governments were considered in the development of this final rule. Since the issues identified by tribal governments were not unique to their concerns, EPA has addressed these issues generally in its response to comments.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

Executive Order 13045: ''Protection of Children From Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This regulation is not subject to Executive Order 13045 because it is not economically significant as defined under E.O. 12866, and because the Agency does not have reason to believe that it addresses environmental health and safety risks that present a disproportionate risk to children. Today's rule would simply clarify Congress' intent that water transfers generally be subject to oversight by water resource management agencies and State non-NPDES authorities, rather than the permitting program under section 402 of the CWA.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Further, EPA has concluded that this rule is not likely to have any adverse energy effects.

I. National Technology Transfer and Advancement Act

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) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standard bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This rule does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations.

Executive Order (EO) 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations. Today's rule would simply clarify Congress' intent that water transfers generally be subject to oversight by water resource management agencies and State non-NPDES authorities, rather than the permitting program under section 402 of the CWA.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. section 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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 the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective August 12, 2008.

List of Subjects in 40 CFR Part 122

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous substances, Reporting and recordkeeping requirements, Water pollution control.

Dated: June 9, 2008.

Stephen L. Johnson,

Administrator.

■ For the reasons set forth in the preamble, chapter I of title 40 of the Code of Federal Regulations is amended as follows:

PART 122—EPA ADMINISTERED PERMIT PROGRAMS: THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

■ 1. The authority citation for part 122 continues to read as follows:

Authority: The Clean Water Act, 33 U.S.C. 1251 *et seq.*

■ 2. Section 122.3 is amended by adding paragraph (i) to read as follows:

§ 122.3 Exclusions.

* * * * *

(i) Discharges from a water transfer. Water transfer means an activity that conveys or connects waters of the United States without subjecting the transferred water to intervening industrial, municipal, or commercial use. This exclusion does not apply to pollutants introduced by the water transfer activity itself to the water being transferred.

[FR Doc. E8–13360 Filed 6–12–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0596; FRL–8367–7]

(Z)-7,8-epoxy-2-methyloctadecane (Disparlure); Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the (Z)-7,8-epoxy-2-methyloctadecane on all food and feed crops when used to treat trees, shrubs, and pastures resulting in unintentional spray and drift from application as well as unintentional

spray and drift to non-target vegetation including non-food, food, and feed crops. Aberdeen Road Company d/b/a Hercon Environmental submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of (Z)-7,8-epoxy-2-methyloctadecane. This active ingredient (AI) is also known as Disparlure.

DATES: This regulation is effective June 13, 2008. Objections and requests for hearings must be received on or before August 12, 2008, 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–2007–0596. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. 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: Andrew Bryceland, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6928; e-mail address: *bryceland.andrew@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. 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 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, as amended by FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. 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–2007–0596 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 on or before August 12, 2008.

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 your copies, identified by docket ID number EPA–HQ–OPP–2007–0596, 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. Background and Statutory Findings

In the **Federal Register** of August 1, 2007 (72 FR 42070) (FRL–8141–5), 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 tolerance petition (PP 6F7141) by Aberdeen Road Company d/b/a Hercon Environmental, P.O. Box 453, Emigsville, PA 17318–0435. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of (Z)-7,8-epoxy-2-methyloctadecane. This notice included a summary of the petition prepared by the petitioner Aberdeen Road Company d/b/a Hercon Environmental.

There was only one comment received in response to the notice of filing. The commenter suggested that there should not be an exemption for (Z)-7,8-epoxy-2-methyloctadane because the commenter felt that ''plants should not have to grow with toxic chemicals on them;'' that the Agency ''is not protecting the public health of the American public which is dying from all kinds of cancers;'' and further of not properly evaluating pesticides in general.

