their business clients. They too are developing industry-specific compliance guides; however, an essential first step in developing industry-specific guides is knowing what has already been developed and what is underway. By serving as a focal point for the distribution and notification of sector-specific activities throughout the nation, the compliance assistance centers can potentially prevent the duplication of efforts of state and local assistance programs.

## II. What Do the Centers Provide

Compliance Assistance Centers function as communication centers rather than physical ''walk-ins.'' Each center provides some or all of the following services via the Internet and toll-free telephone numbers:

- Easy access to industry-specific, multi-media federal regulations, interpretations, and compliance guides; also, certain state and local information;
- Compliance tools that can be used by small business, regulators, inspectors, and technical assistance providers to audit, determine emissions and wastes, and calculate the costs of compliance;
- Process-specific training for regulators and technical assistance providers who seek more in-depth knowledge of the businesses they regulate;
- A place to ask questions and get answers, through specialized conferences and forums, and access to experts who can answer compliance and technical questions;
- Databases of technologies and techniques that can help small businesses come into compliance, with an emphasis on pollution prevention methods that save money.

## III. How To Reach the Centers

Following are the Internet addresses and contact names and telephone numbers for the four existing centers:

*a. National Metal Finishing Resource Center*

NMFRC provides technical assistance and information on environmental compliance and pollution prevention to the metal finishing industry.

*Internet:* http://www.nmfrc.org

*Contacts:* National Center for Manufacturing Science, Paul Chalmer, 313–995–4911; U.S. EPA, Scott Throwe, 202–564–7013.

*b. Printer's National Compliance Assistance Center*

PNEAC provides compliance assistance and pollution prevention information to the printing industry.

*Internet:* http://www.hazard.uiuc.edu/pneac/pneac.html

*Contacts:* Illinois Hazardous Waste Research and Information Center, Gary Miller, 217–333–8942; U.S. EPA, Doug Jamieson, 202–564–7041.

*c. GreenLink™—the Automotive Compliance Information Assistance Center.*

GreenLink™ provides compliance assistance to the automotive service industry. To obtain voice, facsimile, or mailed information, call the center's toll-free number, 1–888–GRN–LINK.

*Internet:* http://www.ccar-greenlink.org

*Contacts:* U.S. EPA, Everett Bishop, 202–564–7032; Coordinating Committee for Automotive Repair, Sherman Titens, 816–561–8388.

*d. National Agriculture Compliance Assistance Center*

This Center provides information to help producers of agricultural commodities and their supporting businesses meet their environmental requirements; prevent pollution before it occurs; and reduce costs by identifying flexible, common-sense ways to achieve compliance.

*Internet:* http://es.inel.gov/oeca/ag/aghmpg.html

*Contacts:* U.S. EPA, Ginah Mortensen, 913–551–7207 (fax: 913–551–7270).

## IV. How to Get Involved With Future Centers

EPA has developed partnerships for the Transportation Compliance Assistance Center and the Printed Wiring Board Manufacturing Center. For more information, contact Virginia Lathrop (transportation) at 202–564–7057 and Keith Brown (PWB manufacturing) at 202–564–7124. EPA is currently developing the Chemical Manufacturing and Local Government Centers. If you are interested in learning more about the Chemical Manufacturing Center please contact Emily Chow at 202–564–7071. For more information on the Local Government Environmental Network, which will provide a central location for state and local access to federally-developed compliance assistance information related to local governments, contact Wendy Miller at 202–564–7102 or John Dombrowski at 202–564–7036.

Dated: April 4, 1997.

**Elaine Stanley,**

*Director, Office of Compliance.*

[FR Doc. 97–9579 Filed 4–11–97; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

**[PF–730; FRL–5599–7]**

### Notice of Filing of Pesticide Petitions

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various agricultural commodities.

**DATES:** Comments, identified by the docket control number PF–730, must be received on or before May 14, 1997.

**ADDRESSES:** By mail submit written comments to: Public Response and Program Resources Branch, Field Operations Divison (7505C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

**FOR FURTHER INFORMATION CONTACT:** By mail: Joanne Miller, PM-23, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 237, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305-6224; e-mail: miller.joanne@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues

of certain pesticide chemicals in or on various raw agricultural commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain 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 supports grantinig of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice, as well as the public version, has been established for this notice of filing under docket control number PF–730 (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number (PF–730) and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

**Authority:** 21 U.S.C. 346a.

## List of Subjects

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

Dated: April 2, 1997.

**Stephen L. Johnson,**

*Director, Registration Division, Office of Pesticide Programs.*

## Summaries of Petitions

Below summaries of the pesticide petitions are printed. The summaries of the petitions were prepared by the petitioners. 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.

