworks Safety Zone, Seattle, WA:*

(i) *Location.* All waters of Lake Washington, from surface to bottom, extending out to a 500 foot radius from the launch site at 47°38′37″ N, 122°20′08″ W.

(ii) *Effective time and date.* 10 p.m. to 11 p.m. on August 11, 2007.

(26) *Town and Country Markets Fireworks Safety Zone, Bainbridge, WA:*

(i) *Location.* All waters of Eagle Harbor, from surface to bottom, extending out to a 1300 foot radius from the launch site at 47°37′06″ N, 122°30′24″ W.

(ii) *Effective time and date.* 9 p.m. to 11 p.m. on August 25, 2007.

(b) *Definitions. Designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port.

(c) *Regulations.* In accordance with the general regulations in Section 165.23 of this part, no person or vessel may enter or remain in this zone unless authorized by the Captain of the Port or his designated representatives.

Dated: June 5, 2007.

Mark J. Huebschman,

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

[FR Doc. E7–11951 Filed 6–19–07; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0178; FRL–8132–9]

Lactofen; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a regional tolerance for residues of lactofen in or on vegetables, fruiting, group 08, and okra. Interregional Research Group Number 4 (IR–4)

requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective June 20, 2007. Objections and requests for hearings must be received on or before August 20, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2006–0178. 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 web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; e-mail address: *jackson.sidney@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 those engaged in the following activities:

- 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 to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The 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. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e–CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2006–0178 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before August 20, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2006–0178, by one of the following methods:

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

II. Petition for Tolerance

In the **Federal Register** of April 12, 2006 (71 FR 18744) (FRL–7773–3), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5E6930) by IR–4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.432 be amended by establishing a tolerance for residues of the herbicide, lactofen, (1-(carboethoxy) ethyl 5-2-chloro-4-(trifluoromethyl) phenoxy-2-nitrobenzoate), in or on vegetable, fruiting, and okra at 0.01 parts per million (ppm). That notice referenced a summary of the petition prepared by Valent U.S.A. Corporation, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of the FFDCA defines ''safe'' 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.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .'' These provisions were added to the FFDCA by the Food Quality Protection Act (FQPA) of 1996.

Consistent with section 408(b)(2)(D) of the FFDCA, and the factors specified in section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned for tolerance for residues of lactofen in/ on vegetables, fruiting, group 08, at 0.02 ppm and okra at 0.02 ppm . EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their 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. Specific information on the studies received and the nature of the adverse effects caused by lactofen as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in support documents to this action under Docket ID number EPA–HQ–OPP–2006–0178.

B. 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 NOAEL in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the LOAEL doseof concern are identified is sometimes used for risk assessment. Uncertainty/safety factors (UF) 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 aggregate 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 uncertainty/safety factors. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable uncertainty/safety factors is not exceeded.

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/fedrgstr/EPA-PEST/1997/November/Day-26/p30948.htm*.

A summary of the toxicological endpoints for lactofen used for human risk assessment can be found at www.regulations.gov in document ''Lactofen: Human Health Risk Assessment for Proposed Uses of Fruiting Vegetables and Okra'' at page number 13 in docket ID number EPA–HQ–OPP–2006–0178. To locate this information on the Regulation.gov website follow these steps:

- Select ''Advanced Search'', then ''Docket Search.''
- In the ''Docket ID number'' field type the docket number in the following format - ''OPP-year-docket number'' e.g., OPP-2005–9999).
- Click the ''Submit'' button.
- Click on the docket to open.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to lactofen, EPA considered exposure under the petitioned-for tolerances as well as all existing lactofen tolerances in (40 CFR 180. 432). Exposure assessment also considered exposures as a result of acifluorfen, an environmental degrade of lactofen.

EPA assessed dietary exposures from lactofen in food 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.