Agency Response: (Z)-7,8-epoxy-2-methyloctadecane is a naturally

occurring substance produced by the female gypsy moth (*Lymantria dispar*) as a pheromone to attract the male gypsy moth. The activity of this pesticide is specific to the Gypsy moth, and when applied to forests, it confuses the male gypsy moth searching for a mate; this reduces the moth population's ability to successfully reproduce itself without killing individuals in the population. The Agency's assessment of the naturally occurring pheromone's specific, non-toxic mode of action, its low acute toxicity and exposure profiles (see Unit III.), and its intended non-food uses indicate negligible dietary risks associated with the unintended application of (Z)-7,8-epoxy-2-methyloctadecane to areas adjacent to agricultural areas (Refs. 2 and 3).

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of 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. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require 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.... '' Additionally, section 408(b)(2)(D) of FFDCA requires that 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.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information 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.

The AI, (Z)-7,8-epoxy-2-methyloctadecane (also known as Disparlure), is an aliphatic hydrocarbon compound containing 19 carbons and a single epoxide bond. It is a naturally occurring lepidopteran pheromone produced by female gypsy moths (*Lymantria dispar*) to attract males. When used as a pesticide, the pheromone is intended to disrupt mating by disorienting males during their in-flight search for females. (Z)-7,8-epoxy-2-methyloctadecane was registered by the Agency in 1986 as a non-food use pesticide to lower the incidences of gypsy moth mating in residential, municipal, and shade tree areas; recreational areas such as campgrounds, golf courses, parks and parkways; ornamental and shade tree forest planting; shelter belts, rights of way and other easements. While (Z)-7,8-epoxy-3-methyloctadecane is not intended to be sprayed directly on food or feed crops, the Agency has expressed concern that there may be a potential for regular and significant exposure from residues of the pesticide on food and feed crops as a result of unintentional spray or drift. Therefore, at the recommendation of the Agency, a request to establish an exemption for the requirement of a tolerance has been made by the applicant.

This tolerance exemption is supported by toxicity data on a structurally related substance, epoxylated soybean oil (ESO), in anticipation of frequent and significant exposure to food and feed crops near treated areas. All the data normally required to support a tolerance exemption are not available for (Z)-7,8-epoxy-2-methyloctadecane; therefore, the data on ESO was submitted to address concerns about inadvertent residues on food or feed crops. The Agency has agreed to consider the toxicity data on epoxylated soybean oil, since it is chemically similar to (Z)-7,8-epoxy-2-methyloctadecane (Disparlure), and the data requirements normally required for a food use can support an assessment of potential dietary risks associated with possible residues of the pesticide from spray drift (Refs. 1, 2 and 3).

Historically the AI, (Z)-7,8-epoxy-2-methyloctadecane, has been used as a non food use pesticide and, therefore, no data that address the data requirements required by the Agency in support of food use pesticides have been generated using this AI. Therefore, in order to satisfy these data requirements and address the issue of whether or not food and feed crops that are inadvertently affected by residues of (Z)-7,8-epoxy-2-methyloctadecane are safe, the Agency has bridged from toxicity data generated on a structurally related substance, epoxylated soybean oil, to both satisfy the food use toxicity data requirements for (Z)-7,8-epoxy-2-methyloctadecane and to conduct a risk assessment. As stated in this Unit, data normally required for a food use can support an assessment of potential dietary risks associated with possible residues of the pesticide from spray drift (Refs. 1 and 3).

ESO is a compound that is structurally related to (Z)-7,8-epoxy-2-methyloctadecane and has already been fully assessed by the Agency as an inert ingredient. ESO and (Z)-7,8-epoxy-2-methyloctadecane are similar, from a structural perspective, in that both compounds contain one or more epoxide bonds, thus the basis for the Agency's decision to allow the bridging of toxicity data from ESO to (Z)-7,8-epoxy-2-methyloctadecane. Epoxide bonds are three-membered rings, made up of 2 carbons and 1 oxygen, bonded together in a triangular shape. The epoxide bond is very unstable in the environment and this instability makes the bond very reactive such that it reacts to whatever is in the environment (i.e. proteins, nucleophiles) (Refs. 3 and 4). This information is key in determining the potential risks to the (Z)-7,8-epoxy-2-methyloctadecane compound since it is the reactive epoxide groups in both compounds that mostly contribute to the toxicological activity itself (Refs. 3 and 4). Epoxides in general are formed outside of the body (environmental epoxides) or they are synthesized in the body. Environmental epoxides are generally less toxic than epoxides that are synthesized in the body (Refs. 3 and 4). Both epoxides behave in the environment in the same way. The epoxide content of (Z)-7,8-epoxy-2-methyloctadecane is double that of ESO. While this information does suggest that (Z)-7,8-epoxy-2-methyloctadecane could be more reactive than ESO, this potential toxicity is essentially attributed to the fact that (Z)-7,8-epoxy-2-methyloctadecane has more epoxide groups (16%) than ESO (8%). Even

