0.024 ppb is the annual average FIRST concentration. To determine drinking water exposure, drinking water levels of comparison (DWLOCs) were calculated and used as a point of comparison against the model estimates of the pesticide concentration in drinking water. For acequinocyl, the acute and chronic DWLOC values were greater than the estimated concentration DWEC in surface water and ground water for each population group. Therefore, exposures to acequinocyl in drinking water do not pose a significant human health risk.

2. *Non-dietary exposure*. There are no residential uses for acequinocyl.

*D. Cumulative Effects*

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

*E. Safety Determination*

1. *U.S. population*. The acute dietary food exposure to acequinocyl was estimated at 2.21% of acute RfD for the total U.S. population. The calculated DWLOCs ranged from 2,791 to 10,405 ppb for all the population subgroups. The surface water and ground water DWECs for acequinocyl were estimated to be 1.561 ppb and 0.006 ppb, respectively. Since the acute DWECs are less than the DWLOCs for all population subgroups, the acute aggregate risk estimates are below the level of concern. The chronic dietary food exposure to acequinocyl was estimated at 5.6% of chronic RfD for total U.S. population. The calculated DWLOCs ranged from 213 to 892 ppb for all the population subgroups. The surface water and ground water DWECs for acequinocyl were estimated to be 0.024 ppb and 0.006 ppb, respectively. Since the chronic DWECs are less than the DWLOCs for all population subgroups, the chronic aggregate risk estimates are below the level of concern.

2. *Infants and children*. The acute dietary food exposure to acequinocyl was estimated at 4.81% of acute RfD for all infants (<1 year), 6.33% of acute RfD for children 1 to 6 and 8.18% of acute RfD for children 1 to 2 (most highly exposed). The calculated DWLOCs ranged from 2,791 to 10,405 ppb for all the population subgroups. The surface water and ground water DWECs for acequinocyl were estimated to be 1.561 ppb and 0.006 ppb, respectively. Since the acute DWECs are less than the DWLOCs for all population subgroups including infants, the acute aggregate risk estimates are below the level of concern. The chronic dietary food exposure to acequinocyl was estimated at 12.4% of chronic RfD for all infants (<1 year), and 21.2% of chronic RfD for children 1 to 6 (most highly exposed). The calculated DWLOCs ranged from 213 to 892 ppb for all the population subgroups. The surface water and ground water DWECs for acequinocyl were estimated to be 0.024 ppb and 0.006 ppb, respectively. Since the chronic DWECs are less than the DWLOCs for all population subgroups including infants, the chronic aggregate risk estimates are below the level of concern.

*F. International Tolerances*

To date, no Codex, Canadian or Mexican tolerances exists for acequinocyl.

[FR Doc. 04–3936 Filed 2–24–04; 8:45 am]

BILLING CODE 6560–50–S

## ENVIRONMENTAL PROTECTION AGENCY

**[OPP–2004–0030; FRL–7344–6]**

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

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

**ACTION:** Notice.

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

**DATES:** Comments, identified by docket identification (ID) number OPP–2004–0030, must be received on or before March 26, 2004.

**ADDRESSES:** Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION.**

**FOR FURTHER INFORMATION CONTACT:** Daniel C. Kenny, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7546; e-mail address: *kenny.dan@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Does this Action Apply to Me?*

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

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

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

*B. How Can I Get Copies of this Document and Other Related Information?*

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2004–0030. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket

facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in EPA's Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

*C. How and to Whom Do I Submit Comments?*

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2004–0030. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to *opp-docket@epa.gov*, Attention: Docket ID Number OPP–2004–0030. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2004–0030.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP–2004–0030. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

*D. How Should I Submit CBI to the Agency?*

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is 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 docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed 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 a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

**List of Subjects**

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

Dated: February 12, 2004.

**Lois Rossi,**

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

**Summary of Petition**

The petitioner's summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. 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.

**Makhteshim-Agan of North America, Inc.**

*PP 2F6430*

EPA has received a pesticide petition (2F6430) from Makhteshim-Agan of North America, Inc. (MANA), 551 Fifth Avenue, Suite 1100, New York, NY 10176 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of novaluron in or on the raw agricultural commodity pome fruits (excluding pears) at 1.0 parts per million (ppm), apple pomace at 6.0 ppm, pears at 2 ppm, cottonseed at 0.3 ppm, cotton gin by-products at 17 ppm, tuberous and corm vegetables (Crop Subgroup 1–C) at 0.05 ppm, cattle meat at 0.3 ppm, cattle meat-by-products at 6.0 ppm, cattle fat at 6.0 ppm, cattle liver at 0.4 ppm, cattle kidney at 0.4 ppm, and milk at 0.4 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

*A. Residue Chemistry*

1. *Plant metabolism*. The qualitative nature of the residue of novaluron in plants is adequately understood based on acceptable apple, cabbage, cotton, and potato metabolism studies. These plant metabolism studies have demonstrated that novaluron does not metabolize and is non-systemic (does not translocate within the plant). The results observed in the plant and livestock metabolism studies show similar metabolic pathways. The residue of concern, which should be regulated, is the parent compound, novaluron, only.