The Agency did not identify an endpoint for an acute dietary exposure assessment for the general population due to the lack of toxicological effects of concern attributable to a single exposure (dose) in studies available in the data base including oral developmental toxicity studies in rats and rabbits. An acute dietary exposure assessment was conducted for the population subgroup, female ages 13-49, only. In estimating acute dietary exposure, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03), which incorporates consumption data from United States Department of Agriculture (USDA) Continuing Surveys of Food Intakes by Individuals (CSFII), 1994–1996 and 1998. As to residue levels in food, EPA assumed all foods for which there are proposed or existing tolerances were treated and contain tolerance-level residues.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the DEEM/FCID™, Version 2.03, which incorporates food consumption data from USDA's 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intakes by Individuals (CSFII). The chronic dietary analysis assumed all crops for which there are proposed or existing tolerances were treated and contain tolerance-level residues.

iii. *Cancer*. Lactofen has been classified as ''not likely'' to be carcinogenic in humans because of available data on lactofen support activation of the peroxisome proliferator activated receptor alpha (PPARα) as the mode of action which induced liver tumors in rodents. While the proposed mode of action for liver tumors in rodent is qualitatively possible in humans, it is quantitatively implausible and unlikely to take place in humans based on quantitative species toxicodynamic differences in PPARα activation. The quantification of risk is not required.

iv. *Exposure assessment for acifluorfen*. Lactofen degrades in the environment to acifluorfen. Sodium acifluorfen is a registered agricultural pesticide. Accordingly, an aggregate assessment for acifluorfen exposure resulting from both use of lactofen and sodium acifluorfen was also conducted. As to residue levels of acifluorfen in food from use of sodium acifluorfen, EPA assumed all foods for which there are tolerances were treated and contain tolerance level residues.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient

monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for lactofen in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the environmental fate characteristics of lactofen. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

The drinking water assessment of lactofen is complicated by the fact that lactofen has a major degradate in common with another registered herbicide, sodium acifluorfen. Lactofen and sodium acifluorfen also have common use sites. The Agency considered the contribution of acifluorfen as an environmental degradate of lactofen and from sodium acifluorfen in the aggregate assessment. The drinking water residues used in the dietary risk assessment were incorporated directly into this dietary exposure from drinking water assessment. Therefore, EPA estimated drinking water concentrations for both lactofen and acifluorfen from lactofen applications. Water residues were incorporated into DEEM-FCID as the food categories ''water, direct, all sources'' and ''water, indirect, all sources.''

The Tier 2 surface water estimated drinking water concentrations (EDWCs) and estimated environmental concentrations (EECs) for lactofen and acifluorfen were generated with standard Florida pepper and Florida tomato cropping scenarios using EPA's pesticide root zone model (PRZM3) and EXAMS. PRZM simulates pesticide fate and transport as a result of leaching, direct spray drift, runoff and erosion from an agricultural field and EXAMS estimates environmental fate and transport of pesticides in surface water body for a 30–year period (1961–1990). The EDWCs and EECs assessment for surface water uses single or multiple sites which typically represent a high-end exposure scenario from pesticide use on a particular cropped or non-cropped site. Ground-water concentrations were estimated using the Tier 1 screening model screening concentration in ground water (SCI-GROW). The models and its description are available at EPA internet site: *http://www.epa.gov/oppefed1/models/water/*.

Based on the PRZM3/EXAMS model, the EDWCs in surface water (lactofen and the acifluorfen derived from lactofen) for acute exposures are estimated to be 1.48 parts per billion (ppb) and 22.5 ppb for lactofen and acifluorfen, respectively, and for chronic exposures 0.044 ppb and 3.9 ppb for lactofen and acifluorfen, respectively. By comparison, the EDWC for chronic exposure for acifluorfen derived from sodium acifluorfen use on soybeans is 3.3 ppb.

For ground water, the SCI-GROW estimates of lactofen and acifluorfen EDWCs from application of lactofen for both acute and chronic exposures are 0.006 ppb lactofen and 2.0 ppb acifluorfen. By comparison, the SCI-GROW estimate of acifluofren EDWCs in ground water from applications of sodium acifluorfen is 3.67 ppb.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the lactofen acute dietary risk assessment, the water concentration value of 1.48 ppb was used to assess the contribution to drinking water. For the lactofen chronic dietary risk assessment, the water concentration of value 0.044 ppb was used to assess the contribution to drinking water. For the acifluorfen acute dietary risk assessment, the water concentration value of 22.5 ppb was used to assess the contribution to drinking water. For the acifluorfen chronic dietary risk assessment, the water concentration of value 3.9 ppb was used to assess the contribution to drinking water. Acifluorfen from lactofen and sodium acifluorfen were not combined because they are not expected to be used in the same area.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

There are no products containing lactofen as an active ingredient that are registered for use in a residential or other non-occupational setting. No residential exposure assessment is required.