though there are more reactive epoxide groups that belong to (Z)-7,8-epoxy-2-methyloctadecane, these reactive epoxides are environmental epoxides (i.e. found outside the body), and based on the literature, and as stated in Unit IV., the second paragraph, environmental epoxides are less toxic than those synthesized in the body (Refs. 3 and 4).

As stated in this Unit, environmental epoxides, such as (Z)-7,8-epoxy-2-methyloctadecane react in the environment. When the AI is released into the environment the epoxide groups of the AI will most likely interact with nucleophilic sites in the environment, such as proteins in food, and will not be absorbed in their active form (Refs. 3 and 4). Based on the behavior of environmental epoxides, such as this AI, the Agency has extrapolated the potential risks (if any) to humans and animals from consuming food and/or feed commodities the contain residues of (Z)-7,8-epoxy-2-methyloctadecane as a result of indirect or unintended spray or drift. The Agency has determined that even if residues of the AI were to occur on food/feed commodities, the reaction of epoxides in (Z)-7,8-epoxy-2-methyloctadecane (Disparlure) would in all probability react with proteins (such as those already found in foods) during digestion and would not be absorbed in their active form to cause any toxicological effects (Refs. 3 and 4). Additionally, there are also a number of ways the body can detoxify epoxides like Disparlure if they are absorbed in an active form (Ref. 4). These are:

1. Spontaneous decomposition,
2. Nonenzymatic reaction with glutathione,
3. Reaction with glutathione catalyzed by glutathione transferase,
4. Hydration by epoxide hydrolase, and
5. Minor mechanisms such as cytochrome P450 hydrolysis (Refs. 3 and 4).

Further, acute oral toxicity studies on both substances indicated that their toxicity is low (Toxicity Category IV) which is consistent with these general characteristics of environmental epoxides. Therefore, use of toxicity data on ESO to define endpoints for the assessment of dietary exposure estimates associated with inadvertent treatment of food or feed crops with (Z)-7,8-epoxy-2-methyloctadecane (Disparlure) is reasonable. ESO data - including application of maximum uncertainty factors - define endpoints used in risk characterization for (Z)-7,8-epoxy-2-methyloctadecane, and data requirements to support the petition for exemption from the requirement of tolerances for the AI have been waived by the Agency based on the negligible risks described in this Unit.

A. Acute Toxicity

Acute oral toxicity (rat) (OPPTS GLN 870.1100): Based on acute oral toxicity studies in rats, (Z)-7,8-epoxy-2-methyloctadecane has very low toxicity and is classified into Toxicity Category IV. No adverse effects or deaths were seen in rats that received an oral dose of undiluted (Z)-7,8-epoxy-2-methyloctadecane at 5,000 milligram per kilogram of bodyweight (mg/kg/bw) (Master Record Identification (MRID) Number 45529801). ESO also has very low acute oral toxicity lethal dose $(LD)_{50}$ > 5,000 mg/kg (Toxicity Category IV; Refs. 2 and 3).

B. Chronic Toxicity and Carcinogenicity (OPPTS GLN 870.3100; 870.4100 and 870.4200)

Information from *The Scientific Panel on Food Additives (European Commission on Food Safety)* was considered which included a two–year chronic oral toxicity study in rats given diets containing up to 5% ESO. The no observed adverse effect level (NOAEL) was approximately 140 mg/kg/day and the lowest observed adverse effect level (LOAEL) was approximately 1,400 mg/kg/day. Observed effects were slight changes in liver, kidney and uterus weights. The published summary also concluded that ESO was not carcinogenic when fed to rats. Based on the data, a tolerable daily intake of 1 mg/kg/day was determined for ESO (Refs. 1, 2, and 3).

