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

health and the environment. The reorganization also improved and enhanced our abilities to reach out to small business sectors with information to help them comply. At this five year anniversary, EPA has been conducting outreach efforts to obtain feedback on compliance and enforcement activities issues, on ways to further improve public health and the environment through compliance efforts, and on the actions the Agency has taken over the past five years. Recently, EPA held two national conferences entitled ''Protecting Public Health and the Environment through Innovative Approaches to Compliance.'' As part of this effort, the Office of Enforcement and Compliance Assurance (OECA) also published a **Federal Register** document soliciting comments on how EPA can further protect and improve public health and the environment through new compliance and enforcement approaches (see 64 FR 10144, March 2, 1999). Conference summaries and a copy of the **Federal Register** document are available at OECA's website at *http://www.epa.gov/oeca/polguid/oeca5sum.html*. From outreach efforts such as the conferences held earlier this year and from meetings and conference calls with interested stakeholder groups specifically concerning small business issues such as the Small Business Policy, OECA received feedback that improvements to the Policy could be made. In response to that feedback, OECA has been looking at ways to improve the Policy, and is now proposing modifications to the Small Business Policy and requesting additional comments on the Policy.

Under the Policy, EPA will waive or mitigate civil penalties whenever a small business makes a good faith effort to comply with environmental requirements by discovering violations, promptly disclosing the violations, and correcting them. Assuming the facility meets all the criteria in the policy, including those on violation history, corrections period, and lack of harm, EPA will waive 100% of the civil penalty. Moreover, EPA will defer to State and Tribal actions that are consistent with the criteria set forth in this Policy.

These proposed changes would modify the Final Policy issued in June 1996. See 61 FR 27984, June 3, 1996. The Agency would like comments from the public on the following proposed changes and on any other issues concerning the Policy.

1. Expand Options for Discovery of Violations. One proposed change is to allow small businesses to obtain penalty relief by using any means of voluntary discovery as well as on-site compliance assistance or environmental audits. Voluntary discovery could include compliance management systems (CMS), pollution prevention assessments, participation in mentoring programs, training classes, use of on-line compliance assistance centers, and use of checklists. The Agency wants to encourage participation in those programs or activities that could increase compliance, improve efficiency, and reduce pollution. These programs and activities need not be associated with environmental regulatory agencies, but may be associated with trade associations, professional associations, universities, and the like. EPA will consider application of this Policy to violations discovered through activities required in ''partnership'' programs on a project-by-project basis.

There are a variety of activities and sources of information that a small business can use to learn more about the regulatory requirements. EPA and the States provide various forms of compliance assistance. Some State assistance programs are run as confidential services to the small business community. If a small business wishes to obtain a corrections period after receiving compliance assistance from a confidential program, the business must promptly disclose the violations to the appropriate regulatory agency and comply with the other provisions of this Policy.

2. *Penalty Reduction.* Penalties are made up of two components: gravity and economic benefit. The gravity component mitigation typically involves the nature of the violations, the duration of the violations, the environmental or public health impacts of the violations, good faith efforts by the small business to promptly remedy the violation, and the facility's overall record of compliance with environmental requirements. Under this Policy, the Agency will grant 100% mitigation of (completely eliminate) the gravity component of the penalty for violations found through any method provided all the other criteria in the policy are met. The Agency believes the incentive of 100% gravity mitigation should encourage small businesses to disclose violations and correct them within the specified time period.

The Policy provides that EPA may seek the economic benefit portion of the penalty if a small business has obtained a significant economic benefit from the violations, for example, if a business significantly reduced its expenses by not purchasing and installing an emission control device to meet its regulatory requirements. Prompt disclosure and correction of violations discovered often results in no economic benefit having been accrued. To date, the vast majority of the disclosures under the Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations Policy (Audit Policy) and all of the disclosures under the Small Business Policy have not necessitated recovery of economic benefit. The Audit Policy is another EPA policy that provides penalty mitigation for discovering, disclosing, and correcting violations. The main differences between it and the Small Business Policy are that the Audit policy may be used by businesses of any size, it provides two different levels of penalty mitigation based upon how the violation was discovered, and the correction period is shorter.