### 1. K-I Chemical, U.S.A. Inc.

*PP 7F4821*

EPA has received a pesticide petition (PP 7F4821) from K-I Chemical, U.S.A. Inc., 11 Martine Avenue, 9th Floor, White Plains, New York 10606, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C 346a, to amend 40 CFR part 180 by establishing a tolerance for residues of the herbicide fluthiacet-methyl: Acetic acid, [[2-chloro-4-fluoro-5-[(tetrahydro-3-oxo-1H,3H-[1,3,4]thiadiazolo[3,4-a] pyridazin-1-ylidene)amino]phenyl]thio]-methyl ester in or on the raw agricultural commodites field corn grain and sweet corn grain (K + CWHR) at 0.02 ppm and corn forage and fodder at 0.05 ppm. The proposed analytical method is gas chromatography using a nitrogen phosphorus detector and a large-bore fused silica column.

*A. Fluthiacet-methyl uses:*

Fluthiacet-methyl, Acetic acid, [[2-chloro-4-fluoro-5-[(tetrahydro-3-oxo-1H,3H-[1,3,4]thiadiazolo[3,4-a]pyridazin-1-ylidene)amino]phenyl]thio]-methyl ester, is a new herbicide active ingredient in the imide chemistry class. A petition for tolerance for fluthiacet-methyl in soybeans (Pesticide Petition Number 6F04614) submitted by Novartis Crop Protection, Inc. is pending EPA review. K-I, Chemical, U.S.A. has submitted a petition for tolerance in corn. Fluthiacet-methyl will be formulated as a 4.75% wettable powder, packaged in water-soluble bags, and sold under the trade name Action herbicide. Action is a highly selective herbicide for use in soybeans and corn postemergence, and is particularly effective in controlling velvetleaf. Control of other broadleaf weeds in corn and soybeans is enhanced and the spectrum of control is broadened when Action is tank mixed with other postemergence herbicides registered for use in these crops.

Action offers effective weed control at extremely low use rates. The maximum use rate per season is 0.0089 lb. active ingredient (3 oz. of formulated product) per acre consisting of a maximum of two applications. There is a wide application window extending in corn from the 2-leaf stage (leaves fully expanded with collars exposed) to 48 inches tall or prior to tasseling, whichever comes first, and the amount of Action to apply depends on the weed species and weed height. Tank mixing Action with other postemergence herbicides further reduces the amount required to control target weeds.

The purpose of this petition is to establish a tolerance for fluthiacet-methyl in field and sweet corn. The tolerance proposed in section 408(d)(2)(A)(vii) is:

| Comodity | Part per million (ppm) |
|---|---|
| corn, sweet - grain (k + CWHR) | 0.02 ppm |
| corn, field - grain | 0.02 ppm |
| corn - forage and fodder | 0.05 ppm |

*B. Fluthiacet-methyl Safety*

In support of the pending petition for tolerance in soybeans, and hereby referenced by K-I Chemical, Novartis Crop Protection (Ciba) submitted a full battery of toxicology studies including, acute effects, chronic feeding, oncogenicity, teratogenicity, mutagenicity, and reproductive toxicity tests. The studies indicate that fluthiacet-methyl has a low order of acute toxicity with acute effects in catgegory III and IV, is not neurotoxic, does not pose a genotoxicity hazard, and is not a reproductive toxicant or a teratogen.

Potential exposure to fluthiacet-methyl via the diet or drinking water and through handling is very limited. Because of rapid environmental degradation, extremely low residues in food crops, and water-soluble packaging, considerable margins of safety exist for dietary exposure for all subgroups of the population and for worker exposure as well.

The following mammalian toxicity studies have been conducted to support the proposed tolerance for fluthiacet-methyl:

A rat acute oral study with an $LD_{50}$ > 5,000 mg/kg.

A rabbit acute dermal study with an $LD_{50}$ > 2,000 mg/kg.

A rat inhalation study with an $LC_{50}$ > 5.05 mg/liter.

A primary eye irritation study in the rabbit showing moderate eye irritation.

A primary dermal irritation study in the rabbit showing no skin irritation.

A primary dermal sensitization study in the Guinea pig showing no sensitization.

28–day dermal toxicity study in rats with a NOEL equal to or higher than the limit dose of 1,000 mg/kg.

6–Week dietary toxicity study in dogs with a NOEL of 162 mg/kg/day in males

and 50 mg/kg/day in females based on decreased body weight gain and modest hematological changes.

90–day subchronic dietary toxicity study in rats with a NOEL of 6.2 mg/kg/day based on liver changes and hematological effects.

24–month combined chronic toxicity/carcinogenicity study in rats with a NOEL of 2.1 mg/kg/day. Based on reduced body weight development and changes in bone marrow, liver, pancreas and uterus the MTD was exceeded at 130 mg/kg/day.

A positive trend of adenomas of the pancreas in male rats treated at 130 mg/kg/day and above may be attributable to the increased survival of the rats treated at high doses.

18–month oncogenicity study in mice with a NOEL of 0.14 mg/kg/day. Based on liver changes, the MTD was reached at 1.2 mg/kg/day. The incidence of hepatocellular tumors was increased in males treated at 12 and 37 mg/kg/day.