C. Developmental Toxicity (OPPTS GLN 870.3700 and 870.3800)

The European Food Safety Authority (EFSA) report (2004) also described a developmental toxicity study in which ESO was given to pregnant rats during gestation at daily oral doses of 0, 100, 300 or 1,000 mg/kg/day (Ref. 1). No maternal or developmental effects were noted at any dose level according to the summary submitted (Ref. 3).

D. Reproductive Toxicity (OPPTS GLN 870.3800)

The EFSA review indicated that ESO was administered daily by oral gavage to rats at the 100, 300 and 1,000 mg/kg bw/day dose levels for 71 and 15 days before mating in males and females, respectively, until day 21 post-partum of F1 litters; no toxic effects were noted in parental animals or their offspring (Ref. 1). Under the experimental conditions, the highest tested dose of 1,000 mg/kg bw/day was found to be the NOAEL, and no LOAEL was reported (Ref. 3).

E. Genotoxicity (OPPTS GLN 870.5000; MRID 45309502)

A bacterial reverse mutation assay using *Salmonella typhimurium* and *Escherichia coli* was conducted on (Z)-7,8-epoxy-2-methyloctadecane with and without activation. The study concluded that (Z)-7,8-epoxy-2-methyloctadecane was not mutagenic in bacteria under the conditions of the study.

F. Hazard Characterization

In assessing the hazard associated with (Z)-7,8-epoxy-2-methyloctadecane, its has been characterized in terms of epoxylated soybean oil. All toxicological effects were observed at or above limit doses (≥5,000 mg/kg/bw for acute oral toxicity and ≥1,000 mg/kg/bw/day for reproductive, developmental and chronic toxicity studies) (Ref. 3). Based upon the Agency's standard hazard assessment protocol, if there is an incomplete data set for assessment of developmental toxicity (studies in two species) and a one-generation reproduction toxicity study (rather than a multi-generation reproduction study), an uncertainty factor of 3X is retained for consideration of the sensitivity of infants and children (Ref. 3). Moreover, there is uncertainty regarding the structure-activity relationship between Disparlure and ESO (16% versus 7–8% epoxide by weight, respectively) and the lack of repeated-dose studies on both substances to adequately support bridging from ESO data to Disparlure (at least one repeated-dose study on both substances) for purposes of assessing the dietary risks associated with use of the mating disruptor (Ref. 3). To account for this, an additional 10X uncertainty factor is applied (Ref 3). Therefore, the 1,000 mg/kg/day endpoint was divided by 1,000 for general population risk characterizations (uncertainty factors of 10X for interspecies extrapolation, 10X for intraspecies variation, and 10X for uncertainties regarding bridging from data on a surrogate substance) to determine a reference dose (RfD) of 1 mg/kg/day; a population adjusted dose (PAD) of 0.33 mg/kg/day for infants and children is determined when the FQPA safety factor (3X) is retained (Ref. 3).

Comparing this with the maximum estimated exposure for pesticidal use of Disparlure, the result does not exceed the Agency's level of concern (LOC) because the estimated exposure is less than 1% of the RfD (Ref. 3). Based on the behavior of epoxides in the environment and during ingestion, we conclude that toxicologically significant

residues will not result (refer to Unit III.; Refs. 3 and 4). Even when the maximum potential for inadvertent residues from the non-food uses of this pesticide are compared with the most conservative estimate of hazard, there is reasonable certainty that no harm will result to the U.S. population from exposure to this pesticide when used according to label instructions (Ref. 3). In the event that a food-use is requested, the Agency would require repeated-dose studies such as a 90–day subchronic feeding study (OPPTS 870.3100) and a prenatal developmental toxicity study (OPPTS 870.3700) on Disparlure.

