ACTION: Notice of intent to disclose information.

SUMMARY: The purpose of this document is to inform submitters of risk management plans (RMPs) containing information claimed or designated as confidential business information (CBI) that EPA will be distributing RMPs, including the confidential information they may contain, to another federal agency, the Chemical Safety and Hazard Investigation Board (the ''Chemical Safety Board'' (CSB) or ''Board''), according to the requirements of 40 CFR 2.209(c).

DATES: RMPs, including the CBI they may contain, will be distributed to the CSB 10 days after publication of this document in the **Federal Register**.

ADDRESSES: Comments or questions on this document should be mailed or submitted to the address noted in the following **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Dorothy McManus, Chemical Emergency Preparedness and Prevention Office, Environmental Protection Agency, 401 M St. SW (5104), Washington, DC 20460, (202) 260–8606.

SUPPLEMENTARY INFORMATION: Section 112(r) of the Clean Air Act (CAA) establishes a program for the prevention and mitigation of accidental releases of extremely hazardous substances at chemical plants and other stationary sources. As required by section 112(r)(7)(B), EPA has issued regulations (40 CFR part 68) requiring sources with more than a threshold quantity of extremely hazardous substances listed by EPA to develop and implement a risk management program and submit a RMP describing that program to the Agency. Under section 112(r)(7)(B)(iii), all RMPs must also be submitted to the Chemical Safety and Hazard Investigation Board. The Board is an independent federal agency established under section 112(r)(6) of the CAA to investigate serious accidental releases of extremely hazardous substances and to take other specified actions regarding the prevention of accidental releases.

EPA established procedures for claiming, substantiating, and protecting CBI in submitted RMPs in Accidental Release Prevention Requirements; Risk Management Programs Under Clean Air Act Section 112(r)(7), Amendments; Final Rule (see 64 FR 964, January 6, 1999). Further, EPA stated in the preamble of that rule that any information claimed or designated as CBI in RMPs will be provided to the CSB in accordance with EPA's existing CBI regulations at 40 CFR 2.209(c), Disclosure to other Federal agencies (see 64 FR 964, January 6, 1999). Under that provision, ''EPA may disclose business information to another Federal agency if—(1) EPA receives a written request for disclosures of the information from a duly authorized officer or employee of the other agency * * * (2) The request * * * sets forth the official purpose for which the information is needed; and (3) When the information has been claimed as confidential or has been determined to be confidential, the responsible EPA office provides notice to each affected business of the type of information to be disclosed and to whom it is to be disclosed. At the discretion of the office, such notice may be given by notice published in the **Federal Register** at least 10 days prior to disclosure * * *''

EPA and the CSB entered into a Memorandum of Understanding (MOU) in March of this year. The MOU notes that CSB has responsibilities under section 112(r)(6) of the CAA with respect to risk management plans (RMPs) submitted pursuant to EPA's regulations implementing section 112(r)(7) of the CAA. In order to fulfill its responsibilities, the CSB needs to have access to all submitted RMPs, including any information contained in RMPs that is claimed or designated as CBI. In accordance with the terms of 40 CFR 2.209(c), the CSB in the MOU indicated its need for access to all RMPs, including any CBI in RMPs. In the MOU, EPA indicated it would notify RMP submitters via a **Federal Register** document that it will provide the CSB with access to all RMPs, including any CBI in RMPs. In addition, with respect to submitted RMPs, EPA will advise the CSB of any unresolved business confidentiality claims and any determinations that information is entitled to confidential treatment. Further, the CSB will protect from disclosure any information in RMPs that is subject to an unresolved business confidentiality claim or that has been designated by EPA as CBI.

Given the foregoing, this **Federal Register** document serves to notify owners or operators of sources covered by the risk management program that all submitted RMPs, including any CBI in RMPs, will be disclosed by EPA to the CSB.

Jim Makris,

Director, Chemical Emergency Preparedness and Prevention Office.