Teratology study in rats with a maternal and developmental NOEL equal to or greater than 1,000 mg/kg/day.

Teratology study in rabbits with a maternal NOEL greater than or equal to 1,000 mg/kg/day and a fetal NOEL of 300 mg/kg based on a slight delay in fetal maturation.

2–generation reproduction study in rats with a NOEL of 36 mg/kg/day, based on liver lesions in parental animals and slightly reduced body weight development in parental animals and pups. The treatment had no effect on reproduction or fertility.

Acute neurotoxicity study in rats. Neurotoxic effects were not observed. The NOEL was 2,000 mg/kg.

90–day subchronic neurotoxicity study in rats. The NOEL was 0.5 mg/kg/day based on reduced body weight gain. No clinical or morphological signs of neurotoxicity were detected at any dose level.

*In vitro* gene mutation tests: Ames test - negative; Chinese hamster V79 test - negative; rat hepatocyte DNA repair test - negative; *E. Coli* letal DNA damage test - negative.

*In vitro* chromosomal aberration tests: Chinese hamster ovary - positive at cytotoxic doses; Chinese hamster lung - positive at cytotoxic doses; human lymphocyes - positive at cytotoxic doses.

*In vivo* chromosome aberration tests: Micronucleus assays in rat liver - negative; mouse bone marrow test - negative.

1. *Threshold effects.* Using the Guidelines for Carcinogenic Risk Assessment published September 24, 1986 (51 FR 33992), K-I Chemical believes the Agency will classify fluthiacet-methyl as a Group ''C'' carcinogen (possible human carcinogen) based on findings of benign and malignant liver tumors in male mice. These tumors most likely resulted from a chronic regenerative and proliferative response of the affected epithelial cells. This response is a non-genotoxic, threshold effect which is due to the accumulation of cytotoxic porphyrins. A positive trend of proliferative pancreatic changes in male rats is likely attributable to the increased survival of the rats in the high dose groups. The lesions observed are not uncommon in the rat strain used.

Because the effects observed are threshold effects, K-I Chemical believes that exposure to fluthiacet-methyl should be regulated using a margin of exposure approach. The RfD for fluthiacet-methyl can be defined at 0.0014 milligrams (mg)/kilogram(kg)/day based on an 18-month feeding study in mice with a No-Observed Effect Level (NOEL) of 0.14 mg/kg/day and an uncertainty factor of 100.

2. *Non-threshold effects.* Based on the results of an extensive program of genotoxicity studies, fluthiacet-methyl is not mutagenic *in vivo.* As outlined above, effects observed in toxicology studies are attributable to an epigenetic, cytotoxic mechanism, resulting in degenerative and inflammatory changes in the target organs. It is therefore justified that exposure to fluthiacet-methyl should be regulated using a margin of exposure approach.

3. *Aggregate exposure.* In this assessment, K-I Chemical has conservatively assumed that 100% of all soybeans and corn used for human consumption would contain residues of fluthiacet-methyl and all residues would be at the level of the proposed tolerances. The potential dietary exposure to fluthiacet-methyl was calculated on the basis of the proposed tolerance which is based on an LOQ of 0.01 ppm in soybeans and 0.02 ppm in corn (2x LOQ). The anticipated residues in milk, meat and eggs resulting from feeding the maximum allowable amount of soybean and corn commodities to cattle and poultry were calculated, and the resulting quantities were well below the analytical method LOQ. Therefore, tolerances for milk, meat and eggs are not required. Assuming 100% crop treated values, the chronic dietary exposure of the general U.S. population to fluthiacet-methyl would correspond to 2.3% of the RfD.

Other potential sources of exposure of the general population to residues of pesticides are residues in drinking water. Although fluthiacet-methyl has a slight to medium leaching potential; the risk of the parent compound to leach to deeper soil layers is negligible under practical conditions in view of the fast degradation of the product. For example, the soil metabolism half-life was extremely short, ranging from 1.1 days under aerobic conditions to 1.6 days under anaerobic conditions. Even in the event of very heavy rainfalls immediately after application, which could lead to a certain downward movement of the parent compound, parent fluthiacet-methyl continues to be degraded during the transport into deeper soil zones.

Considering the low application rate of fluthiacet-methyl, the strong soil binding characteristics of fluthiacet-methyl and its degradates, and the rapid degradation of fluthiacet-methyl in the soil, there is no risk of ground water contamination with fluthiacet-methyl or its metabolites. Thus, aggregate riskof exposure to fluthiacet-methyl does not include drinking water.

Fluthiacet-methyl is not registered for any other use and is only proposed for use on agricultural crops. Thus, there is no potential for non-occupational exposure other than consumption of treated commodities containing fluthiacet-methyl residue.

K-I Chemical also considered the potential for cumulative effects of fluthiacet-methyl and other substances. However, a cumulative exposure assessment is not appropriate at this time because there is no information available to indicate that effects of fluthiacet-methyl in mammals would be cumulative with those of another chemical compound. Thus K-I Chemical is considering only the potential risk of fluthiacet-methyl in its aggregate exposure assessment.

