combinations that are major contributors to risk.

The monitoring data being used in the OP cumulative assessment, USDA's PDP data, are the Agency's preferred data for risk assessment. The number of samples analyzed in the PDP for these food commodity/OP combinations ranged from 275 to 2,600 samples. USDA's PDP program has been collecting data on pesticide residues found on foods since 1991, primarily for purposes of estimating dietary exposure to pesticides. For several years, EPA has routinely used the PDP database in developing assessments of dietary risk. The PDP's sampling procedures were designed to capture actual residues of the pesticide and selected metabolites in the food supply as close as possible to the time of consumption. Data collected close to actual consumption, such as PDP data, depicts a more realistic estimate of exposure, i.e., residues that could be encountered by consumers. The real-world nature of PDP data makes it preferable for the purposes of this assessment than pesticide field trials, which are another data source available to the Agency. Field trial data are designed to test for residues under exaggerated application scenarios, and are primarily used in establishing tolerances.

The PDP is designed to focus on foods highly consumed by children and to reflect foods typically available throughout the year. PDP's commodity testing profile includes not only fresh fruits and vegetables, but also canned and frozen fruits/vegetables, fruit juices, whole milk, wheat, soybeans, oats, corn syrup, peanut butter, rice, poultry, beef, and drinking water. The PDP generally collects foods at wholesale distribution centers and stores them frozen until analysis. Foods are washed and inedible portions are removed before analysis but these foods are not further cooked or processed. A complete description of the PDP and all data through 1999 are available on the internet at www.ams.usda.gov/science/pdp.

PDP data are not available for all food commodities with current OP registrations, including a limited number of food commodity tolerances that are listed in this notice. When PDP data are not available for a commodity, EPA uses data when it is appropriate to do so from commodities that are measured by PDP to serve as surrogate data sources. This well established practice of using surrogate, or ''translated,'' data is based upon the concept that families of commodities with similar cultural practices and insect pests are likely to have similar pesticide use patterns. For example, data on peaches can be used as surrogate data for apricots. The practice of translating data from tested sources to similar situations that have not been directly tested has been used for some time by EPA in the development of pesticide-specific dietary exposure assessments when monitoring data are unavailable. The methods of translation, specifically, what commodities may be used to represent other commodities, have been made public. EPA is using translated data where appropriate for the purposes of the OP cumulative risk assessment and tolerance reassessment as discussed in this notice.

EPA has examined the PDP data that is being used for the OP cumulative risk assessment and found that residues of the parent pesticide or any tested metabolite were reported in less than one percent of the samples analyzed for the 37 OP tolerances listed below. As a result, EPA has concluded that these tolerances make, at most, a minimal contribution to the cumulative risk from OP pesticides, and, therefore, these tolerances are considered reassessed. EPA expects to announce as reassessed other tolerances that have fewer than one percent detections in PDP in future notices as appropriate in light of their individual OP assessments.

The following 37 tolerances are considered reassessed at this time:

Azinphos methyl (40 CFR 180.154)
Fruit, citrus, group
Eggplant
Grape
Parsley, leaves
Parsley, root
Pepper
Spinach
Strawberry
Tomato, postharvest

Chlorpyrifos (40 CFR 180.342)
Bean, lima
Bean, snap
Brussels sprouts
Cabbage
Cabbage, chinese
Legume vegetables, succulent or dried (except soybean)
Pumpkin
Radish
Rutabaga
Strawberry
Turnip

Disulfoton (40 CFR 180.183)
Cabbage
Lettuce
Pepper
Potato
Soybean
Wheat, grain

Mevinphos (40 CFR 180.157)
Broccoli
Cucumber
Pepper
Strawberry
Tomato

Oxydemeton methyl (40 CFR 180.330)
Cucumber
Pepper
Squash, summer

Phorate (40 CFR 180.206)
Wheat, grain

Phosalone (40 CFR 180.263)
Apple

Phosmet (40 CFR 180.261)
Cherry

List of Subjects

Environmental protection, Chemicals, Pesticides and pests.

Dated: July 31, 2002.