[FR Doc. 99–19436 Filed 7–28–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[PF–884; FRL–6095–6]

Notice of Filing a Pesticide Petition to Establish a Tolerance for Certain Pesticide Chemicals 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 certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by docket control number PF–884, must be received on or before August 30, 1999.

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'' section. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–884 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Thomas Harris, Insecticide-Rodenticide Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 308–9423; and e-mail address: harris.thomas@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	Examples of potentially affected entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	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 in the ''FOR FURTHER INFORMATION CONTACT'' section.

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 control number PF–884. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–884 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, 401 M St., SW., 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 5.1/6.1 or ASCII file format. All comments in electronic form must be identified by docket control number PF–884. 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 in the ''FOR FURTHER INFORMATION CONTACT'' section.

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. Offer alternative ways to improve the rule or collection activity.

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

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

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports 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: July 23, 1999.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

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 petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical

residues or an explanation of why no such method is needed.

Novartis Crop Protection, Inc.

1. EPA has received a request from Novartis Crop Protection, Inc., PO Box 18300, Greensboro, NC 27419 referencing pesticide petitions PP 8F3592, 7F3500, 4E4419 and 5F4508, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR 180.449 by establishing permanent tolerances for residues of abamectin (avermectin B_1) and its delta 8,9-isomers in or on the agricultural commodities cattle, fat at 0.015 parts per million(ppm); cattle, meat byproducts at 0.02 ppm; cattle, meat at 0.02 ppm; citrus, dried pulp at 0.10 ppm; citrus, oil at 0.10 ppm; citrus, whole fruit at 0.02 ppm; cottonseed at 0.005 ppm; cotton gin by-products at 0.15 ppm; hops, dried at 0.20 ppm; milk at 0.005 ppm; and potatoes at 0.005 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The subject tolerances, except for cotton gin by-products, were established as time-limited tolerances with an expiration date of September 1, 1999 (62 FR 13833–13839, March 24, 1997) (FRL–5597–7). Three issues identified in the referenced **Federal Register** document were the cause of the subject tolerances only being extended as time-limited tolerances. The three issues (cotton gin by-product residue data, review of the Monte Carlo dietary risk assessment, indoor residential risk assessment) are now resolved. The present petition proposes that these time-limited tolerances be converted to permanent tolerances.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of abamectin in plants and animals is adequately understood and the residues of concern include the parent insecticide, abamectin or avermectin B_1 (which is a mixture of a minimum of 80% avermectin B_{1a} and a maximum of 20% avermectin B_{1b}) and the delta 8,9-isomer of the B_{1a} and of the B_{1b} components of the parent insecticide. Under photolytic conditions in the laboratory and in the field, abamectin undergoes isomerization around the 8,9-double bond to produce small amounts of the delta-8,9 isomer. The photo-oxidative half-life of the delta-8,9 isomer is 4.5 hours and that of avermectin B_{1a} is 6.5 hours.

2. *Analytical method*. The analytical method involves homogenization, filtration, partition and cleanup with analysis by high performance liquid chromatography fluorescence detection. The methods are sufficiently sensitive to detect residues at or above the tolerances proposed. All methods have undergone independent laboratory validation as required by PR Notice 88–5.

3. *Magnitude of residues*. Data to support the new and proposed conversion of the present time-limited tolerances to full tolerances with no expiration date have been previously submitted under Pesticide Petitions PP 7F3500, 8F3592, 4E4419, 5F4508, 5E4566, and Food Additive Petition 8H5550.

B. Toxicological Profile

1. *Acute toxicity*. The database includes the following studies: A rat acute oral study with a LD_{50} of 4.4 to 11.8 milligrams/kilogram (mg/kg) (males) and 10.9 to 14.9 mg/kg (females). An acute oral toxicity in the CF-1 mouse with the delta 8,9-isomer has LD_{50} greater than 80 mg/kg. A rabbit acute dermal study with a $LD_{50} > 2,000$ mg/kg. A rat acute inhalation study with a $LC_{50} > 5.73$ milligrams/liter (mg/L). A primary eye irritation study in rabbits which showed irritation. A primary dermal irritation study in rabbits which showed no irritation. A primary dermal sensitization study in guinea pigs which showed no skin sensitization potential. An acute oral toxicity study in monkeys with a no observed adverse effects level (NOAEL) of 1.0 mg/kg based upon emesis at 2.0 mg/kg.

