(1–6 years), children (7–12 years), females (13–19 years), females (13–50 years), males (13–19 years), males (>20 years), and seniors (>55 years). In this analysis, all evaluated population subgroups had an exposure equal to 0% of the cRfD. The corresponding MOE was >1,000,000.

i. *Food*. Since clothianidin is not currently registered, projected percent crop treated values were used for the chronic and acute dietary analyses.

ii. *Drinking water*. For drinking water, the models SCI-GROW (ground water), and FIRST (surface water), were selected to calculate the potential exposure of clothianidin in drinking water. Each model generated an acute water concentration, and the higher of the two concentrations was selected to represent the acute exposure, and similarly for the chronic exposure. The acute environmental exposure was determined to be 3.24 µg/L (from surface water), and the chronic environmental exposure was 0.724 µg/L (from ground water). Both exposures result from clothianidin used as a seed treatment on corn. Based on the standard exposure scenarios for drinking water (70 kg adult - 2 L/day; 10 kg child - 1 L/day), the human exposure and risk can be estimated. Using the acute (0.60 mg/kg/day) and chronic (0.097 mg/kg/day) RfDs, the human risk from exposure to clothianidin in drinking water was determined to be less than 0.03% of the RfD in adults, and less than 0.08% of the RfD in children (the maximum human exposure was 0.32 µg/kg/day, for acute exposure for children).

2. *Non-dietary exposure*. Clothianidin is currently not registered for use on any residential non-food site. Therefore, residential exposure to clothianidin residues will be through dietary exposure only.

D. Cumulative Effects

There is no information available to indicate that toxic effects produced by clothianidin are cumulative with those of any other compound.

E. Safety Determination

1. *U.S. population*. Using the conservative exposure assumptions described above and based on the completeness of the toxicity data, it can be concluded that total aggregate exposure to clothianidin from all proposed uses will equal to 0% of the RfD for the overall U.S. population. All evaluated population subgroups had an expousre equal to 0% of the RfD. EPA generally has no concerns for exposures below 100% of the RfD, because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. Thus, it can be concluded that there is a reasonable certainty that no harm will result from aggregate exposure to clothianidin residues.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of clothianidin, the data from developmental toxicity studies in both the rat and rabbit, a 2-generation reproduction study in rats and a developmental neurotoxicity study in rats have been considered.

The developmental toxicity studies evaluate potential adverse effects on the developing animal resulting from pesticide exposure of the mother during prenatal development. The reproduction study evaluates effects from exposure to the pesticide on the reproductive capability of mating animals through two generations, as well as any observed systemic toxicity.

The developmental neurotoxicity studies evaluate the neurobehavioral and neurotoxic effects on the developing animal resulting from the exposure of the mother. FFDCA section 408 provides that EPA may apply an additional uncertainty factor for infants and children based on the threshold effects to account for prenatal and postnatal effects and the completeness of the toxicity data base. Based on the current toxicological data requirements the toxicology data base for clothianidin relative to prenatal and postnatal development is complete, including the developmental neurotoxicity study. None of the studies indicated the offsprings to be more sensitive. All effects were secondary to severe maternal toxicity. The RfD for clothianidin was calculated using the NOAEL of 9.7 mg/kg bw/day from the 2–year chronic/oncogenicity study. This NOAEL is lower than the NOAEL from the 2-generation reproduction study, the developmental studies, and the developmental neurotoxicity study. Moreover, using a toxicologically justified UF of 100, the RfD for a non-oncogenic clothiandin was established at a level 0.097 mg/kg/day, a value that offers a measure of safety that is still 1.7-fold higher than the highest RfD (imidacloprid at 0.057 mg/kg/day) of the 10 competitive compounds compared in this report.

F. International Tolerances

No CODEX Maximum Residue Levels have been established for residues of clothianidin on any crops at this time.