Lois A. Rossi,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 02–20456 Filed 8–13–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0175; FRL–7191–7]

Notice of Filing Pesticide Petitions to Establish Tolerances for a Certain Pesticide Chemical in or on Food

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 a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2002–0175, must be received on or before September 13, 2002.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP–2002–0175 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'' 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 ID number OPP–2002–0175. 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 ID number OPP–2002–0175 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 ID number OPP–2002–0175. 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 ID 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 pesticide petitions 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 the 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 support granting of the petitions. Additional data may be needed before EPA rules on the petitions.

List of Subjects

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

Dated: July 31, 2002.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petitions

The petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the summaries verbatim without editing them in any way. The summaries 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)

Dow Agro Sciences LLC

PP 1E6227, 1E6241, 1E6283, 1E6291, 1E6320, 1E6329, 1E6333, 1E6334, 1E6335, 1E6399, and 1E6340

EPA has received pesticide petitions (PP) (1E6227, 1E6241, 1E6283, 1E6291, 1E6320, 1E6329, 1E6333, 1E6334, 1E6335, 1E6399 and 1E6340) from the Interregional Research Project Number 4 (IR-4), P.O. Box 231, Rutgers University, New Brunswick, NJ 08903 and PP 4F4379 from Dow Agro Sciences LLC, Indianapolis, IN 46268, proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish tolerances for clopyralid in or on the raw agricultural commodities as follows:

1. PP 1E6227 proposes a tolerance for flax seed at 3.0 part per million (ppm).

2. PP 1E6241 proposes a tolerance for strawberry at 1.0 ppm.

3. PP 1E6283 proposes a tolerance for hop, dried cones at 5.0 ppm.

4. PP 1E6291 proposes tolerances for rapeseed seed, rapeseed forage, canola seed, mustard seed, and crambe seed at 3 ppm, and canola meat at 6.0 ppm.

5. PP 1E6320 proposes a tolerance for spinach at 5.0 ppm.

6. PP 1E6329 proposes a tolerance for the stone fruit group at 0.5 ppm.

7. PP 1E6333 proposes tolerances for garden beet tops at 3.0 ppm and garden beet roots at 4.0 ppm.

8. PP 1E6334 proposes a tolerance for mustard greens at 5.0 ppm.

9. PP 1E6335 proposes tolerances for turnip roots at 1.0 ppm and turnip greens at 4.0 ppm.

10. PP 1E6340 proposes a tolerance for cranberry at 4 ppm.

11. PP 4F4379 proposes tolerances for sweet corn, kernel plus cob with husks removed at 1.0 ppm, sweet corn forage at 7.0 ppm, sweet corn stover at 10.0 ppm, pop corn grain at 1.0 ppm, pop corn stover at 10.0 ppm, liver of cattle, goat, horse, and sheep at 3.0 ppm, meat byproducts, except liver, of cattle, goat, horse and sheep at 36.0 ppm, and milk at 0.2 ppm.

12. PP 1E3999 proposes a tolerance for the Brassica, head and stem, subgroup at 2.0 ppm.

EPA has determined that the petitions 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 petitions. Additional data may be needed before EPA rules on the petitions. This notice includes a summary of the petition prepared by Dow Agro Sciences LLC, Indianapolis, IN 46268.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism in plants is adequately understood. No metabolites of significance were detected in plant metabolism studies.

2. *Analytical method*. There is a practical analytical method for detecting and measuring levels of clopyralid in or on food with a limit of quantitation (LOQ) of 0.05 ppm that allows monitoring of food with residues at or above the levels set in these tolerances. EPA has provided information on this method to FDA. The method is available to anyone who is interested in pesticide residue enforcement.

3. *Magnitude of residues*. For flax, magnitude of residue data on flax in Canada were used. The maximum residue limits for clopyralid in Canada are 0.2 ppm for flax. Trial sites conducted in Canada include Manitoba and Alberta which borders North Dakota and Minnesota. Clopyralid was applied at 150 to 300 g ai/ha (0.13 to 0.27 lb ai/acre). The maximum combined residue was 0.22 ppm.

For mustard greens, magnitude of residue data were collected from field trials conducted in New Jersey, California, South Carolina, Texas, Florida, Michigan, and Tennessee. Each of eight field trial sites consisted of one untreated control plot and one treated plot. The treated plots received one application of the test substance at a rate of approximately 0.187 lb ai/acre. Marketable greens (mustard plants) were collected approximately 30 days following the application. In treated greens (mustard) samples, clopyralid residues ranged from 0.48 to 4.4 ppm.