2. *Genotoxicty*. The Ames assays conducted with and without metabolic activation were both negative. The V-79 mammalian cell mutagenesis assays conducted with and without metabolic activation did not produce mutations. In an alkaline elution/rat hepatocyte assay, abamectin was found to induce single strand DNA breaks without significant toxicity in rat hepatocytes treated in vitro at doses greater than 0.2 mM. This *in vitro* dose of 0.2 mM is biologically unobtainable *in vivo*, due to the toxicity of the compound. However, at these potentially lethal doses, *in vivo* treatment did not induce DNA single strand breaks in hepatocytes. In the mouse bone marrow assay, abamectin was not found to induce chromosomal damage. There are also many studies and a great deal of clinical and follow-up experience with regard to ivermectin, a closely similar human and animal drug.

3. *Reproductive and developmental toxicity*. The following reproductive and developmental tixocity studies were conducted:

i. A 2–generation study in rats with a NOAEL of 0.12 mg/kg/day in pups based upon retinal folds, decreased body weight, and mortality. The NOAELs for systemic and reproductive toxicity were 0.4 mg/kg/day. In the 2–generation reproduction study in rats with the delta 8,9-isomer, the NOAEL was 0.4 mg/kg/day and the lowest observed adverse effect level (LOAEL) was greater than 0.4 mg/kg/day (the highest dose tested).

ii. An oral teratology study in the CF-1 mouse with a maternal NOAEL of 0.05 mg/kg/day based upon decreased body weights and tremors. The fetal NOAEL was 0.20 mg/kg/day based upon cleft palates. An oral teratology study with the delta 8,9-isomer in CF-1 mice with a maternal NOAEL of 0.10 mg/kg/day based upon decreased body weights. The fetal NOAEL was 0.06 mg/kg/day based upon cleft palate. An oral teratology study in rabbits with a maternal NOAEL of 1.0 mg/kg/day based upon decreased body weights and tremors. The fetal NOAEL was 1.0 mg/kg/day based upon clubbed feet. An oral teratology study in rats with a maternal and fetal NOAEL at 1.6 mg/kg/day, the highest dose tested. An oral teratology study with the delta 8,9-isomer with a maternal NOAEL in CF-1 mice that expressed P-glycoprotein greater than 1.5 mg/kg/day, the highest and only dose tested. No cleft palates were observed in fetuses that expressed normal levels of P-glycoprotein, but fetuses with low or no levels of P-glycoprotein had increased incidence of cleft palates.

4. *Subchronic toxicity*. A rat 8–week feeding study with a NOAEL of 1.4 mg/kg/day based upon tremors. A rat 14–week oral toxicity study with a NOAEL of 0.4 mg/kg/day, the highest dose tested. A dog 12–week feeding study with a NOAEL of 0.5 mg/kg/day based upon mydriasis. A dog 18–week oral study with a NOAEL of 0.25 mg/kg/day based upon mortality. A CD-1 mouse 84–day feeding study with a NOAEL of 4 mg/kg/day based upon decreased body weights.

5. *Chronic toxicity*. A rat 53–week oncogenicity feeding study, negative for oncogenicity, with a NOAEL of 1.5 mg/kg/day based upon tremors. A CD-1 mouse 94–week oncogenicity feeding study, negative for oncogenicity, with a NOAEL of 4 mg/kg/day based upon decreased body weights. A dog 53–week chronic feeding study, negative for oncogenicity, with a NOAEL of 0.25 mg/kg/day based upon mydriasis.