2. *Analytical method*. An adequate analytical method, gas chromatography/electron capture detector (GC/ECD), is available for enforcing tolerances of novaluron residues in or on plant and animal commodities. The amount of novaluron in most crop matrices is determined using GC with ECD. GC is also used to determine residues of novaluron in milk, bovine fat, kidney, liver, and meat.

3. *Magnitude of residues*—i. *Pome fruits*. Field residue trials were conducted on pome fruits (total of 23 trials on apples including a processing study, and 10 trials on pears), in several locations in the U.S. and Canada (2000–2002). In view of the proposed use directions (maximum seasonal rate of 1 lb active ingredient per acre, up to 4 applications, pre-harvest-interval of 14 days), the maximum novaluron residue found on apples was 0.876 ppm, which is below the proposed tolerance of 1.0 ppm for pome fruit (excluding pears). The highest residues measured on pears following 6 applications at a seasonal rate of 2 lb active ingredient per acre were 1.9 ppm, which is below the proposed tolerance of 2 ppm. Residues in juice from apple processing were below 0.05 ppm, demonstrating that there was no concentration in juice and therefore no need for proposing a tolerance. The proposed tolerance for apple pomace of 6 ppm is supported by using the highest average residues measured in the field (0.774 ppm) multiplied by the established concentration factor of 7.2 from the available apple processing study.

ii. *Cotton*. Seventeen residue trials were conducted in the U.S. over a 2-year period (2000–2002). The novaluron residues in cottonseed ranged from less than 0.05 to 0.23 ppm, and in cotton gin by-products the residues ranged from 3.5 ppm to 14.8 ppm, following the proposed use directions. Therefore, tolerances of 0.3 ppm for cottonseed and 17 ppm for cotton gin by-products are being requested.

iii. *Tuberous and corm vegetable subgroup (Crop Subgroup 1–C)*. A series of potato residue trials in support of the tuberous and corm vegetable subgroup was conducted over a 2-year period (1999–2000) in Europe (Germany, France, Spain, and Italy). Treatments were made twice at 0.022 lb active ingredient per acre with the last application 21 days before harvest, in addition to residue decline studies with sampling dates of 0, 3, 7, 14, and 21 days after the last application. No residues were detected above 0.01 ppm limit of quantitation (LOQ), even at sampling dates right after the last application. Data from field trials conducted in Oregon and Pennsylvania (2002), using an exaggerated rate of 0.25 lb active ingredient per acre at 21 and 7 days before harvest, also indicate that no measurable residues were detected (LOQ = 0.05 ppm). Therefore, the generated data set is in full support of the proposed tolerance of 0.05 ppm.

*B. Toxicological Profile*

1. *Acute toxicity*. In an acute oral toxicity study in rats, novaluron had a lethal dose $(LD)_{50}$ >5,000 mg/kg. A dermal toxicity study in rats resulted in an $LD_{50}$ greater than 2,000 mg/kg. The lethal concentration $(LC)_{50}$ for acute

inhalation in rats was greater than 5.15 milligrams/Liter (mg/L). In rabbits, novaluron is not a skin irritant but it is a mild eye irritant. Novaluron is not a sensitizer in guinea pigs.

2. *Genotoxcity*. The mutagenic potential of novaluron was investigated in several *in vivo* and *in vitro* studies. Results in two Ames assays, an *in vivo* mouse micronucleus assay, an *in vitro* unscheduled DNA synthesis (UDS) assay, an *in vitro* cell mutation assay, and an *in vitro* human lymphocyte clastogenicity test were negative. Novaluron is therefore considered to have no potential to induce mutagenicity.