For turnip roots and tops, magnitude of residue data were collected from field trials conducted in Tennessee, North Carolina, Texas, Georgia, Wisconsin, and California. Each of the six field trial sites consisted of one untreated control plot and one treated plot. The treated plots received one application of the test substance at a rate of approximately 0.187 lb ai/acre. At the North Carolina trial, a banded application was made to simulate regional practices; broadcast applications were made at the five remaining trials. Marketable turnip tops and roots were collected approximately 15 days and 30 days following the application, respectively. In treated tops samples, clopyralid residues ranged from 0.64 to 3.2 ppm. Clopyralid residues in treated roots samples ranged from 0.059 to 0.56 ppm.

For garden beet, magnitude of residue data were collected from field trials conducted in Florida, Michigan, New York, Texas, Wisconsin, and Washington. Each of the seven field trial sites consisted of one untreated control plot and one treated plot. The treated plots received one application of the test substance at a rate of approximately 0.187 lb ai/acre. Marketable beet (garden) roots and tops were collected approximately 30 days following the application, respectively. In treated tops samples, clopyralid residues ranged from 0.36 to 2.8 ppm. Clopyralid residues in treated roots samples ranged from 0.71 to 3.0 ppm.

For stone fruit, cherry field trials were conducted in Michigan, Washington, and New Jersey. Cherry plots were treated once by a broadcast application directed to the orchard floor with clopyralid at approximately 0.5 lb ai/acre. Samples were taken 21 to 31 days after the last treatment. All cherries were pitted prior to freezing. Peach trials were conducted in New Jersey, Michigan, North Carolina, and California. One application of clopyralid at approximately 0.5 lb ai/acre was made to a band on each side of the trees in the treated plots. The fruit in the New Jersey trials matured quickly and were harvested after 20 to 21 days. In North Carolina, the peaches were harvested after 20 days because insect and disease pressure threatened to ruin the crop. All peaches were pitted prior to freezing. Plum trials were conducted in New Jersey, Washington, and California. One application of clopyralid at approximately 0.5 lb ai/acre was made to a bank on each side of the trees in the treated plots. The fruit in one California trial matured quickly and was harvested after 21 days. The other California trial included collection of both fresh and dried plums. All plums were pitted prior to freezing or drying.

No detectable residues of clopyralid were found in any of the untreated peach samples. The treated samples from California and one of the treated samples from North Carolina also had no detectable residues. The residues in the other samples were no higher than 0.35 ppm. No detectable residues of clopyralid were found in any of the untreated or treated cherries in this study. No detectable residues of clopyralid were found in any of the untreated plums or dried plums. No detectable residues of clopyralid were found in the treated plum samples from California. The treated plum samples from New Jersey and Washington had residues in the range 0.05 to 0.41 ppm. The dried plum samples had residues in the range 0.16 to 0.19 ppm.

For hops, magnitude of residue data were collected from field trials conducted in Oregon and Washington. Each field trial site consisted of one untreated control plot and one treated plot. The treated plots received two applications of the test substance at a rate of 0.38 lb ai/acre + 5%. All applications were made post-emergence, directed, 21 to 22 days apart. Dried hop cone samples were collected 27 to 32 days following the final application. Residue concentrations from treated samples ranged from a high 4.14 ppm to a low 0.3 ppm. All residues found in treated samples fell between the highest and lowest concentrations tested in method validation, 0.1 ppm and 0.5 ppm. None of the untreated samples were found to contain clopyralid above the instrumental detection limit of 0.08 ppm.

For cranberry, field trials were conducted in Maine, New Jersey, Oregon, Washington, and Wisconsin. Clopyralid was broadcast onto fruiting cranberry vines at approximately 0.25 lb ai/acre to the treated plots, twice, at an interval of 13 to 16 days. Treated and untreated cranberries were harvested 44 to 51 days after the second application and stored frozen. No detectable residues of clopyralid were found on untreated cranberries from any of the field trials. Residues on treated samples were in the range 0.88 to 3.1 ppm.

For spinach, field trials were conducted in Texas, New York, California, Tennessee, South Carolina, and Georgia. Clopyralid was applied once at a rate of 0.092 to 0.290 lb ai/acre 20 to 22 days before harvest. Spinach was harvested and stored frozen. Residues on treated samples were in the range 0.056 to 3.8 ppm.