6. *Animal metabolism*. Rats were given oral doses of 0.14 or 1.4 milligrams/kilogram of bodyweight (mg/kg bw) per day of abamectin or 1.4 mg/kg bw per day of the delta-8,9 isomer. Over 7 days, the percentages excreted in urine were 0.3–1% of the administered dose of abamectin and 0.4% of the dose of the isomer. The animals eliminated 69–82% of the dose of abamectin and 94% of the dose of isomer in feces. In rats, goats and cattle, unchanged parent compound accounted for up to 50% of the total radioactive residues in tissues. The 24-hydroxymethyl derivative of abamectin was found in rats, goats and cattle treated with the compound and in rats treated with the delta-8,9 isomer, and the 3′-*O*-demethyl derivative was found in rats and cattle administered abamectin and in rats administered the isomer.

7. *Metabolite toxicology*. There are no metabolites of concern based on a differential metabolism between plants and animals. The potential hazard of the 24-hydroxymethyl or the 3′-*O*-demethyl animal metabolites was evaluated in thorough toxicology studies with abamectin, photolytic break-down product, the delta 8,9-isomer.

8. *Endocrine disruption*.There is no evidence that abamectin is an endocrine disrupter. Evaluation of the rat multigenerational study demonstrated no effect on the time to mating or on the mating and fertility indices, suggesting no effects on the estrous cycle, on mating behavior, or on male or female fertility at doses up to 0.4 mg/kg/day, the highest dose tested. Furthermore, the range finding study demonstrated no adverse effect on female fertility at doses up to 1.5 mg/kg/day, the highest dose tested. Similarly, chronic and subchronic toxicity studies in mice, rats, and dogs did not demonstrate any evidence of toxicity to the male or female reproductive tract, or to the thyroid or pituitary (based upon organ weights and gross and histopathologic examination). In the developmental studies, the pattern of toxicity observed does not seem suggestive of any endocrine effect. Finally, experience with ivermectin in breeding animals, including sperm evaluations in multiple species, shows no adverse effects suggestive of endocrine disruption.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. The acute dietary Reference Dose (aRfD) is 0.0025 mg/kg/day from a 1–year dog study. The NOAEL is 0.25 mg/kg/day, and the LOAEL is 0.50 mg/kg/day based on mydriasis (pupil dilation) which was observed after 1 week of dosing. An uncertainty factor of 100 to account for interspecies extrapolation (10x) and intraspecies variability (10x) was recommended. EPA has also retained the 10X safety factor for infants and children resulting in an aRfD of 0.00025 mg/kg for appropriate populations. EPA has determined that the studies conducted with the CF-1 mouse are not relevant to human safety assessment. A Monte Carlo acute dietary exposure analysis predicted the percent population adjusted dose (PAD) used for the general population is 35% at the 99.9 percentile. Children 1–6 years old constitute the sub-population with the highest predicted exposure. The predicted percent PAD utilization for this subgroup is 70% for 99.9% of the individuals.

EPA has established the RfD for abamectin at 0.0012 mg/kg/day from a 2–generation reproduction study in rats. The developmental NOAEL is 0.12 mg/kg/day, and the developmental LOAEL is 0.40 mg/kg/day based on decreased pup body weight and viability during lactation, and increased incidence of retinal rosettes in F2b weanlings. An uncertainty factor of 100 to account for interspecies extrapolation (10x) and intraspecies variability (10x) was recommended. EPA has also retained the 10X safety factor for infants and children resulting in an aRfD of 0.00012 mg/kg/day for appropriate populations dietary exposure analysis for abamectin in the most exposed population (non-nursing infants <1 year old) shows the percent PAD utilization to be only 19%. For average U.S. populations (48 states), dietary exposure for abamectin shows a minimal utilization of 7% of the PAD.

ii. Drinking water. EPA modeling data (Generic expected environmental concentration/Screening concentration In Ground Water indicated worst case estimated environmental concentrations (EEC) of 0.485 micrograms/liter (µg/L) avermectin for acute and 0.239 µg/L for chronic exposure, both in surface water from the same use of abamectin on strawberries (the maximum use rate on the label). Refined modeling data Pesticide Root Zone Model-Exposure Analysis Modeling System (PRZM--EXAM) indicate a worst case EEC of 0.88 µg/L for acute and 0.57 µg/L for chronic, both calculated for an abamectin use on strawberries grown on black plastic mulch. EPA noted and Novartis agrees that the certainty of the concentrations estimated for strawberries is low, due to uncertainty on the amount of runoff from plant beds covered in plastic mulch and uncertainty on the amount of degradation of abamectin on black plastic compared to soil.