[FR Doc. 01–28524 Filed 11–13–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1052; FRL–6808–9]

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–1052, must be received on or before December 14, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1052 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt Jamerson, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9368; e-mail address: jamerson.hoyt@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be

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

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

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person*. The Agency has established an official record for this action under docket control number PF–1052. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA., from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1052 in the subject line on the first page of your response.

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

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

3. *Electronically*. You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–1052. Electronic comments may also be filed online at many Federal Depository Libraries.

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

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

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

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

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, reporting and recordkeeping requirements.

Dated: October 30, 2001.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the views of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Interregional Research Project Number 4 (IR-4)

9E5037, and 1E6326, and 1E6345

EPA has received three pesticide petitions (9E5037 (canola), 1E6326 (dill), and 1E6345 (safflower)) from Interregional Research Project Number 4 (IR-4) 681 U.S. Highway # 1, South, North Brunswick, NJ 08902–3390 proposing, pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of ethalfluralin in or on the raw agricultural commodities (RACs) canola, safflower and dill at 0.05 parts per million (ppm).

EPA has determined that this petition contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. Nature of residue studies with $_{14}$C ethalfluralin have demonstrated very low terminal residues and that ethalfluralin *per se* is the residue of concern in plants grown in soil treated with this compound and that there are no significant metabolic products. These studies indicate that it is appropriate to base a tolerance on residues of the parent compound, ethalfluralin.

2. *Analytical method*. A residue method has been developed and validated at a limit of quantitation (LOQ) of 0.02 µg/g for the determination of ethalfluralin in canola seed which utilizes capillary gas chromatography with mass selective detection (GC)/MSD. Validation data were generated using this method during the analysis of the canola seed field samples from the magnitude of residue studies.

For safflower, adequate residue analytical methods are available for purposes of registration based upon the analytical method for sunflower. A GC method, Method I, with electron capture detection is listed in the Pesticide Analytical Manual ((PAM), Vol. II, Section 180.416), for tolerance enforcement. Method I is applicable for analysis of ethalfluralin residues in/on sunflower seed. The limit of detection is 0.01 ppm.

Dill was analyzed by the method ''Determination of Ethalfluralin in Agricultural Crops and Soil.'' Residue method number AM-AA-CA-R025-AB-755, Lilly Research Laboratories, Greenfield, IN (Currently Dow AgroSciences). The LOQ was 0.050 ppm by a GC with a Ni^{63} electron capture detector. Method validation was performed both prior to and concurrently with sample analysis.

3. *Magnitude of residues*. In the magnitude of residue field studies, herbicides containing the active ingredient ethalfluralin [*N*-ethyl-*N*-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl) benzenamine] were applied in 1996 at eight sites as a preplant incorporated application. Sonalan l0G herbicide was applied directly to the soil surface and Sonalan HFP herbicide was diluted in water and applied in a spray volume of 16–23 gallons/acre. The applications were made to field plots of canola at the rate of 1.25 lb active ingredient/acre at all sites except Georgia and Washington, and at the rate of 0.75 lb active ingredient/acre (Georgia and Washington). Three to five days after application a second incorporation was done and canola seeds were planted. Samples of canola seed were collected at normal harvest, 87–216 days after the last application. Residues in canola seed collected at normal harvest were non-detectable based on a method lower limit of detection of 0.004 ppm.

For safflower, the magnitude of residue data from sunflower are surrogate data for safflower. The registered uses of ethalfluralin on sunflowers along with the established tolerances on these commodities are supported by acceptable field residue data from trials reflecting the maximum registered use patterns. In all cases, the residues were <0.01ppm. The reregistration requirements for processing studies were fulfilled. Adequate processing studies have been conducted on sunflower seed. Field residue data resulting from up to 5X label rates showed non-detectable (<0.01ppm) residues of ethalfluralin in sunflower seed.