For strawberry, field trials were conducted in Oregon, California, North Carolina, New Jersey, and Michigan. Clopyralid applied foliar post-emergence in the late summer or early fall at a use rate of approximately 0.25 lb ai/acre, followed by a second application of approximately 0.125 lb ai/acre at 28 to 31 days before harvest resulted in residues of clopyralid ranging from 0.10 to 0.505 ppm. When applied at 0.50 lb ai/acre followed by a second application of approximately 0.25 lb ai/acre at 28 to 31 days before harvest resulted in residues of clopyralid ranging from 0.295 to 1.61 ppm.

For sweet corn, field trials were conducted in California, Georgia, Illinois, Michigan, Minnesota, North Carolina, New York, Ohio and Pennsylvania. Clopyralid was applied once as a post-emergent broadcast spray with water as a carrier at the rate of 0.66 to 0.70 percent treated (pt)/acre (0.25 to 0.26 lb ai/acre). The application was made when the corn was 12 to 18 inches in height and prior to tasseling. The ears were removed before the remaining plant (forage) was chopped. Residues were detected at the following ppm ranges: Grain, 0.087–0.12; forage, 0.34–2.0; ears (K + CWHR) 0.029–0.23; cannery waste, no residues were detected above the limit of quantitation (LOQ) of the method.

For popcorn, field trials were conducted in Indiana, Iowa, Nebraska and Ohio. Clopyralid was applied once as a post-emergent broadcast spray with water as the carrier at the rate of 0.67 pt/acre (0.25 lb ai/acre). The application was made when the popcorn was 22 to 24 inches in height. Green forage was collected when kernels were in the milk stage (i.e., at a pre-harvest interval of 45 to 55 days). Kernels and fodder were collected at normal harvest (i.e., at pre-harvest intervals of 78 to 129 days). Residues were detected at the following ppm ranges: Grain, 0.03–0.91; fodder, no detectable residues above the LOQ of the method - 0.60; forage, 0.14–1.2.

In the magnitude of residue field studies for canola, crambe, and mustard seed, the first study had three field trials, one each in Georgia, South Dakota, and Washington. Each field trial site consisted of one untreated control plot and one treated plot. The treated plots received one broadcast application of the test substance 70 to 74 days before harvest. The test substance was applied to the treated plot at a rate of 0.211 lb ai/acre to 0.256 lb ai/acre. Residues of clopyralid detected in the field treated samples ranged from 0.42 to 1.32 ppm. The second field study had three field trials, one each in Georgia, South Dakota, and Washington. Again, each field trial site consisted of one untreated control plot and one treated plot. The treated plots received one broadcast application of the test substance 48 to 49 days before harvest. The test substance was applied to the treated plot at a rate of 0.231 lb ai/acre to 0.255 lb ai/acre. Two additional samples from the Washington trial (one treated and one untreated) were sent for processing into oil and meal. Residues of clopyralid detected in the field treated samples of canola seed ranged from >0.05 to 1.86 ppm. There were no detectable residues of clopyralid in either the canola oil or canola meal samples.

B. Toxicological Profile

1. *Acute toxicity*. Clopyralid has low acute toxicity. The rat oral LD_{50} is 5,000 milligrams/kilogram (mg/kg) or greater for males and females. The rabbit dermal LD_{50} is greater than 2,000 mg/kg and the rat inhalation LC_{50} is greater than 1.0 mg/L air (the highest attainable concentration). In addition, clopyralid is not a skin sensitizer in guinea pigs and is not a dermal irritant. Technical clopyralid is an ocular irritant, but ocular exposure to the technical material would not normally be expected to occur to infants or children or the general public. End use formulations of clopyralid have similar low acute toxicity profiles and most have low ocular toxicity as well.

2. *Genotoxicty*. Clopyralid is not genotoxic. The following studies have been conducted and all were negative for genotoxic responses: Ames bacterial mutagenicity assay (with and without exogenous metabolic activation); host-mediated assay *in vivo* cytogenetic test, rat; *in vivo* cytogenetic test, mouse; *in vivo* dominant lethal test, rat; *in vitro* unscheduled DNA synthesis assay in primary rat hepatocyte cultures; *in vitro* mammalian cell gene mutations assay in Chinese hamster ovary cell cultures (with and without exogenous metabolic activation).