3. *Reproductive and developmental toxicity*—i. A 2-generation rat reproduction study was conducted with dose levels of 1,000, 4,000, and 12,000 ppm (74.2, 297.5, 894.9 mg/kg/day, and 84, 336.7, 1009.8 mg/kg/day for males and females, respectively). There were no effects on fertility or pregnancy at any dose. The no observed adverse effect level (NOAEL) was determined to be 12,000 ppm (894.9 and 1009.8 mg/kg/day for males and females, respectively).

ii. *Teratology studies were conducted in the rat and rabbit*. No treatment-related mortalities were observed in either study. No effect on survival, development or growth of fetuses was noted in either species in either study. The maternal and fetal NOAEL was determined to be 1,000 mg/kg/day (highest dose tested (HDT)) in the rat study. In the rabbit study the maternal and fetal NOAEL was 1,000 mg/kg/day. The fetal effect in the rabbit study was weight gain at 1,000 mg/kg/day. These two studies demonstrate that novaluron was not teratogenic in either rats or rabbits based on the study results.

4. *Subchronic toxicity*. Rats, mice, and dogs all show the same toxicologic response. Generally, novaluron induces small increases in methemoglobin; red cells are sequestered; and, compensatory hematopoiesis occurs. The severity of these changes is well within the physiological capacity of the animals and is judged not adverse.

Rats treated topically with novaluron in a 28-day study at 0, 75, 400, and 1,000 mg/kg/day did not show signs of systemic toxicity. Small treatment-related increases in methemoglobin were seen in both sexes at 1,000 mg/kg/day and in females at 400 mg/kg/day. The highest methemoglobin value seen in females was 1.28% compared with 0.86% in controls. Organ weights, macroscopic and microscopic examination of organs and tissues did not reveal any treatment-related changes.

i. *Two 13-week rat studies were conducted*. In one study, doses were administered at 50, 100, 200, 400 ppm (3.52, 6.93, 13.83, 27.77 mg/kg/day and 4.38, 8.64, 17.54, and 34.39 mg/kg/day for males and females, respectively). The NOAEL was 400 ppm, the HDT (27.77 and 34.39 mg/kg/day for males and females, respectively). In the second 13-week rat study, doses were administered at 50, 100, 10,000, and 20,000 ppm (4.2, 8.3, 818.5, 1666.9 mg/kg/day and 4.7, 8.9, 871, 1820.6 mg/kg/day for males and females, respectively). The NOAEL was determined to be 8.3 mg/kg/day. The lowest observed adverse effect level (LOAEL) of 818.5 mg/kg/day, is based on histopathological parameters in the spleen.

ii. A 13-week mouse study was conducted with dose levels of 30, 100, 1,000, 10,000 ppm (4.2, 12.8, 135.9, 1391.9 mg/kg/day and 4.7, 15.2, 135.6, 1493.1 mg/kg/day, for males and females, respectively). The NOAEL was determined to be 100 ppm (12.8 and 15.2 mg/kg/day, male and females, respectively). The LOAEL was 1,000 ppm (135.9 and 135.6 mg/kg/day, males and females, respectively) based on increased body weight gain, low erythrocyte counts, and secondary splenic changes. There were no clinical treatment-related signs noted.

iii. *Two 13-week dog studies were conducted*. One study resulted in an NOAEL of 100 mg/kg/day and a LOAEL of 300 mg/kg/day based on low erythrocyte counts and secondary splenic and liver changes. No clinical treatment-related signs were noted. Another study, was conducted using only one dose level of 10 mg/kg/day. There were no clinical or histopathological treatment-related signs and the NOAEL was determined to be 10 mg/kg/day.

5. *Chronic toxicity*—i. Chronic toxicity and oncogenicity was evaluated in the rat, mouse and dog. The rat chronic toxicity and oncogenicity was conducted with dose levels of 25, 700, 20,000 ppm (1.25, 35, 1,000 mg/kg/day). The no observed effect level (NOEL) was 25 ppm (1.25 mg/kg/day) based on methemoglobin. There was no evidence of carcinogenicity in this study. A mouse chronic toxicity study was conducted with dose levels of 30, 450, 7,000 ppm (4.5, 67.5, 1,050 mg/kg/day). The NOEL was 30 ppm (4.5 mg/kg/day) based on methemoglobin. There was also no evidence of carcinogenicity in this study. Chronic toxicity was investigated in dogs using dose levels of 10, 100, 1,000 mg/kg/day. The NOEL of 100 mg/kg/day was based on methemoglobin.

ii. A reference dose (RfD) of 0.083 mg/kg/day has been established for novaluron. The RfD is based on a subchronic rat study with a NOAEL of 8.3 mg/kg/day, based on histopathological parameters in the spleen. An uncertainty factor (UF) of 100 is used.

iii. The proposed classification of novaluron is Group E (not likely human carcinogen) due to results of oncogenicity studies that show no evidence of carcinogenicity.