EPA and Novartis believe the estimates of abamectin exposure in water derived from the PRZM-EXAMS model are significantly overstated for several reasons. The PRZM-EXAMS model was designed to estimate exposure from ecological risk assessments and thus uses a scenario of a body of water approximating the size of a 1 hectare (2.5 acres) pond. This tends to overstate drinking water exposure levels for the following reasons. First, surface water source drinking water generally comes from bodies of water that are substantially larger than a 1 hectare (2.5 acres) pond. Second, the modeled scenario also assumes that essentially the whole basin receives an application of the pesticide. Yet in virtually all cases, basins large enough to support a drinking water facility will contain a substantial fraction of the area which does not receive pesticide. Third, there is often at least some flow (in a river) or turnover (in a reservoir or lake) of the water so the persistence of the pesticide near the drinking water facility is usually overestimated. Fourth, even assuming a reservoir is directly adjacent to an agricultural field, the agricultural field may not be used to grow a crop on which the pesticide in question is registered for use. Fifth, the PRZM-EXAMS modeled scenario does not take into account reductions in residue loading due to applications of less than the maximum application rate or no treatment of the crop at all (percent crop treated data). Although there is a high degree of uncertainty to this analysis, these are the best available estimates of concentrations of abamectin in drinking water. Although the peak EEC of 0.88 µg/L slightly exceeds the acute drinking water level of concern, 0.76 µg/L, considering the uncertain nature of the modeling estimate, EPA does not expect aggregate acute exposure to avermectin will pose an unacceptable risk to human health.

2. *Non-dietary exposure*. Avermectin's registered residential uses include indoor crack/crevice and outdoor application to lawns. For lawn uses, EPA conducted a risk assessment for adult applicators and postapplication exposure to avermectin using the EPA's Draft SOPs for Residential Exposure Assessments. The highest predicted exposure, oral hand to mouth for children, resulted in a calculated margin of exposure of 14,000. For children's postapplication exposure to avermectin from indoor crack/crevice products, valid exposure studies demonstrate there is no exposure and therefore no risk for indoor residential

scenarios. Chronic exposures for the residential uses are not expected. Short- and intermediate-term risk for the registered uses do not exceed EPA's level of concern.

D. Cumulative Effects

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The EPA stated in an FR notice published on April 7, 1999 (64 FR 16843–16850) (FRL–6070–6) that it does not have, at this time, available data to determine whether avermectin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment.

E. Safety Determination

1. *U.S. population*. Using the exposure assumptions described above and based on the completeness and reliability of the toxicity data base, Novartis has calculated aggregate exposure levels for this chemical. The calculations show that chronic exposure is below 100 percent of the RfD and the predicted acute exposure is below 100% of the acute RfD for all subpopulations. Novartis concludes that there is a reasonable certainty that no harm will result from aggregate exposure to abamectin residues.

2. *Infants and children*. The FQPA authorizes the employment of an additional safety factor of up to 10X to guard against the possibility of prenatal or postnatal toxicity, or to account for an incomplete data base on toxicity or exposure. EPA has chosen to retain the FQPA 10X safety factor for abamectin based on several reasons including evidence of neurotoxicity, susceptibility of neo-natal rat pups, similarity to ivermectin, lack of a developmental neurotoxicity study, and concern for exposure to infants and children.