Residential exposures to the environmental degradate acifluorfen may occur as a result of the use of sodium acifluorfen, which has registered residential spot treatment uses. The only scenario for residential exposure is a short-term spot treatment. Due to the frequency, duration and location of residential spot treatment applications, the Agency considered exposure to adults applying sodium acifluorfen and does not anticipate post-application dermal exposures.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Lactofen is a member of the diphenyl ether chemical family. The common toxicity that these compounds share is induction of liver effects (liver hypertrophy, increase in liver weight, tumors). Members of this class have been shown to induce rodent liver effects /tumors through the activation of the PPARα. It should be noted that liver hypertrophy and increases in liver weight are part of the range of morphological changes that result from chemically-mediated effects on the PPARα receptor and hepatocarcinogenesis. Although PPARα agonists can induce liver rodent tumors, the potential for PPARα agonists to induce liver tumors in other species, including humans, appears to be unlikely. This is because evidence shows that these other species are quantitatively less sensitive to the effects of PPARα agonism due to toxicodynamic differences between the human and rodent nuclear PPARα receptor. Thus, while this mode of action for liver tumors in rodent is qualitatively possible in humans, it is quantitatively implausible and unlikely to take place in humans. Accordingly, although members of the diphenyl ether family as well as other classes of compounds may share a common hepatocarcinogenic mode of action, cumulative exposure to PPARα agonists is unlikely to induce liver carcinogenesis in humans.

For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408 of the 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 data base 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/safety factors and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity*. Although there is qualitative evidence of increased susceptibility in the prenatal developmental studies in rats and rabbits, the Agency did not identify any residual uncertainties after establishing toxicity endpoints and traditional uncertainty factors to be used in the risk assessment of lactofen. The degree of concern for prenatal and postnatal toxicity is low.

3. *Conclusion*. Several factors weighed in favor of the conclusion that no additional safety factor is needed to protect the safety of infants and children.

- There are no outstanding data gaps for developmental toxicity or reproductive toxicity studies;
- There are no residual uncertainties regarding prenatal and postnatal toxicity; and
- There are no residual uncertainties regarding the exposure of infants and children to lactofen.

Nonetheless, EPA determined that an additional safety factor was needed to address the lack of a NOAEL in the rabbit developmental study. Although sufficient reliable information has been submitted on developmental effects of lactofen in rabbits, no NOAEL was identified in one of the two rabbit developmental studies submitted. The endpoints of concern identified in available studies are: Decreased live young/litter, increased embryonic death/litter, and increased incidence of post-implantation loss. These effects were noted at all dose levels (5, 15, 50 mg/kg/day) thus a NOAEL was not established. Consequently, a LOAEL to NOAEL factor is appropriate and the risk assessment applies a 3X uncertainty factor. A FQPA uncertainty factor of infants and children and will be used for the LOAEL to NOAEL extrapolation. The 3X factor is considered to be protective because the incidence of the effects at the lowest dose tested was only marginally higher than the historical controls.

For sodium acifluorfen, the available toxicology database provides sufficient information for selecting various toxicity endpoints and doses for assessing the risks. The Agency evaluated the hazard and exposure data for sodium acifluorfen and recommended retaining the safety factor at 10X due to the data gap for the developmental neurotoxicity study in rats. In accordance with the current EPA policy, the 10x factor will be applied to all exposure durations.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate 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 uncertainty/safety factors. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-term, intermediate-term, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable uncertainty/safety factors is not exceeded.

1. *Acute risk*. Acute (1–day) exposures to lactofen may result from consuming treated food and drinking water. No endpoints were identified for the general population so the only assessment was conducted for females ages 13-49. The results of the acute aggregate assessment for lactofen for food and drinking water show that all exposures are below the level of concern, with the lactofen assessments at less than 1% of the aPAD.

The acute aggregate assessment for acifluorfen includes food exposure from tolerance level residues (from sodium acifluorfen applications) and water exposures of acifluorfen as an environmental degradate of lactofen. No acute endpoints were identified for the general population so the only assessment was conducted for females ages 13-49. All exposures are below the level of concern, with the acifluorfen assessments at 6% of the aPAD.