4. *Safety to the U.S. population.* Using the very conservative exposure assumptions described above coupled with toxicity data for fluthiacet-methyl, K-I Chemical calculated that aggregate, chronic exposure to fluthiacet-methyl will utilize no more than 2.3% of the RfD for the U.S. population. Because the actual anticipated residues are well below tolerance levels and the percent crop treated with fluthiacet-methyl is expected to be less than 25% of planted corn or soybeans, a more realistic estimate is that dietary exposure will likely be at least 20 times less than the conservative estimate previously noted (the margins of exposure will be accordingly higher). Exposures below 100 percent of the RfD are generally not of concern because the RfD represents the level at or below which daily aggregate dietary exposure over a

lifetime will not pose appreciable risks to human health.

Also the acute dietary risk to consumers will be far below any significant level; the lowest NOEL from a short term exposure scenario comes from the teratology study in rabbits with a NOEL of 300 mg/kg. This NOEL is 2,000-fold higher than the chronic NOEL which provides the basis for the RfD (see above). Acute dietary exposure estimates which are based on a combined food survey from 1989 to 1992 predict margins of exposure of at least one million for 99.9% of the general population and for women of child bearing age. Margins of exposure of 100 or more are generally considered satisfactory.

Therefore, K-I Chemical concludes that there is a reasonable certainty that no harm will result from aggregate exposure to fluthiacet-methyl residues.

5. *Safety to infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of fluthiacet-methyl, K-I Chemical considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. A slight delay in fetal maturation was observed in a teratology study in rabbits at a daily dose of 1,000 mg/kg. In a 2-generation reproduction study fluthiacet-methyl did not affect the reproductive performance of the parental animals or the physiological development of the pups. The NOEL was 500 ppm for maternal animals and their offspring, which is 50,000 fold higher than the RfD.

*Reference dose.* Using the same conservative exposure assumptions as was used for the general population, the percent of the RfD that will be utilized by aggregate exposure to residues of fluthiacet-methyl is as follows: 1.5% for nursing infants less than 1 year old, 5.9% for non-nursing infants, and 5.2% for children 1-6 years old. K-I Chemical concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to residues of fluthiacet-methyl.

6. *Estrogenic effects.* Based on the results of short-term, chronic, and reproductive toxicity studies there is no indication that fluthiacet-methyl might interfere with the endocrine system. Considering further the low environmental concentrations and the lack of bioaccumulation, there is no risk of endocrine disruption in humans or wildlife.

7. *Chemical residue.* There are no Codex maximum residue levels established for residues of fluthiacet-methyl on corn. The nature of the residues in corn and animals (goat and hen) is adequately understood following application of fluthiacet-methyl. Residues do not concentrate in processed commodities. K-I Chemical has submitted practical analytical methods (AG-603B and AG-624) for detecting and measuring the level of fluthiacet-methyl in or on corn and corn commodities and in animal tissues with a limit of detection that allows monitoring residues at or above the levels set for the proposed tolerance. The limit of quantitation of the crop method is 0.01 ppm in corn and corn commodities, 0.05 ppm in animal tissues and 0.01 ppm in milk. The crop method involves extraction, filtration, and solid phase clean up. Residue levels of fluthiacet-methyl are determined by gas chromatographic analysis utilizing a nitrogen phosphorus detector and a fused-silica column. The animal tissue method involves extraction, filtration, and partition. Determination of residue levels in animal tissues is by HPLC with UV detection via column switching using C1 and C18 columns. The analyte of interest in animal tissues and milk is the major animal metabolite CGA-300403. EPA can provide information on these methods to FDA. The methods will be available to anyone who is interested in pesticide residue enforcement from the Field Operations Division, EPA Office of Pesticide Programs.

The residue of concern in corn is fluthiacet-methyl per se. Twenty one field residue studies were conducted with corn grown in nineteen states. Fifteen of the studies were on field corn and six on sweet corn. Residues of fluthiacet-methyl in treated corn grain and ears were less than the method LOQ (<0.01 ppm). Residues in forage after the day of application were less than the proposed tolerance of 0.05 ppm. The proposed tolerances of 0.02 ppm in grain and 0.05 ppm in forage and fodder are adequate to cover residues likely to occur when Action herbicide is applied to corn as directed.

A feeding study in cattle has been submitted and tolerances for residues of fluthiacet-methyl in meat and milk will not be requested. The results from hen and goat metabolism studies, wherein fluthiacet-methyl was fed at exaggerated rates, showed that the transfer of fluthiacet-methyl residues from feed to tissues, milk and eggs is extremely low. No detectable residues of fluthiacet-methyl (or metabolite CGA-300403) would be expected in meat, milk, poultry, or eggs after feeding the maximum allowable amount of treated corn and soybeans. This conclusion is based on residue data from the corn and soybean metabolism and field residue chemistry studies coupled with the residue transfer from feed to tissues, milk and eggs obtained in the goat and hen metabolism studies.