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

In general, the epoxide (oxirane ring formed by an oxygen and two carbon atoms) is the reactive group in (Z)-7,8-epoxy-2-methyloctadecane and other epoxides, and is expected to contribute the most to biological or toxicological activity of (Z)-7,8-epoxy-2-methyloctadecane (Ref. 4; see Ref. 3). The unstable oxirane ring can open and react with DNA, protein, or other nucleophilic substances. This means that if (Z)-7,8-epoxy-2-methyloctadecane were to be ingested then most likely the epoxide would react with the proteins in food during digestion (i.e. it would be digested). As stated in the literature (deBethizy and Hayes (Ref. 4), epoxides formed in animals are apparently more toxic than those present in the environment because they react with proteins and DNA in the animal's tissue (Refs. 3 and 4). If the AI were to result on food/feed commodities, the epoxide or reactive group of that AI is more likely to break down and react with nucleophiles and proteins that are found in food and would not be absorbed in their active form (Refs. 3 and 4). However, even if they are absorbed in their active form, epoxides can be detoxified in the human body via:

1. Spontaneous decomposition,
2. Nonenzymatic reaction with glutathione,
3. Reaction with glutathione catalyzed by glutathione transferase,
4. Hydration by epoxide hydrolase, and
5. Minor mechanisms such as cytochrome P450 hydrolysis (Ref.s 3 and 4).

In general, these considerations are expected to reduce the potential risk.

A. Dietary Exposure

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and on all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

Given the use pattern of this AI, residues of the AI on food/feed crops as a result of unintentional spray or drift, as stated throughout this document, is not expected. However, the Agency has determined that even if residues of the AI were to occur on food/feed commodities, the reactive groups of the active would not be absorbed in their active form to cause any toxicological effects. While it is reasonable to assume that no toxicological effects would occur given the unliklihood of absorption and the low toxicity of the AI, the EPA has further examined the potential for dietary exposure from unintentional spray or drift and absorption and has estimated the potential risks (if any) to humans, including infants and children, from the consumption of food commodities that have been inadvertently treated with the AI. Assuming that dietary exposure has occurred the Agency considered potential exposure estimates for two representative scenarios including pasture grass and apple orchards.

1. *Food* — i. *Apples*. The Agency used apples as one representative in conducting its food assessment since apples are a significant commodity by a sensitive subpopulation (infants and children). For the apple exposure analysis, the Agency obtained a kg apples/A value from U.S. Department of Agriculture (USDA) statistics and used the worst-case application rate of 60 grams (g) (Z)-7,8-epoxy-2-methyloctadecane/Acre (A) (two applications of 30 g/A per season) for an apple orchard (unintentional application). The maximum potential concentration of (Z)-7,8-epoxy-2-methyloctadecane was estimated to be 6 mg/AI/kg of apples (i.e., 6 parts per million (ppm); Ref 3). This 6 ppm value is an overestimate because its determination assumes: All the (Z)-7,8-epoxy-2-methyloctadecane is directly applied to an apple orchard (a misuse) and all of the AI applied will be on or in the apples (not sticking to foliage or other inedible plant parts). (Z)-7,8-epoxy-2-methyloctadecane residues are also likely to be reduced by their reactivity, the AI's physical/chemical properties, and washing or processing treated apples before their consumption (Ref. 3).

Based on the amount of the AI/kg of crop it was determined that the amount of (Z)-7,8-epoxy-2-methyloctadecane consumed from treated apples for the general population, children, and adults would be 0.005, 0.03 and 0.002 mg/A.I./kg/bw per day, respectively (Ref. 3). As noted in the introduction to this Unit IV. Aggregate Exposures, by the time Disparlure-treated apples are consumed, the epoxides in the AI are likely to have broken down or reacted with nucleophiles such as proteins in the apples and would not be absorbed in their active form (Refs. 3 and 4).