In dill the magnitude of residue field studies, herbicides containing the active ingredient ethalfluralin [*N*-ethyl-*N*-(2-methyl-2-propenyl)-2,6-dinitro-4-(trifluoromethyl) benzenamine] were applied in 1997 at three sites. Ethalfluralin formulated as Curbit EC was applied directly to the soil surface diluted in water and applied in a spray volume of 36 gallons/acre. The applications were made to field plots of canola at the rate of 1.5 lb active ingredient/acre and incorporated by sprinkler irrigation. Samples of dill were collected at normal harvest, 91–100 days after the last application. Residues in fresh and dried dill collected at normal harvest were non-detectable based on a method lower limit of detection of 0.05 ppm.

B. Toxicological Profile

1. *Acute toxicity*. Ethalfluralin is of relatively low toxicity. The rat oral LD_{50} is >10,000 milligrams/kilograms (mg/kg). The acute dermal LD_{50} in rabbits is >2,000 mg/kg and the acute rat inhalation LC_{50} is >0.94 milligrams/Liter (mg/L) air. Ethalfluralin produced slight eye irritation and slight dermal irritation in rabbits. A guinea pig dermal sensitization study conducted by the modified Buehler method found no sensitization, whereas a study conducted by the Magnusson and Kligman maximization method showed a positive sensitization reaction. The signal word for the technical grade active ingredient is Caution.

2. *Genotoxicty*. Ethalfluralin was weakly mutagenic in activated strains TA1535 and TA100 of *Salmonella typhimurium*,but not in strains TA1537, TA1538, and TA98 in an Ames assay. In a modified Ames assay with *Salmonella typhimurium* and *Escherichia coli*, ethalfluralin was weakly mutagenic in strains TA1535 and TA100, with and without activation, and in strain TA98 without activation, at the highest dose. No mutagenicity was found in the mouse lymphoma assay for forward mutation. Ethalfluralin did not induce unscheduled DNA synthesis in rat hepatocytes. In chinese hamster ovary cells, ethalfluralin was negative without S9 activation, but it was clastogenic with activation.

3. *Reproductive and developmental toxicity*. The maternal no observed adverse effect level (NOAEL) of ethalfluralin in rats was 50 mg/kg/day. The maternal lowest observed adverse effect level (LOAEL) was 250 mg/kg/day, based on decreased body weight (bwt) gain and dark urine. In this rat study there was no observable developmental toxicity. The developmental NOAEL in rats was 1,000 mg/kg/day, the highest dose. In rabbits the NOAELs for maternal and developmental toxicity were 75 mg/kg/day. The maternal LOAEL at 150 mg/kg/day was based on abortions and decreased food consumption. These effects as well as decreased weight gain, enlarged liver, and orange urine were found at 300 mg/kg/day. In this study developmental toxicity was observed. The developmental LOAEL in rabbits was 150 mg/kg/day, based on slightly increased resorptions, abnormal cranial development, and increased sternal variants. In a three-generation rat reproduction study, the parental NOAEL was 12.5 mg/kg/day. The parental LOAEL was 37.5 mg/kg/day, based on depressed mean body weight gains in males in all generations. No

treatment-related effects were noted on reproductive parameters and the NOAEL was 37.5 mg/kg/day or greater. A 7–month multigeneration bridging study was conducted with doses equivalent to 0, 8, 20, or 61 mg/kg/day in the diet of Fischer 344 rats. The parental NOAEL was 20 mg/kg/day. The parental LOAEL was 61 mg/kg/day, based on increased liver weights. No treatment-related effects were noted on reproductive parameters and the reproductive NOAEL was equal to or greater than 61 mg/kg/day.

4. *Subchronic toxicity*. Ethalfluralin was evaluated in five subchronic dietary studies which showed NOAELs of 560 ppm in a 3–month mouse study, 12 mg/kg/day in a 1–year mouse study, 29 mg/kg/day in a 3–month rat study, 3.9 mg/kg/day in male rats and 4.9 mg/kg/day in female rats in a 1–year study, and 27.5 mg/kg/day in a 3–month dog study. A 21–day dermal study in rabbits showed no systemic toxicity, while slight to severe dermal irritation was observed.