Both the lactofen and acifluorfen assessments are likely to be overestimates of risk because they assume all of the crops (for which there are registered uses) consumed in the U.S. are treated and bear tolerance-level residues.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to lactofen from food and water will utilize <1% of the cPAD for all the population subgroups. There are no residential uses for lactofen that result in chronic residential exposure to lactofen.

The results of the long-term aggregate assessment for acifluorfen show that for food and drinking water, all exposures are below the level of concern. The most highly exposed subgroup in the acifluorfen assessment at 37% of the cPAD was infants, less than 1–year old.

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Lactofen is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water.

An aggregate assessment was conducted for exposure to acifluorfen. Registered residential uses of sodium acifluorfen include spot treatments only. The short term endpoint selected applies to females ages 13-49, but is protective of all populations. The acifluorfen aggregate assessment for this exposure duration includes the average food exposure assuming tolerance level residues, average water exposure (acifluorfen as an environmental degradate of lactofen), and residential handler exposures. The MOE for the aggregate assessment is 16,000, which exceeds the target MOE of 1,000. Therefore, the acifluorfen short term aggregate risks are not of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term assessment is not required for lactofen as there are no residential uses of lactofen.

Intermediate-term exposure is not expected for acifluorfen because residential uses of sodium acifluorfen are limited to spot treatments that do not include broadcast application to lawns.

5. *Aggregate cancer risk for U.S. population*. For the reasons discussed in Unit III.C.1.iii. the chronic aggregate assessments are protective of the carcinogenic effects for both lactofen and acifluorfen.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to lactofen residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Acceptable gas chromatography with electron capture detection (GC/ECD) methods are available in the Pesticide Analytical Manual (PAM) Vol. II for the enforcement of tolerances of lactofen and metabolites in plant commodities. A modified version of Method B is listed in the EPA Index of Pesticide Analytical Methods under lactofen. Samples from the pepper and tomato field trials were analyzed using established GC/ECD enforcement methods or modified versions of established enforcement methods. The validated limits of quantitation (LOQs) were 0.01 ppm for peppers and 0.02 ppm from all other trials. The methods are adequate for data collection based on acceptable method validation and concurrent recovery data.

B. International Residue Limits

There are no established or proposed Codex, Canadian, or Mexican maximum residue limits (MRLs) for lactofen in any crops. Therefore, there are no international compatibility issues with respect to U.S. tolerances.

V. Conclusion

Therefore, the regional tolerance is established for residues of [the herbicide lactofen, 1-(carboethoxy)ethyl 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate, in or on the following raw agricultural commodities: Vegetables, fruiting, group 8 at 0.02 ppm, and okra at 0.02 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. 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). Because this rule has been exempted from review under Executive Order 12866, this 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule 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).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule 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* (65 FR 67249, November 6, 2000) do not apply to this rule. In addition, this rule does not 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).

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).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: June 7, 2007.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is 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 180.432 is amended by adding text to paragraph (c) to read as follows:

§ 180.432 Lactofen; tolerances for residues.

* * * * *

(c) *Tolerances with regional registrations.* Tolerances with regional registrations, as defined in 180.1(n) are established for residues of the herbicide, lactofen, 1-(carboethoxy)ethyl 5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-nitrobenzoate, in or on the following food commodities:

Commodity	Parts per million
Okra	0.02
Vegetables, fruiting, group 08	0.02

* * * * *

[FR Doc. E7–11797 Filed 6–19–07; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2006–0968; FRL–8135–5]

Imidacloprid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, all expressed as the parent, in or on peanut, peanut hay and peanut meal; pearl millet grain, forage, hay and straw; proso millet grain, forage, hay and straw; kava roots and leaves; raspberry, wild; soybean forage and hay; and aspirated grain fractions. It also amends existing tolerances for combined residues of imidacloprid and its metabolites containing the 6-chloropyridinyl moiety in or on caneberry subgroup 13-A and soybean seed. Bayer CropScience LLC and Interregional Research Project No. 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). This regulation also corrects a typographical error in the commodity term for the existing tolerance on the herbs subgroup, fresh herbs.

DATES: This regulation is effective June 20, 2007. Objections and requests for hearings must be received on or before August 20, 2007, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2006–0968. 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 web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*,or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Barbara Madden, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6463; e-mail address: *madden.barbara@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 those engaged in the following activities:

- 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 to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The 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. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of the FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2006–0968 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before August 20, 2007.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2006–0968, 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.