ii. *Pasture*. A pasture grass exposure analysis was presented in the applicant's petition, which was based on maximum recommended single application rates (30 g/AI/A) and a model for estimating potential exposure for grazing cattle (described at *http://www.epa.gov/oppefed1/ecorisk_ders/toera_analysis_exp.htm*). The largest estimate was determined to be 0.14 mg Disparlure/kg cattle body weight per day (Ref. 3). This estimate of the potential exposure was based on the assumption that all the Disparlure applied to an acre of short grass would be consumed as if the AI was intentionally applied to the pasture rather than drifting from a nearby treated area (Ref. 3). A more realistic assumption in the exposure analysis was that 10% or less of the pasture grass would be impacted by spray drift, thereby reducing the exposure estimate to 0.014 mg Disparlure/kg cattle bw/day (Ref. 3). Also, applications in any given area would not be done more than one or two days each year which further reduces the potential exposure to cattle. As noted in the second paragraph of Unit IV., the metabolic pathways that break down epoxides in animals are expected to further reduce the potential for dietary exposure preventing detection or bioaccumulation of Disparlure residues in cattle feeding on inadvertently treated pasture grass. Therefore, a dietary assessment for meat, milk and meat by-products was not conducted by the Agency (Ref 3).

2. *Drinking water exposure*. Exposure to residues of (Z)-7,8-epoxy-2-methyloctadecane in consumed drinking water is unlikely because of the reactivity of such epoxides in the environment (see discussion under Unit IV. Aggregate Exposure; Refs. 3 and 4),

and the AI is not directly applied to water. Therefore, drinking water exposure is not expected to pose any quantifiable risks due to a lack of residues of toxicological concern.

B. Other Non-Occupational Exposure

There are no residential, school, or day care uses proposed for (Z)-7,8-epoxy-2-methyloctadecane (Disparlure). Since the proposed use is for agricultural non-food crops the potential for non-occupational, non-dietary exposures to (Z)-7,8-epoxy-2-methyloctadecane by the general population, including infants and prolonged inhalation exposure to non-sticking flakes in unlikely (Ref. 2).

V. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish an exemption from 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.'' These considerations include the possible cumulative effects of such residues on infants and children. EPA has considered the potential for cumulative effects of (Z)-7,8-epoxy-2-methyloctadecane and other substances in relation to common mechanism of toxicity. Common mechanisms of toxicity are not relevant to a consideration of cumulative exposure to (Z)-7,8-epoxy-2-methyloctadecane because it is not toxic to mammalian systems. Because, since Disparlure is an environmental epoxides (formed outside the body) which are generally considered less toxic than epoxides synthesized inside the body (Ref. 4). The reactive epoxide in Disparlure's structure would most likely react with proteins in food during digestion and would not be absorbed in their active form to induce toxicological effects (Ref. 4). There are also a number of ways the body can detoxify epoxides like Disparlure if they are absorbed in an active form (Ref. 4). Also the acute oral toxicity study on Disparlure indicated that the toxicity is low (Toxicity Category IV). Thus, the Agency does not expect any cumulative or incremental effects from exposure to residues of (Z)-7,8-epoxy-2-methyloctadecane when applied/used as directed on the label and in accordance with good agricultural practices. Additionally, when comparing the most conservative estimate of hazard to the maximum potential for inadvertent residues from the non-food uses of Disparlure, the result does not exceed the Agency's LOC (i.e.: Estimated exposure is less than 1% of the RfD; Ref. 3). Margins of Exposure (MOE) based on estimated exposure and hazard (the 140 mg/kg/day NOAEL from a chronic toxicity study in rats) range from 4,600 to 65,000 (Ref. 3). When the resulting MOE is greater than 100, the Agency's LOC is not exceeded and there is reasonable certainty of no harm to human health (Ref. 3).

VI. Determination of Safety for U.S. Population, Infants and Children

1. *U.S. population*. The Agency has determined that there is reasonable certainty that no harm will result to the U.S. Population from aggregated exposure to residues of (Z)-7,8-epoxy-2-methyloctadecane. This includes all dietary exposures and other exposures for which there is reliable information. The Agency has arrived at this conclusion based on the chemicals low acute toxicity, it is a naturally occurring lepidopteran pheromone produced by female gypsy moths (*Lymantria dispar*), is similar in chemical structure to compounds of low chronic toxicity (ESO), and has a very low potential for human exposure. (Ref. 2).