3. *Reproductive and developmental toxicity*. Developmental toxicity was studied using rats and rabbits. The developmental study in rats resulted in a developmental no observed adverse effect level (NOAEL) of >250 mg/kg/day (a maternally toxic dose) and a maternal toxicity NOAEL of 75 mg/kg/day. A 1974 study in rabbits revealed no evidence of developmental or maternal toxicity at 250 mg/kg/day; thus, the developmental and maternal NOEL was >250 mg/kg/day. A more recent study in rabbits (1990) resulted in developmental and maternal NOAELs of 110 mg/kg/day based on maternal toxicity at 250 mg/kg/day. Based on all of the data for clopyralid, there is no evidence of developmental toxicity at dose levels that do not result in maternal toxicity.

In a 2-generation reproduction study in rats, pups from the high dose group which were fed diets containing clopyralid had a slight reduction in body weight during lactation and an increase in liver weights in F1a and F1b weanlings. The NOAEL for parental systemic toxicity was 500 mg/kg/day. There was no effect on reproductive parameters at >1,500 mg/kg/day nor was there an adverse effect on the morphology, growth or viability of the offspring; thus, the reproductive NOAEL is >1,500 mg/kg/day.

4. *Subchronic toxicity*. The following studies have been conducted using clopyralid. In a rat 90–day feeding study, Fischer 344 rats were fed diets containing clopyralid at doses of 5, 15, 50, or 150 mg/kg/day with no adverse effects attributed to treatment. In a second study, Fischer 344 rats were fed diets containing clopyralid at doses of 300, 1,500, and 2,500 mg/kg/day. Effects at the highest doses were decreased food consumption accompanied by decreased body weights and weight gains in both males and females. Slightly increased mean relative liver and kidney weights were noted in males of all doses and in females at the top two doses. Because there were no other effects, the kidney and liver weight effects were judged as being adaptive rather than directly toxic. The NOAEL was 1,500 mg/kg/day for males and females. The NOAEL was 300 mg/kg/day for females. In a mouse 90–day feeding study, B6C3F1 mice were fed diets containing clopyralid at doses of 200, 750, 2,000, or 5,000 mg/kg/day. A slight decrease in body weight occurred at the top dose in both sexes. The liver was identified as the target organ based on slight increases in liver weights and minimal microscopic alterations at the higher dose levels. The liver changes were considered to be reversible and adaptive. The NOAEL for males was 2,000 mg/kg/day and for females was 750 mg/kg/day. In a 180–day feeding study, beagle dogs were fed diets containing clopyralid at doses of 15, 50, or 150 mg/kg/day; there were no adverse effects. In a second dietary study, dogs also were fed diets containing clopyralid at doses of 15, 50, or 150 mg/kg/day; the only effect was an increase in the mean relative liver weight in females at the 150 mg/kg/day. In a 21–day dermal study, clopyralid was applied by repeated dermal application to New Zealand White rabbits at dose levels up to 1,000 mg/kg/day. Treatment produced no systemic effects.

5. *Chronic toxicity*. In a chronic toxicity and oncogenicity study, Sprague-Dawley rats were fed diets containing clopyralid at doses of 5, 15, 50 or 150 mg/kg/day. The only effect was a trend toward a decreased body weight of female rats receiving the 150 mg/kg/day dose and the NOAEL was 50 mg/kg/day. In a second study, clopyralid was fed to Fischer 344 rats in the diet at doses of 15, 150, or 1,500 mg/kg/day. The effects were confined almost entirely to the 1,500 mg/kg/day dose groups and included slightly decreased food consumption and body weights, slightly increased liver and kidney weights and macroscopic and microscopic changes in the stomach. No tumorigenic response was present. The NOAEL for this study was 150 mg/kg/day. B6C3F1 mice were maintained for 2 years on diets formulated to provide targeted dose levels of 10, 500, or 2,000 mg/kg/day. The only evidence of toxicity was body weight depression in males dosed at 2,000 mg/kg/day. There was no evidence of tumorigenic response at any dose level. Based on the chronic toxicity data, EPA has established the reference dose (RfD) for clopyralid at 0.5 mg/kg/day. The RfD for clopyralid based on a 2–year chronic oncogenicity study in rats with a NOAEL of 50 mg/kg/day and an uncertainty (or safety) factor of 100.