In studies with processed corn fractions, no concentration of fluthiacet-methyl was observed and tolerances in processed commodities will not be required. In addition, confined rotational crop studies indicated that fluthiacet-methyl will not be taken up by rotational crops.

Analytical Method AG-603B has been submitted for analysis of residues of fluthiacet-methyl in soybeans and in corn and its processed fractions. This method can be provided to the FDA. Residue levels of fluthiacet-methyl are determined by gas chromatography and the limit of detection for the method is 0.01 ppm.

8. *Environmental fate.* Action degraded rapidly under laboratory and field conditions. Laboratory hydrolysis under basic conditions was T1/2 5 hours at pH 9 and stable under acidic conditions (T1/2 485 days at pH 5). The soil metabolism half-life was extremely short, ranging from 1.1 days under aerobic conditions to 1.6 days under anaerobic conditions. Photodegradation was rapid in soil (T1/2 0.5 days) and moderate in solution at pH 5 (5 days). Because of the extremely low use rate and very short half-life in the field, field dissipation experiments were conducted with radiolabeled chemical. After bare-ground application, the half-life of Action was 1 day in sandy loam and 1.8 days in clay loam. All degradates identified in the field were also identified in the laboratory studies.

Parent and aged leaching laboratory experiments showed that the mobility of Action ranged from slight to medium by soil type. Based on estimates of relative mobility (Koc), Action was classified as having medium mobility in sand and low mobility in loam, silt loam and clay. The major degradation products of Action were found to have high to low mobility classifications based on Koc estimations. Although the data suggest that some of the degradates are highly mobile a high degree of soil binding is expected based on results of the laboratory and the field experiments. Since weeds and crop will intercept the majority of this product when it is applied, and given the extremely low use rate and high degree of soil binding, Action herbicide is not expected to leach into groundwater.

**2. Novartis Crop Protection**

*PP 6F4751*

EPA has received a pesticide petition (PP 6F4751) from Novartis Crop Protection, Inc., P. O. Box 18300, Greensboro, North Carolina 27419, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR 180.368 by establishing a tolerance for residues of the herbicide metolachlor in or on the raw agricultural commodity tomatoes at 0.1 ppm. The proposed analytical method is available for enforcement purposes. Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Novartis Crop Protection has submitted the following summary of information, data and arguments in support of their pesticide petition. This summary was prepared by Novartis Crop Protection and EPA has not fully evaluated the merits of the petition. EPA edited the summary to clarify that the conclusions and arguments were the petitioners and not necessarily EPA's and to remove certain extraneous material.

*A. Metolachlor Uses*

Metolachlor is a chloroacetanilide herbicide registered primarily for grass control on a wide variety of crops. It is proposed for use on tomatoes at a maximum rate of 3 lbs. active ingredient per acre depending on soil texture and organic matter content. One application may be made preplant incorporated, preplant before transplanting, post-directed or post-over-the-top. A 90–day preharvest interval is to be observed.

*B. Metabolism and Analytical Method*

1. *Metabolism*. The qualitative nature of the metabolism of metolachlor in plants and animals is well understood. Metabolism in plants involves conjugation of the chloroacetyl side chain with glutathione, with subsequent conversion to the cysteine and thiolactic acid conjugates. Oxidation to the corresponding sulfoxide derivatives occurs and cleavage of the side chain ether group, followed by conjugation with glucose. In animals, metolachlor is rapidly metabolized and almost totally eliminated in the excreta of rats, goats, and poultry. Metabolism in plants and animals proceeds through common Phase 1 intermediates and glutathione conjugation.

2. *Analytical methodology*. Novartis Crop Protection has submitted a practical analytical method involving extraction by acid reflux, filtration, partition and cleanup with analysis by gas chromatography using Nitrogen/Phosphorous (N/P) detection. The methodology converts residues of metolachlor into a mixture of CGA-37913 and CGA-49751. The limit of quantitation (LOQ) for the method is 0.03 ppm for CGA-37913 and 0.05 ppm for CGA-49751.

*C. Magnitude of Residue*

Thirteen field trials were conducted in major tomato production areas across the United States. Both tomato and its processed fractions were analyzed for residues of metolachlor, measured as CGA-37913 and CGA-49751. One application of metolachlor at 3.0 lbs. ai/A (1X) was made post-foliar to tomato transplants. Exaggerated rate applications (2X, 3X and 5X) were also made. Two of the 13 trials were used for processing into tomato commodity products. No residues (LOQ of 0.08 ppm) were found at the 1X rate in the RAC tomatoes. In processed commodities at the 1X rate of 3.0 lbs ai/A, residues of metolachlor were found below the method LOQ in tomato puree (0.4 ppm) and above the method LOQ in dry pomace and tomato paste (0.16 and 0.13 ppm, respectively). Because residues in tomato puree and paste (commodities listed in Table 1 of OPPTS 860.1000 as processed commodities of tomatoes) are less than 2X the LOQ of 0.08 ppm, tolerances are not required according to OPPTS 860.1520 (f)(3). No transfer of residues to beef and dairy cattle or poultry is expected from the use of metolachlor on tomatoes.