2. *Infants and children*. FFDCA section 408 provides that EPA shall apply an additional tenfold MOE for infants and children in the case of threshold effects. Margins of exposure are often referred to as uncertainty or safety factors, and are used to account for potential prenatal and postnatal toxicity and any lack of completeness of the database. Based on available data and other information, EPA may determine that a different MOE will define a level of concern for infants and children or that a MOE approach is not appropriate. Based on all the available information the Agency reviewed on (Z)-7,8-epoxy-2-methyloctadecane, including a lack of threshold effects, the Agency concluded that (Z)-7,8-epoxy-2-methyloctadecane is practically non-toxic to mammals, including infants and children. Since there are no effects of concern, the provision requiring an additional margin of safety does not apply.

VII. Other Considerations

A. Endocrine Disruptors

There is no evidence to suggest that (Z)-7,8-epoxy-2-methyloctadecane functions in a manner similar to any known hormone, or that it acts as an endocrine disrupter.

B. Analytical Method

Because this is an exemption from the requirement of a tolerance without numerical limitations, no analytical method is required.

C. Codex Maximum Residue Level

There are no CODEX maximum residue levels for residues for (Z)-7,8-epoxy-2-methyloctadecane for unintentional spray or drift from application when treating trees and shrubs along or within pastures, as well as unintentional spray and drift to non-target vegetation including native and ornamental species, and food and feed crops.

VIII. Conclusions

Based on the low toxicity in animal testing, and the expected low exposure to humans, no risk to human health is expected from use of the chemical on food crops.

IX. References

1. EFSA. (2004) Opinion of the Scientific Panel on Food Additives, Flavorings, Processing Aids and Materials in Contact with Food (AFC) on a request from the Commission related to the use of Epoxidized soybean oil in food contact materials. EFSA Journal 64: 1–17.

2. Gonzales, A. (June 27, 2007) USEPA Memorandum - Tolerance Exemption Petition Review for (Z)-7,8-epoxy-2-methyloctadecane.

3. Gardner, R. & A. Gonzales (January 8, 2008) USEPA Memorandum - Dietary Risk Considerations Supporting a Petition for Exemption from the Requirement of a Tolerance for (Z)-7,8-epoxy-2-methyloctadecane.

4. de Bethizy, J.D., and J.R. Hayes. 2001. ''Metabolism: Determinant of Toxicity'' Ch. 3 in *Principles and Methods of Toxicology*, 4th Edition. A.W. Hayes, ed. Taylor & Francis. Philadelphia, PA. pp. 123–124.

X. 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 final rule has been exempted from review under Executive Order 12866, this final 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 9, 2000) do not apply to this final rule. In addition, this final 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).

XI. 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: May 30, 2008.

Marty Monell,

Acting Director, 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 180.1283 is added to subpart D to read as follows:

§ 180.1283 (Z)-7,8-epoxy-2-methyloctadecane (Disparlure); exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of (Z)-7,8-epoxy-2-methyloctadecane on all food and feed crops that occur when it is used to treat trees, shrubs, and pastures and such use results in unintentional spray and drift to non-target vegetation including non-food, food, and feed crops. This active ingredient is also known as Disparlure.

[FR Doc. E8–13232 Filed 6–12–08; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–1107; FRL–8366–6]

Fenoxaprop-ethyl; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of fenoxaprop-ethyl and its metabolites in or on grass hay and forage. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on grasses grown for seed. This regulation establishes a maximum permissible level for residues of fenoxaprop-ethyl and its metabolites in these feed commodities. The time-limited tolerances expire and are revoked on December 31, 2010.

DATES: This regulation is effective June 13, 2008. Objections and requests for hearings must be received on or before August 12, 2008, 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–2007–1107. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. 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 either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Andrea Conrath, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9356; e-mail address: *conrath.andrea@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111).