6. *Carcinogenicity*. Using Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), clopyralid would be classified as Group E for carcinogenicity (no evidence of carcinogenicity) based on the results of the carcinogenicity studies. There was no evidence of carcinogenicity in 2–year feeding studies in mice and rats at the dosage levels tested. The doses tested are adequate for identifying a cancer risk. Thus, a cancer risk assessment would not be appropriate.

7. *Animal metabolism*. Disposition and metabolism of clopyralid were tested in male and female rats at a dose of 5 mg/kg (oral). The majority of a radioactive dose was excreted in 24 hours of all dose groups. Fecal elimination was minor. Detectable levels of residual radioactivity were observed in the carcass and stomach at 72 hours post-dose. High performance liquid chromotography (HPLC) and thin layer chromotography (TLC) analysis of urine and fecal extracts showed no apparent metabolism of clopyralid.

8. *Metabolite toxicology*. There are no clopyralid metabolites of toxicological significance.

9. *Endocrine disruption*. There is no evidence to suggest that clopyralid has an effect on the endocrine system.

C. Aggregate Exposure

1. *Dietary exposure*. Acute dietary risk assessment is 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 rat developmental toxicity study to assess risk from acute dietary exposure, which is also the value used for assessment of acute dietary risk in this analysis. An acute RfD of 0.75 mg/kg/day was calculated, based on a NOAEL of 75 mg/kg/day and an uncertainty factor of 100 (10 for interspecies extrapolation and 10 for intraspecies variation). The maternal NOAEL was 75 mg/kg/day based on decreased weight gain during gestation days 6–9. The developmental NOEL was >250 mg/kg/day, indicating no additional sensitivity for developing young relative to adults. The acute RfD of 0.75 mg/kg/day was used to assess acute dietary risk for the general population, including infants and children.

Chronic dietary exposure to clopyralid is possible due to the potential presence of clopyralid residue in certain foods and drinking water. Chronic dietary risk was evaluated using a chronic RfD of 0.5 mg/kg/day, which is based on a NOAEL of 50 mg/kg/day from a chronic rat study along with an uncertainty factor of 100.

Since there was no evidence of carcinogenicity in the toxicology studies, a cancer risk assessment is not applicable.

i. *Food*. The dietary exposure assessment was based on all commodities with tolerances for clopyralid established at 40 CFR 180.431 together with the following proposed tolerances: Sweet corn: 3.0 ppm; popcorn: 3.0 ppm; canola: 3.0 ppm; flax seed: 0.3 ppm; hops: 5.0 ppm; strawberries: 1.0 ppm; mustard seed: 3 ppm; mustard greens: 5 ppm; stone fruits (crop group 12): 0.5 ppm; spinach: 5 ppm; garden-beet tops: 3 ppm; garden-beet roots: 4 ppm; turnip tops: 4 ppm; turnip roots: 1 ppm; and cranberry: 4 ppm. Crambe seed tolerance at 3 ppm is also requested, although it was not included within the residue file, since it is not considered by the Dietary Exposure Evaluation Model (DEEM) version 7.76 due to low cultivated area and low consumption patterns. The DEEM 7.76, 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 1994–96 USDA Continuing Surveys of Food Intake by Individuals (CSFII 1994–96).

a. *Acute*. A Tier 1 acute dietary risk assessment was conducted with the conservative assumptions of 100% crop

treated and tolerance level residues for 108 crop commodities. Acute dietary risk was assessed using an acute RfD of 0.75 mg/kg/day. Even with conservative assumptions used in this analysis, acute dietary exposure was estimated to occupy only 3.97% of the acute RfD for the overall U.S. population, at the 95th percentile. Acute dietary exposure for children 1–6 years old, the population subgroup estimated to have the highest exposure, occupies only 6.91% of the acute RfD, at the 95th percentile. Adverse effects are not expected for exposures occupying 100% or less of the RfD. Therefore, acute exposure and risk from food is well within acceptable levels.

b. *Chronic*. A Tier 1 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 2.3% of the RfD for the general U.S. population. Chronic dietary exposure for children 1–6 years old, the population subgroup estimated to have the highest exposure, occupies only 5.4% the chronic RfD. Therefore, chronic exposure and risk from food is well within acceptable levels.

ii. *Drinking water*. There is no established Maximum Contaminant Level (MCL) or Health Advisory Level (HAL) for residues of clopyralid in drinking water. High-end potential drinking water concentrations of clopyralid were estimated for ground water and surface water using the Screening Concentration in Ground Water (SCI-GROW) and Generic Expected Environmental Concentration (GENEEC) models respectively. Both GENEEC and SCI-GROW are Tier I screening level models that provide very conservative Estimated Environmental Concentrations (EECs) of pesticide residue in surface water and ground water, respectively. The EECs of a pesticide in surface water and ground water can be 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 in food and from residential uses.