*D. Codex Alimentarius Commission (CODEX)*

There are no maximum residue levels (MRL's) established for residues of metolachlor in or on raw agricultural commodities.

*E. Toxicological Profile of Metolachlor*

1. *Acute toxicity*. Metolachlor has a low order of acute toxicity. The combined rat oral $LD_{50}$ is 2,877 mg/kg. The acute rabbit dermal $LD_{50}$ is > 2,000 mg/kg and the rat inhalation $LD_{50}$ is > 4.33 mg/L. Metolachlor is not irritating to the skin and eye. It has been shown to be positive in guinea pigs for skin sensitization. End use formulations of metolachlor also have a low order of acute toxicity and cause slight skin and eye irritation.

2. *Subchronic toxicity*. Metolachlor was evaluated in a 21–day dermal toxicity study in the rabbit and a 6–month dietary study in dogs; NOELs of 100 mg/kg/day and 7.5 mg/kg/day were established in the rabbit and dog, respectively. The liver was identified as the main target organ.

3. *Chronic toxicity*. A 1–year dog study was conducted at dose levels of 0, 3.3, 9.7, or 32.7 mg/kg/day. The Agency-determined RfD for metolachlor is based on the 1 year dog study with a NOEL of 9.7 mg/kg/day. The RfD for metolachlor is established at 0.1 mg/kg/day using a 100-fold uncertainty factor. A combined chronic toxicity/oncogenicity study was also conducted in rats at dose levels of 0. 1.5, 15 or 150 mg/kg/day. The NOEL for systemic toxicity was 15 mg/kg/day.

4. *Developmental/Reproduction*. The developmental and teratogenic potential of metolachlor was investigated in rats and rabbits. The results indicate that metolachlor is not embyrotoxic or teratogenic in either species at maternally toxic doses. The NOEL for developmental toxicity for metolachlor was 360 mg/kg/day for both the rat and rabbit while the NOEL for maternal toxicity was established at 120 mg/kg/day in the rabbit and 360 mg/kg/day in the rat. A 2–generation reproduction study was conducted with metolachlor in rats at feeding levels of 0, 30, 300 and 1,000 ppm. The reproductive NOEL of 300 ppm (equivalent to 23.5 to 26 mg/kg/day) was based upon reduced pup weights in the F1a and F2a litters at the 1,000 ppm dose level(equivalent to 75.8 to 85.7 mg/kg/day). The NOEL for parental toxicity was equal to or greater than the 1,000 ppm dose level.

5. *Carcinogenicity*. An evaluation of the carcinogenic potential of metolachlor was made from two sets of oncogenicity studies conducted with metolachlor in rats and mice. Using the Guidelines for Carcinogenic Risk Assessment published September 24, 1986 (51 FR 33992) and the results of the November, 1994 Carcinogenic Peer Review, EPA has classified metolachlor as a Group C carcinogen and recommended using a Margin of Exposure (MOE) approach to quantify risk. This classification is based upon the marginal tumor response observed in livers of female rats treated with a high (cytotoxic) dose of metolachlor (3,000 ppm). The two studies conducted in mice were negative for oncogenicity.

6. *Genotoxicity*. Assays for genotoxicity were comprised of tests evaluating metolachlor's potential to induce point mutations (Salmonella assay and an L5178/TK+/- mouse lymphoma assay), chromosome aberrations (mouse micronucleus and a dominant lethal assay) and the ability to induce either unscheduled or scheduled DNA synthesis in rat hepatocytes or DNA damage or repair in human fibroblasts. The results indicate that metolachlor is not mutagenic or clastogenic and does not provoke unscheduled DNA synthesis.

*F. Threshold Effects*

1. *Chronic effects*. Based on the available chronic toxicity data, EPA has established the RfD for metolachlor at 0.1 mg/kg/day. The RfD for metolachlor is based on a 1–year feeding study in dogs with a No-Observed Effect Level (NOEL) of 9.7 mg/kg/day and an uncertainty factor of 100.

2. *Acute toxicity*. Based on the available acute toxicity data, it is believed metolachlor does not pose any acute dietary risks.

*G. Non-threshold Effects*

*Carcinogenicity*. Using its Guidelines for Carcinogenic Risk Assessment published September 24, 1986 (51 FR 33992), EPA has classified metolachlor as Group 'C' for carcinogenicity (possible human carcinogen) based on findings of a carcinogenic effect in the liver of the female rat. Because this carcinogenic response was only observed at the high dose of 3,000 ppm, a dose associated with evidence of liver damage, it is likely that this response occurred via a non-genotoxic, threshold-based mechanism. Therefore, EPA is regulating exposure to metolachlor using a margin of exposure approach. A NOEL of 15 mg/kg/day from the 2 year rat feeding study was determined to be appropriate for use in the Margin of Exposure carcinogenic risk assessment. However, because the chronic reference dose is lower (9.7 mg/kg/day) than the oncogenic NOEL (15 mg/kg/day), the EPA is using the Reference Dose for quantification of human risk.