5. *Chronic toxicity*. Ethalfluralin was administered to Fisher 344 rats in the diet for 2 years in combined chronic toxicity and carcinogenicity replicate studies. The doses were equivalent to 0, 4.2, 10.7, or 32.3 mg/kg/day. The NOAEL for systemic effects was 32.3 mg/kg/day. Mammary gland fibroadenomas were found in dosed female rats at statistically significant incidences in the mid and high doses. Ethalfluralin was administered to B6C3F1 mice in the diet for 2 years in combined chronic toxicity and carcinogenicity replicate studies. The doses were equivalent to 0, 10.3, 41.9, or 163.3 mg/kg/day. No increased incidence of neoplasms was attributed to the treatment. The NOAEL was 10.3 mg/kg/day. The mid dose (LOAEL) and high dose showed focal hepatocellular hyperplasia in both sexes. There were increased relative liver, kidney, and heart weights in females. Some blood changes were found also, including decreased hematocrit, hemoglobin, and erythrocyte count accompanied by increased mean corpuscular hemoglobin concentration in high dose females. Alkaline phosphatase values were increased at the high dose in both sexes. Body weight gain decreased at the high dose.

Beagle dogs were given 0, 4, 20, or 80 mg/kg/day orally, by capsule, for 1–year. The NOAEL was 4 mg/kg/day. The LOAEL was 20 mg/kg/day, based on increased urinary bilirubin, variations in erythrocyte morphology, increased thrombocyte count, and increased erythroid series of the bone marrow. Elevated alkaline phosphatase levels were found at the two higher doses and siderosis of the liver at the high dose.

EPA's Office of Pesticide Program's Carcinogenicity Peer Review Committee concluded that ethalfluralin should be classified as Group C, a possible human carcinogen, based on increased mammary gland fibroadenomas and adenomas/fibroadenomas combined in female rats. The tumor incidences were statistically significant at both the mid and high dose, and exceeded of the upper range of historical controls. Based on a low dose extrapolation, the Q_1* of 8.9×10^{-2} $(mg/kg/day)^{-1}$ has been calculated.

6. *Animal metabolism*. Fischer 344 rats were treated orally with a single low dose, a single high dose, or repeated low doses of radiolabeled ethalfluralin. Absorption of ethalfluralin was estimated at 79–87% of the dose for all dose levels. Ethalfluralin was rapidly and extensively metabolized, and 95% of the chemical was excreted in urine and feces by 7 days. The major route of elimination for the radiolabel was in the feces, 50.9–63.2%, and the levels remaining in the tissues after 72 hours were negligible. The major metabolites in urine and feces were identified.

7. *Metabolite toxicology*. The residue of concern is ethalfluralin *per se*, as specified in 40 CFR 180.416. Thus there is no need to address metabolite toxicity.

8. *Endocrine disruption*. There is no evidence to suggest that ethalfluralin has an effect on any endocrine system.

C. Aggregate Exposure

1. *Dietary exposure*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an acute effect of concern occurring as a result of a 1–day or single exposure. EPA has previously used a NOAEL of 75 mg/kg/day from a rabbit developmental toxicity study as the toxicity endpoint for assessing acute dietary risk in females 13–50 years of age. An acute reference dose (RfD) of 0.75 mg/kg/day was calculated, based on a NOAEL of 75 mg/kg/day and an uncertainty factor (UF) of 100 (10 for interspecies extrapolation and 10 for intraspecies variation). EPA has previously added a 3X FQPA safety factor, resulting in an acute population adjusted dose (aPAD) of 0.25 mg/kg/day. Likewise, in this assessment, acute dietary risk to females 13–50 years old was based on an aPAD of 0.25 mg/kg/day.

Chronic dietary exposure to ethalfluralin is possible due to the potential presence of ethalfluralin residue in certain foods. Chronic dietary risk was evaluated using a chronic RfD of 0.04 mg/kg/day, which is based on a NOAEL of 4 mg/kg/day from a chronic dog study along with an UF of 100. EPA previously concluded that an FQPA safety factor of 1X is appropriate for assessing chronic dietary risk.