The EEC of clopyralid in ground water according to SCI-GROW is 2 mg/L. Based on GENEEC, the estimated peak and 56–day concentration of clopyralid in surface water is 27 mg/L. EPA has previously indicated that the 56–day value from GENEEC should be divided by 3 for comparison to short-term and chronic DWLOC values. Therefore, a surface water concentration of 9 mg/L was used for comparison to short-term and chronic DWLOCs.

a. *Acute*. EPA has indicated that peak concentrations of a pesticide in surface water should be used in an acute assessment for comparison with DWLOC values. The peak surface water concentration of clopyralid was estimated to be 27 parts per billion (ppb) while the potential concentration in ground water was estimated to be 2 ppb. The DWLOC for acute exposure was based on an acute RfD of 0.75 mg/kg/day and was calculated to be 13,664 ppb and 8,853 ppb for the overall U.S. population and children 1–6 years old, respectively. Therefore, the acute DWLOC is substantially greater than estimated high-end concentrations of clopyralid in 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, EECs in ground water and surface water for chronic exposures were estimated at 2 ppb and 9 ppb, respectively. The chronic DWLOC was calculated based on a chronic RfD of 0.5 mg/kg/day and accounted for potential chronic exposure to clopyralid through residues in food. The chronic DWLOC for the general U.S. population and children 1–6 years old was calculated to be 17,100 ppb and 4,740 ppb, respectively. Therefore, the chronic DWLOCs are substantially greater than estimated residue concentrations in surface water or ground water, indicating that chronic exposure and risk from drinking water is well with acceptable levels.

2. *Non-dietary exposure*. Clopyralid is registered for residential use on turf. Therefore, there is potential for both residential applicator exposure and post-application reentry exposure. EPA previously determined that there was no dermal toxicity endpoint since no systemic toxicity was observed at the highest dose tested (HDT) in a rabbit dermal toxicity study. Therefore, a dermal risk assessment is not required for residential exposure. EPA previously selected a maternal NOAEL of 75 mg/kg/day from a rat developmental toxicity study for assessing risk from short-term residential exposure through oral and inhalation routes, which is also the value used in this assessment. Inhalation exposure for residential applicators as well as post-application reentry exposure for children through incidental non-dietary ingestion of clopyralid residues were estimated using default values given in EPA's SOPs for Residential Exposure Assessments. Clopyralid residues have been found to dissipate rapidly from turfgrass, having a half-life of approximately 1–day. Considering the rapid dissipation of residues from turf along with the labeled use pattern, residential exposure may occur over a short-term interval, but would not be expected over an intermediate-term interval. Therefore, a short-term residential risk assessment was conducted, but an intermediate-term assessment was not required.

EPA has previously indicated that it is appropriate to aggregate chronic food and water exposure with short-term residential exposures for clopyralid. In addition to its use in assessment of risk from short-term residential exposure, the short-term NOAEL of 75 mg/kg/day was also used for assessing risk from dietary and drinking water exposure during a short-term interval. A Tier 1 estimate of aggregated exposure for adults from food and from inhalation for residential applicators resulted in a Margin of Exposure (MOE) of 6,800. Additionally, a short-term DWLOC for adults was calculated to be 25,800 ppb. Aggregated exposure for children 1–6 years old from food and from incidental non-dietary ingestion of clopyralid residues from treated turf resulted in an MOE of 2,300. Additionally, a short-term DWLOC for children 1–6 years old was calculated to be 7,100 ppb. EPA has indicated that the EECs for chronic exposure through ground water and surface water may also be used for assessing short-term exposure and risk. Therefore, the short-term ground water and surface water EECs are 2 ppb and 9 ppb, respectively. The minimum acceptable MOE was based on an uncertainty factor of 100. Since the short-term MOE for adults and children is well above 100 and DWLOCs are well above EECs for drinking water, aggregated short-term exposures are not expected to exceed a level of concern.