*H. Aggregate Exposure*

1. *Dietary exposure*. For purposes of assessing the potential dietary exposure to metolachlor, aggregate exposure has been estimated based on the TMRC from the use of metolachlor in or on raw agricultural commodities for which tolerances have been previously established (40 CFR 180.368). The incremental effect on dietary risk resulting from the addition of tomatoes to the label was assessed by conservatively assuming that exposure would occur at the proposed tolerance level of 0.1 ppm with 100% of the crop treated. The TMRC is obtained by multiplying the tolerance level residue for all these raw agricultural commodities by the consumption data which estimates the amount of these products consumed by various population subgroups. Some of these raw agricultural commodities (e.g. corn forage and fodder, peanut hay) are fed to animals; thus exposure of humans to residues in these fed commodities might result if such residues are transferred to meat, milk, poultry, or eggs. Therefore, tolerances of 0.02 ppm for milk, meat and eggs and 0.2 ppm for kidney and 0.05 ppm for liver have been established for metolachlor. In conducting this exposure assessment, it has been conservatively assumed that 100% of all raw agricultural commodities for which tolerances have been established for metolachlor will contain metolachlor residues and those residues would be at the level of the tolerance--which results in an overestimation of human exposure.

2. *Drinking water*. Another potential source of exposure of the general population to residues of pesticides are residues in drinking water. Based on the available studies used by EPA to assess environmental exposure, it is not anticipated that exposure to residues of metolachlor in drinking water will exceed 20% of the RfD (0.02 mg/kg/day), a value upon which the Health Advisory Level of 70 ppb for metolachlor is based. In fact, based on experience with metolachlor, it is believed that metolachlor will be infrequently found in groundwater (less than 5% of the samples analyzed), and when found, it will be in the low ppb range.

3. *Non-dietary exposure*. Although metolachlor may be used on turf and ornamentals in a residential setting, that use represents less than 0.1 percent of the total herbicide market for residential turf and landscape uses. Currently, there are no acceptable, reliable exposure data available to assess any potential risks. However, given the small amount of material that is used, it is concluded that the potential for non-occupational exposure to the general population is unlikely.

*I. Cumulative Effects*

The potential for cumulative effects of metolachlor and other substances that have a common mechanism of toxicity has also been considered. It is concluded that consideration of a common mechanism of toxicity with other registered pesticides in this chemical class (chloroacetamides) is not appropriate. Since EPA itself has concluded that the carcinogenic potential of metolachlor is not the same as other registered chloroacetamide herbicides, based on differences in rodent metabolism (EPA Peer Review of metolachlor, 1994), it is believed that only metolachlor should be considered in an aggregate exposure assessment.

*J. Safety Determinations*

1. *U.S. population in general*. Using the conservative exposure assumptions described above, based on the completeness and reliability of the toxicity data, it is concluded that aggregate exposure to metolachlor will utilize 1.4 percent of the RfD for the U.S. population. EPA generally has no concern for exposures below 100 percent of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Therefore, it is concluded that there is a reasonable certainty that no harm will result from aggregate exposure to metolachlor or metolachlor residues.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of metolachlor, data from developmental toxicity studies in the rat and rabbit and a 2–generation reproduction study in the rat have been considered. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from chemical exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to a chemical on the reproductive capability of mating animals and data on systemic toxicity.

Developmental toxicity (reduced mean fetal body weight, reduced number of implantations/dam with resulting decreased litter size, and a slight increase in resorptions/dam with a resulting increase in post-implantation loss) was observed in studies conducted with metolachlor in rats and rabbits. The NOEL's for developmental effects in both rats and rabbits were established at 360 mg/kg/day. The developmental effect observed in the metolachlor rat study is believed to be a secondary effect resulting from maternal stress (lacrimation, salivation, decreased body weight gain and food consumption and death) observed at the limit dose of 1,000 mg/kg/day.