EPA has concluded that ethalfluralin should be classified as group C, a possible human carcinogen, based on increased mammary gland fibroadenomas and adenomas/fibroadenomas combined in female rats. Therefore, a cancer risk assessment was included. Based on a low dose extrapolation, the Q_1* of 8.9×10^{-2} $(mg/kg/day)^{-1}$ has been calculated and was used in this cancer risk assessment.

i. *Food*. The dietary exposure assessment was based on all commodities with tolerances for ethalfluralin established at 40 CFR 180.416 together with the proposed tolerances of 0.05 ppm each for canola, dill, and safflower. The dietary exposure evaluation model, which is produced by Novigen Sciences, Inc. and licensed to Dow AgroSciences, was used to estimate dietary exposure. This software used the food consumption data for the 1989–1991 United States Department of Agriculture Continuing Surveys of Food Intake by Individuals (CSFII 1989–1991).

a. *Acute*. An acute dietary risk assessment was conducted with the conservative assumptions of 100% crop treated and tolerance level residues for all crops. These assumptions result in a very conservative estimate of human exposure and risk. Acute dietary risk for females 13+ years old was assessed using an aPAD of 0.25 mg/kg/day. Even with conservative assumptions used in this analysis, acute dietary exposure was estimated to occupy only 0.05% of the aPAD for females 13+ years old. Adverse effects are not expected for exposures occupying 100% or less of the aPAD. Therefore, acute exposure and risk from food is well within acceptable levels.

b. *Chronic*. Chronic dietary exposure and risk was estimated with the conservative assumptions of 100% crop treated and tolerance level residues for all crops. The estimate of potential chronic exposure and risk is very conservative and estimated risk would be substantially reduced with further refinement to the exposure estimate. Even with the conservative assumptions used in this analysis, chronic exposure is estimated to occupy only 0.1% of the RfD for the general U.S. population. Chronic dietary exposure is estimated to occupy 0.4% of the RfD for non-nursing infants, the population subgroup estimated to have highest potential exposure. Therefore, chronic exposure

and risk from food is well within acceptable levels.

c. *Cancer*. Cancer risk was estimated based on percent crop treated and anticipated residues as provided in EPA's Reregistration Eligibility Decision (RED) for ethalfluralin. Exposure to ethalfluralin from food is estimated to result in a lifetime cancer risk of 7.11 x 10^{-7}. Cancer risks of less than 1 x 10^{-6} are generally considered to be negligible.

ii. *Drinking water*. There are no established maximum contaminant levels for residues of ethalfluralin in drinking water and health advisory levels for ethalfluralin have not been established. EPA has previously used modeling for a screening level assessment of potential ethalfluralin exposure through drinking water. The Agency has used EPA's pesticide root zone model/exposure analysis modeling systems and screening concentrations in ground water to provide a screening level assessment for surface water and ground water, respectively. Based on these models, EPA has indicated the estimated environmental concentrations (EECs) for acute exposures are estimated to be 2.3 parts per billion (ppb) for surface water and 0.02 ppb for ground water. The EECs for chronic exposures are estimated to be 0.052 ppb for surface water and 0.02 ppb for ground water. Estimated concentrations of a pesticide are compared to a drinking water level of comparison (DWLOC) as a surrogate estimate of exposure and risk. The DWLOC is the concentration of a pesticide in drinking water that would be acceptable as an upper limit in light of total aggregate exposure to that pesticide.

a. *Acute*. As indicated previously, EPA has used surface water and ground water EECs of 2.3 ppb and 0.02 ppb, respectively, for comparison with the DWLOC in an acute assessment. The DWLOC for acute exposure in females 13+ years old was based on an aPAD of 0.25 mg/kg/day and was calculated to be 7,500 ppb. Therefore, the acute DWLOC for ethalfluralin is over 3,000 fold greater than the EEC for surface water or ground water, indicating that potential acute exposure and risk from drinking water is well within acceptable levels.