It is the opinion of Novartis that a 3X safety factor is more appropriate for abamectin at this time. EPA has evaluated abamectin repeatedly since its introduction in 1985 and has found repeatedly that the level of dietary exposure is sufficiently low to provide ample margins of safety to guard against any potential adverse effects of abamectin. In addition, valid exposure studies demonstrate there is no exposure via indoor applications of abamectin products. Novartis states that the database for abamectin is complete and that the developmental neurotoxicity study is a new and not yet initially required study. Additionally, there is much more information regarding human risk potential than is the case with most pesticides, because of the widespread animal-drug and human-drug uses of ivermectin, the closely related analog of abamectin.

It is the opinion of Novartis that the use of a full 10X safety factor to address risks to infants and children is not necessary. The established chronic endpoint for abamectin in the neonatal rat is overly conservative. Similar endpoints for ivermectin are not used by the Food and Drug Administration to support the allowable daily intake for ivermectin residues in food from treated animals. No evidence of toxicity was observed in neonatal rhesus monkeys after 14 days of repeated administration of 0.1 mg/kg/day (highest dose tested) and in juvenile rhesus monkeys after repeated administration of 1.0 mg/kg/day (highest dose tested). The comparative data on abamectin and ivermectin in primates also clearly demonstrate the dose response for exposure to either compound is much less steep than that seen in the neonatal rat. Single doses as high as 24 mg/kg of either abamectin or ivermectin in rhesus monkeys did not result in mortality; however, this dose was more than two times the LD_{50} in the adult rat and more than 20 times the LD_{50} in the neonatal rat. The absence of a steep dose-response curve in primates provides a further margin of safety regarding the probability of toxicity occurring in infants or children exposed to avermectin compounds. The significant human clinical experience and widespread animal drug uses of ivermectin without systemically toxic, developmental, or postnatal effects supports the safety of abamectin to infants and children.

F. International Tolerances

The Codex residue definition for MRLs is consistent with that of the United States. Codex MRLs for abamectin include cattle fat 0.1 mg/kg; cattle kidney 0.05 mg/kg; cattle liver 0.1 mg/kg; citrus fruits 0.01 mg/kg; cottonseed 0.01 mg/kg; hops, dry 0.1 mg/kg; cattle milk 0.005 mg/kg; goat milk at 0.005 mg/kg; and potato 0.01 mg/kg.

[FR Doc. 99–19440 Filed 7–28–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6409–8]

Proposed Modifications to the Policy on Compliance Incentives for Small Businesses and Request for Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment on proposed revisions.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to modify the *Policy on Compliance Incentives for Small Businesses* to expand the options allowed under the Policy for discovering violations and to establish a time period for disclosure. This Policy is intended to promote environmental compliance among small businesses by providing incentives for voluntary discovery, disclosure, and prompt correction of violations. The Policy accomplishes this in two ways: by setting forth guidelines for the Agency to reduce or waive penalties for small businesses that come forward to disclose and make good faith efforts to correct violations, and by deferring to States, Tribes, and local governments that offer these incentives.

DATES: Comments must be received on or before September 27, 1999.

ADDRESSES: Mail written comments to the Enforcement and Compliance Docket and Information Center (2201A), Docket Number EC–P–1999–009, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 401 M Street SW, Washington, DC 20460. In person, deliver comments to Enforcement and Compliance Docket Information Center, U.S. Environmental Protection Agency, Rm. 4033, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW, Washington, DC. Copies of the existing Policy and Fact sheet are available at that location as well. Persons interested in reviewing these materials must make advance arrangements to do so by calling 202–564–2614. Comments may also be faxed to 202–501–1011 or submitted electronically to: *docket.oeca@epa.gov*.

FOR FURTHER INFORMATION CONTACT: Ginger Gotliffe, Office of Compliance, telephone 202–564–7072; fax (202) 564–0009; e-mail: gotliffe.ginger@epa.gov.

SUPPLEMENTARY INFORMATION: Five years ago, EPA reorganized its compliance programs. This reorganization was undertaken by Administrator Browner with a goal of making EPA's enforcement and compliance programs more effective in protecting public