A 2-generation reproduction study was conducted with metolachlor at feeding levels of 0, 30, 300 and 1,000 ppm. The reproductive NOEL of 300 ppm (equivalent to 23.5 to 26 mg/kg/day) was based upon reduced pup weights in the F1a and F2a litters at the 1,000 ppm dose level (equivalent to 75.8 to 85.7 mg/kg/day). The NOEL for parental toxicity was equal to or greater than the 1,000 ppm dose level. FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database. Based on the current toxicological data requirements, the database relative to pre- and post-natal

effects for children is complete. Further, for the chemical metolachlor, the NOEL of 9.7 mg/kg/day from the metolachlor chronic dog study, which was used to calculate the RfD (discussed above), is already lower than the developmental NOEL's of 360 mg/kg/day from the metolachlor teratogenicity studies in rats and rabbits. In the metolachlor reproduction study, the lack of severity of the pup effects observed (decreased body weight) at the systemic LOEL (equivalent to 75.8 to 85.7 mg/kg/day) and the fact that the effects were observed at a dose that is nearly 10 times greater than the NOEL in the chronic dog study (9.7 mg/kg/day) suggest there is no additional sensitivity for infants and children. Therefore, it is concluded that an additional uncertainty factor is not warranted to protect the health of infants and children and that the RfD at 0.1 mg/kg/day based on the chronic dog study is appropriate for assessing aggregate risk to infants and children from use of metolachlor.

Using the conservative exposure assumptions described above, the percent of the RfD that will be utilized by aggregate exposure to residues of metolachlor including the proposed use on tomatoes is 1.1 percent for nursing infants less than 1 year old, 3.5 percent for non-nursing infants, 3.0 percent for children 1 to 6 years old and 2.2 percent for children 7 to 12 years old. Therefore, 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 infants and children from aggregate exposure to metolachlor residues.

*K. Estrogenic Effects*

Metolachlor does not belong to a class of chemicals known or suspected of having adverse effects on the endocrine system. There is no evidence that metolachlor has any effect on endocrine function in developmental or reproduction studies. Furthermore, histological investigation of endocrine organs in the chronic dog, rat and mouse studies conducted with metolachlor did not indicate that the endocrine system is targeted by metolachlor, even at maximally tolerated doses administered for a lifetime. Although residues of metolachlor have been found in raw agricultural commodities, there is no evidence that metolachlor bioaccumulates in the environment.

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## FEDERAL HOUSING FINANCE BOARD

**[No. 97–N–2]**

### Notice of Federal Home Loan Bank Members Selected for Community Support Review

**AGENCY:** Federal Housing Finance Board.

**ACTION:** Notice.

**SUMMARY:** The Financial Institutions Reform, Recovery, and Enforcement Act of 1989 added a new Section 10(g) to the Federal Home Loan Bank Act of 1932 requiring that members of the Federal Home Loan Bank (FHLBank) System meet standards for community investment or service in order to maintain continued access to long-term FHLBank System advances. In compliance with this statutory change, the Federal Housing Finance Board (Housing Finance Board) promulgated Community Support regulations (12 CFR Part 936). Under the review process established in the regulations, the Housing Finance Board will select a certain number of members for review each quarter, so that all members that are subject to the Community Reinvestment Act of 1977, 12 U.S.C. § 2901 *et seq.*, (CRA), will be reviewed once every two years. The purpose of this Notice is to announce the names of the members selected for the fifth quarter review (1996–97 cycle) under the regulations. The Notice also conveys the dates by which members need to comply with the Community Support regulation review requirements and by which comments from the public must be received.

**DATES:** Due Date For Member Community Support Statements for Members Selected in Fifth Quarter Review: May 29, 1997.

Due Date For Public Comments on Members Selected in Fifth Quarter Review: May 29, 1997.

**FOR FURTHER INFORMATION CONTACT:** Mitchell Berns, Director, Office of Supervision, (202) 408–2562, Federal Housing Finance Board, 1777 F Street, NW., Washington, DC 20006. A telecommunications device for deaf persons (TDD) is available at (202) 408–2579.

**SUPPLEMENTARY INFORMATION:**

### A. Selection for Community Support Review

The Housing Finance Board currently reviews all FHLBank System members that are subject to CRA approximately once every two years. Approximately one-eighth of the FHLBank members in each district will be selected for review by the Housing Finance Board each calendar quarter. To date, only members that are subject to CRA have been reviewed. In selecting members, the Housing Finance Board follows the chronological sequence of the members' CRA Evaluations post-July 1, 1990, to the greatest extent practicable, selecting one-eighth of each District's membership for review each calendar quarter. However, the Housing Finance Board will postpone review of new members until they have been System members for one year.

Selection for review is not, nor should it be construed as, any indication of either the financial condition or Community Support performance of the institutions listed.

### B. List of FHLBank Members To Be Reviewed in the Fifth Quarter, Grouped by FHLBank District

| Member | City | State |
|---|---|---|
| **Federal Home Loan Bank of Boston—District 1<br>P.O. Box 9106<br>Boston, Massachusetts 02205–9106** | | |
| Lafayette American Bank and Trust Company | Bridgeport | CT |
| People's Bank | Bridgeport | CT |
| Maritime Bank and Trust Company | Essex | CT |
| Farmington Savings Bank | Farmington | CT |
| Glastonbury Bank & Trust | Glastonbury | CT |
| Savings Bank of Manchester | Manchester | CT |
| Liberty Bank | Middletown | CT |
| Naugatuck Savings Bank | Naugatuck | CT |