b. *Chronic*. As indicated previously, EPA has used surface water and ground water EECs of 0.052 ppb and 0.02 ppb, respectively, for comparison with the DWLOC in a chronic assessment. The chronic DWLOC was calculated based on a chronic RfD of 0.04 mg/kg/day and accounted for potential chronic exposure to ethalfluralin through residues in food. The chronic DWLOC for the general U.S. population and non-nursing infants was calculated to be 1,400 ppb and 400 ppb, respectively. Therefore, chronic DWLOCs are substantially greater than estimated residue concentration in surface water or ground water over a chronic exposure period, indicating that chronic exposure and risk from drinking water are well with acceptable levels.

c. *Cancer*. The DWLOC for the cancer risk assessment was calculated to be 0.12 ppb. Surface water and ground water EECs of 0.052 ppb and 0.02 ppb, respectively, were used for comparison with the DWLOC. The EECs are below the DWLOC, indicating that the cancer risk would generally be considered negligible.

2. *Non-dietary exposure*. Ethalfluralin is not currently registered for use on any residential non-food sites, and thus, it is not expected that non-occupational, non-dietary exposures will occur.

D. Cumulative Effects

EPA at this time has not established methodologies to resolve the complex issues concerning common mechanism of toxicity in a meaningful way. Although ethalfluralin is a member of the dinitroaniline class of herbicides, there is no information available, at this time to determine whether ethalfluralin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Based on the metabolic profile, ethalfluralin does not appear to produce a toxic metabolite produced by other substances. Therefore, only aggregate exposure and risk were considered.

E. Safety Determination

1. *U.S. population*. Using conservative exposure assumptions previously described, chronic dietary exposure to residues of ethalfluralin from current and proposed uses was estimated to occupy only 0.1% of the RfD for the general U.S. population. EPA generally has no concern for exposures below 100% of the RfD since the RfD represents the level at or below which daily exposure over a lifetime will not pose appreciable risks to human health. Additionally, the chronic DWLOC was found to be substantially greater than EECs for ethalfluralin in surface water or ground water, indicating risk is well within acceptable levels. Cancer risk resulting from potential exposure to ethalfluralin through food and drinking water was estimated. Cancer risk from potential dietary and drinking water exposure for the general U.S. population was found to be within a range that EPA has generally considered negligible. Thus, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, it is concluded that there is a reasonable certainty that no harm will result to the general U.S. population from aggregate exposure to ethalfluralin residues from current and proposed uses.

2. *Infants and children*. Risk for developmental toxicity from acute exposure to ethalfluralin was evaluated for females 13+ years old. As indicated in the previous discussion, risk from aggregate acute exposure to ethalfluralin through food and drinking water is well within acceptable levels. It can be concluded that there is a reasonable certainty that no harm will result for both females 13+ years old, and for the prenatal development of infants, from aggregate acute exposure to ethalfluralin.

Chronic aggregate exposure and risk was evaluated for non-nursing infants, the population subgroup predicted to be most highly exposed. As indicated previously, risk from aggregate chronic exposure through food and drinking water is well within acceptable levels. Thus, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, it can be concluded with reasonable certainty that no harm will result to infants and children from chronic aggregate exposure to ethalfluralin based on current and proposed uses.

F. International Tolerances

There are no Codex, Canadian or Mexican maximum residue limits established for ethalfluralin.

[FR Doc. 01–28198 Filed 11–13–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–181082; FRL–6810–4]

Pesticide Emergency Exemptions; Agency Decisions and State and Federal Agency Crisis Declarations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted or denied emergency exemptions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for use of pesticides as listed in this notice. The exemptions or denials were granted during the period December 2000 to October 2001 to control unforseen pest outbreaks.

FOR FURTHER INFORMATION CONTACT: See each emergency exemption or denial for the name of a contact person. The