6. *Animal metabolism*. Metabolism studies in rats and goats were conducted with the parent material labeled in both the difluorophenyl and chlorophenyl moieties.

Rats absorb little novaluron when it is administered orally. More than 90% of the dietary administered chlorophenyl $^{14}C(U)$ novaluron is recovered in the feces. When the diflurophenyl ring of the molecule is labeled, the recovered $^{14}C$ activity in the feces is lower but still above 75%. The difference is thought to reflect intestinal metabolism by microbial flora and the higher absorption of the diflurophenyl metabolites.

The parent molecule as well as its degradates are absorbed from the gastrointestinal tract (GI). All parent material is metabolized either upon initial entry into the systemic circulation or, if sequestered to the fat, upon its depuration back to the systemic circulation. There is no intact novaluron found in the urine. Novaluron's high octanol-water partition coefficient is responsible for its preferential movement to fat. The half-life in fat calculated from the rat metabolism study is approximately 55 hours.

Two groups of metabolites are formed after oral administration of novaluron. One group is typified by the aniline metabolite 3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy) aniline, referred to as 3–TFA. The other group of metabolites is typified by 2,6-difluorobenzoic acid is from the diflurophenyl moiety of the molecule. Nearly all the metabolites are formed at a level of 1% or less of the applied dose. They are rapidly excreted.

The metabolism in goats mimics that seen in rats.

7. *Metabolite toxicology*. Makhteshim-Agan of North America Inc., has determined that there are no metabolites of toxicological concern and therefore, no metabolites need to be included in the tolerance expression and require regulation.

8. *Endocrine disruption*. No special studies investigating potential estrogenic or other endocrine effects of novaluron have been conducted.

However, inspection of in-life data from toxicology studies does not indicate that novaluron is an endocrine disruptor. Specifically, endocrine organ weights (e.g., thyroid, testes, ovaries, pituitary from the 2-generation study) were not adversely affected by novaluron. Milestones of sexual development were not affected by novaluron; and, reproduction was not adversely affected. Based on these observations, there is no evidence to suggest that novaluron has an adverse effect on the endocrine system.

*C. Aggregate Exposure*

*Dietary exposure*. Tolerances are proposed for residues of novaluron in or on pome fruit (excluding pears), apple pomace, pears, cottonseed, cotton gin by-products, tuberous, and corm vegetables, cattle meat, fat, liver, kidney, meat by-products, and milk. For the purpose of assessing the potential dietary exposure for these proposed tolerances, an exposure assessment was conducted using Exponent's Dietary Exposure Evaluation Model (DEEM) software, consumption data derived from the 1994–1998 United States Department of Agriculture (USDA) Continuing Surveys of Food Intake by Individuals (CSFII), residue levels at proposed tolerance levels, and projected percent crop treated for cotton and pome fruit at market maturity, and assuming 100% crop treated for potatoes.

1. *Food*—i. *Acute dietary exposure*. No acute dietary assessments were conducted since no toxicological endpoint attributable to a single exposure was identified in the available toxicology studies, including the rat and rabbit developmental studies.

ii. *Chronic dietary exposure*. The appropriate RfD value for novaluron is 0.083 mg/kg/day, based upon the NOAEL of 8.3 mg/kg/day from the 13-week oral rat study and an UF of 100. The chronic dietary exposure estimate for the overall U.S. population is 1.5% of the RfD of 0.083 mg/kg/day. Children 1 to 2 years old, the most exposed population subgroup, utilize 7.6% of the RfD. The chronic exposure estimates for the overall U.S. population and 32 population subgroups, including infants and children, were less than 8% of the RfD. Based on these exposure estimates, Makhteshim-Agan of North America, Inc., concludes that there is reasonable certainty of no harm for the use of novaluron on pome fruit, cotton, tuberous, and corm vegetables.

2. *Drinking water*. A comparison of the calculated drinking water level of concern (DWLOC) value to the drinking water estimated concentration (DWEC) is made. If the DWLOC exceeds the DWEC value then there is reasonable certainty that no harm will result from the short-term or the intermediate-term aggregate exposure. There are no monitoring data for novaluron, so the Food Quality Protection Act (FQPA) Index Reservoir Screening Tool (FIRST) model was used to estimate a surface water residue. Estimated DWLOC values are 767 parts per billion (ppb) for children (1 to 2 years old), 2,470 ppb for adult females, and 2,861 ppb for the U.S. population. Since the calculated DWLOC values for the U.S. population and all its subgroups considerably exceed the modeled DWEC of 0.14 ppb in surface water, Makhteskim-Agan of North America Inc., concludes that there is reasonable certainty that no harm will result from aggregate (food and water) exposure to novaluron residues.