D. Cumulative Effects

The potential for cumulative effects of clopyralid and other substances that have a common mechanism of toxicity was considered. The mammalian toxicity of clopyralid is well defined. However, no reliable information exists to indicate that toxic effects produced by clopyralid would be cumulative with those of any other chemical compound. Additionally, clopyralid does not appear to produce a toxic metabolite produced by other substances. Therefore, consideration of a common

mechanism of toxicity with other compounds is not appropriate at this time. Thus, potential exposures to clopyralid were considered only in an aggregate exposure assessment.

E. Safety Determination

1. *U.S. population*. Using the conservative exposure assumptions previously described, acute dietary exposure to residues of clopyralid from current and proposed uses was estimated to occupy only 3.97% 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 exposure will not pose appreciable risks to human health. Additionally, the acute DWLOC was calculated to be over 1,500 fold greater than potential clopyralid residue in drinking water as predicted by conservative screening-level models. A conservative Tier 1 assessment indicated that chronic dietary exposure would occupy only 2.3% of the chronic RfD for the general U.S. population. Additionally, the chronic DWLOC was calculated to be over 1,900 fold greater than surface water or ground water EECs developed by screening-level models. A Tier 1 estimate of short-term dietary and residential exposure resulted in an MOE of 6,800, which is well above the minimum acceptable MOE of 100. Further, the short-term DWLOC is over 2,800 fold greater than the short-term EEC for surface water and ground water. Thus, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, Dow AgroSciences concludes that there is a reasonable certainty that no harm will result to the general U.S. population from aggregate acute, short-term or chronic exposure to clopyralid residues from current and proposed uses.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of clopyralid, data are considered from developmental toxicity studies in the rat and rabbit, and from multiple generation reproduction studies in rats. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproductive studies provide information relating to prenatal and postnatal effects from exposure to the pesticide, on the reproductive capability of mating animals, and data on systemic toxicity.

Based on the results of developmental toxicity and multigenerational reproduction studies, there are no indications of prenatal or postnatal toxicity concerns for infants and children from exposure to clopyralid. 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 prenatal and postnatal toxicity and the completeness of the database. Based on the current toxicological data requirements, the database for clopyralid relative to prenatal and postnatal effects for children is complete. There were no indications of neurotoxicity and developmental toxicity was not observed in the absence of maternal toxicity. It is concluded that there is no indication of increased sensitivity of infants and children relative to adults and that an additional FQPA safety factor is not required.

Using conservative exposure assumptions previously described, acute dietary exposure to residues of clopyralid from current and proposed uses was estimated to occupy only 6.91% of the RfD for children 1–6 years old, the population subgroup estimated to be most highly exposed. EPA generally has no concern for exposures below 100% of the RfD since the RfD represents the level at or below which exposure will not pose appreciable risks to human health. Additionally, the acute DWLOC was calculated to be over 900 fold greater than potential clopyralid residue in drinking water as predicted by conservative screening-level models. A conservative Tier 1 assessment indicated that chronic dietary exposure for children 1–6 years old would occupy only 5.4% of the chronic RfD. Additionally, the chronic DWLOC was calculated to be over 500 fold greater than surface water or ground water EECs developed by screening-level models. A Tier 1 estimate of short-term dietary and residential exposure for children 1–6 years old resulted in an MOE of 2,300, which is well above the minimum acceptable MOE of 100. Further, the short-term DWLOC is over 700 fold greater than the short-term EEC for surface water and ground water. Thus, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, Dow AgroSciences concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate acute, short-term or chronic exposure to clopyralid residues from current and proposed uses.

F. International Tolerances

There are no Codex or Mexican maximum residue limits. Canada has set a maximum residue limit of 2.0 ppm for barley, oats, and wheat, and 7.0 ppm for the milled fractions of barley, oats, and wheat (excluding flour).

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0174; FRL–7191–9]

Notice of Filing Pesticide Petitions to Establish Tolerances for a Certain Pesticide Chemical in or on Food

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 a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2002–0174, must be received on or before September 13, 2002.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket ID number OPP–2002–0174 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–7610; e-mail address: *jackson.sidney@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be 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