*D. Cumulative Effects*

To Makhteskim-Agan of North America's Inc., knowledge, there are currently no available data or other reliable information indicating that any toxic effects produced by novaluron would be cumulative with those of other chemical compounds; thus only the potential risks of novaluron have been considered in this assessment of its aggregate exposure.

*E. Safety Determination*

1. *U.S. population*. No acute dietary assessment was conducted because there is no toxicological endpoint attributable to a single exposure. A conservative chronic exposure analysis was conducted, using tolerance level residues, with adjustments for percent crop treated at product maturity (cotton and pome fruits), and no adjustment for potatoes (100% treated). The chronic novaluron exposure is low, accounting for 0.8% to 7.6% of the RfD, depending on the population subgroup. The chronic exposure for the U.S. population is 0.001243 mg/kg/day, which uses 1.5% of the RfD. The most sensitive population subgroup, children 1 to 2 years old, has a chronic exposure of 0.006339 mg/kg/day, which utilizes only 7.6% of the RfD. Based on the lack of acute toxicity and the chronic exposure analyses, Makhteskim-Agan of North America Inc., concludes that there is reasonable certainty that no harm will result from acute and chronic exposure to novaluron.

2. *Infants and children*—i. *General*. Data from rat and rabbit developmental toxicity studies and a 2-generation rat reproduction study have been used to assess the potential for increased sensitivity of infants and children. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development. Reproduction studies provide information relating to reproductive and other effects on adults and offspring from prenatal and postnatal exposure to the pesticide. FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children to account for prenatal and postnatal toxicity and the completeness of the data base. Makhteskim-Agan of North America Inc., concludes that the toxicology data base for novaluron regarding potential prenatal and postnatal effects in children is complete according to existing Agency data requirements and does not indicate any developmental or reproductive concerns.

ii. *Developmental toxicity studies*. In the rat developmental study, the maternal NOAEL was determined to be 1,000 mg/kg/day based on slight increase in body weight gain and food consumption and the fetal NOAEL was determined to be 1,000 mg/kg/day, the HDT. There was no effect on survival, development or growth of the fetuses. There were no developmental effects noted in the rabbit study, even at the limit dose level (1,000 mg/kg/day), however, slight maternal toxicity (body weight effects) was observed at the limit dose level.

iii. *Reproductive toxicity studies*. There was no evidence of adverse effects on reproductive capability, fertility or pregnancy, observed at any dose level in the rat 2-generation reproductive study. However, there was increased bodyweight and spleen weight, and hemosiderosis of the spleen at the high dose. The NOAEL was 894.9 in males and 1009.8 mg/kg/day in females, the HDT.

iv. *Conclusion*. Based on the absence of fetal effects and pup toxicity in any of the reference studies, Makhteskim-Agan of North America Inc., concludes that reliable data support the use of the standard 100-fold UF, and that an additional UF is not needed to protect the safety of infants and children. In addition, the RfD is based on a NOAEL of 8.3 mg/kg/day (from a 13-week rat study), which is already more than 120-fold lower than the NOAEL in the rabbit developmental toxicity study. Thus, the proposed RfD of 0.083 mg/kg/day is considered to be appropriate for assessing potential risks to infants and children and an additional FQPA safety factor is not warranted. As noted previously, the aggregate chronic exposure assessment utilizes less than 8% of the RfD for the entire U.S.

population and various population subgroups, including the most sensitive subgroup, children 1 to 2 years old. Therefore, Makhteskim-Agan of North America Inc., concludes that there is reasonable certainty that no harm will result to infants and children from aggregate exposure to novaluron residues.

*F. International Tolerances*

There are no Canadian, Mexican, or Codex maximum residue limits established for novaluron. Therefore, international harmonization is not an issue at this time.

[FR Doc. 04–3937 Filed 2–24–04; 8:45 am]

**BILLING CODE 6560–50–S**

## ENVIRONMENTAL PROTECTION AGENCY

**[OPP–2004–0025; FRL–7345–5]**

## Gamma-Cyhalothrin; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

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

**ACTION:** Notice.

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

**DATES:** Comments, identified by docket identification (ID) number OPP–2004–0025, must be received on or before March 26, 2004

**ADDRESSES:** Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** William G. Sproat, Jr., Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8587; e-mail address: *sproat.william@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Does this Action Apply to Me?*

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

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

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

*B. How Can I Get Copies of this Document and Other Related Information?*

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2004–0025. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in EPA's Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

*C. How and to Whom Do I Submit Comments?*

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on