3. *Clarify and Lengthen the Disclosure Period.* Another proposed change is to require that the business fully disclose a violation within 21 calendar days regardless of how the violation was discovered. Currently, the Policy requires ''prompt disclosure'' for compliance assistance discovery and 10 day disclosure for discoveries made through an environmental audit. This modification will clarify the definition of discovery period. It is critical for EPA to get timely reporting of violations in order that it might have a clear notice of the violations and the opportunity to respond if necessary, as well as an accurate picture of a given facility's compliance record. Lengthening the disclosure period will give small businesses more opportunity to make use of the policy and will be consistent with the proposed modification to the Audit Policy. That modification was a result of the Audit Policy evaluation that showed that the 10-day period was unduly restrictive.

4. *Implementation of the Policy.* The Policy has also been modified in format and language to provide the information in a more understandable manner. To increase the usefulness of the Policy, EPA will provide a fact sheet, contacts list, and other information about the Policy at the EPA web site (*http://www.epa.gov/oeca/polguid*), at the Compliance Assistance Centers web sites (all 9 Centers available through *http://www.epa.gov/oeca/mfcac.html*), through EPA Headquarters and Regional contacts and as part of targeted compliance assistance activities and initiatives.

Enhanced implementation of the Policy also involves improved procedures and coordination within EPA. EPA Headquarters and Regional staff working on the Audit Policy as

well as this Small Business Policy are coordinating on issues and procedures to insure national consistency and to improve the timeliness of the Agency's review of each disclosure. EPA will commit to responding to a small business within 60 days of disclosure of a violation.

To date the Small Business Policy has not been used very much. As reported to Congress approximately 150 small entities applied for penalty relief under EPA disclosure policies. Many of these small entities (which include small businesses as defined under this Policy) used the Audit Policy. EPA knows through conversations with State officials that there are many small businesses using State disclosure policies for violations discovered under State regulations. To increase the usage of the Policy once it is finalized, EPA is planning a marketing effort for the Policy. Public comments on effective marketing techniques for small business sectors are encouraged.

5. *Compliance Incentives Issues and Comments.* EPA recently announced the results of its evaluation of the effectiveness of the Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations Policy (Audit Policy) of December 1995, and solicited public comments on proposed changes (see 64 FR 26745, May 17, 1999). To the extent that results from that evaluation and comments to that **Federal Register** document address small business issues with compliance incentives policies such as the Small Business Policy, the Agency will consider that information. Small entities (those businesses that meet the definition of small entity under SBREFA) have used the Audit Policy, so comments about their usage of a compliance incentive policy would be pertinent.

As part of the Agency's evaluations of the two policies and given the similarities between the two Policies, EPA asks for comments in this Notice on the advisability of combining the Audit Policy with the Small Business Policy. In particular, the Agency is interested in whether small businesses would be more likely to audit and self-disclose violations (or seek compliance assistance) if the two policies were merged. EPA is particularly interested in hearing the comments of small businesses on this point.

Dated: July 20, 1999.

Elaine Stanley,

Director, Office of Compliance, Office of Enforcement and Compliance Assurance.

Policy on Compliance Incentives for Small Businesses

A. Introduction and Purpose

The Policy on Compliance Incentives for Small Businesses is intended to promote environmental compliance among small businesses by providing incentives for them to make use of compliance assistance programs, environmental audits, compliance management systems (CMS), or to participate in any activities that may increase the business's understanding of the environmental requirements with which they must comply. The Policy accomplishes this in two ways: by waiving or mitigating civil penalties, and by deferring to States and local governments who offer these incentives consistent with the criteria established in this Policy.

EPA will waive or mitigate civil penalties, whenever a small business makes a good faith effort to comply with environmental requirements by:

(1) Discovering a violation,

(2) Disclosing the violation, and

(3) Correcting the violation within the proper timeframe.

To use the Policy, the facility must meet criteria on violation history, corrections period, lack of harm, and criminal conduct.

B. Background

This Policy implements section 223 of the Small Business Regulatory Enforcement Fairness Act of 1996, signed into law by the President on March 29, 1996.

C. Applicability

This Policy applies to facilities owned by small businesses as defined here. A small business is a person, corporation, partnership, or other entity who employs 100 or fewer individuals (across all facilities and operations owned by the entity).[1] Facilities that are operated by municipalities or other local governments may be covered under the Small Communities Policy (see http://es.epa.gov/oeca/polguid/polguid1.html).

This Policy supersedes the previous version of the policy which became effective on June 10, 1996. To the extent that this Policy may differ from the terms of applicable enforcement response policies (including penalty policies) under media-specific programs, this document supersedes those policies.

D. How Small Businesses Can Qualify for Penalty Mitigation

EPA will eliminate or mitigate civil penalties against small businesses based on the following criteria:

1. Discovery Is Voluntary

The small business discovers a violation on their own before an EPA or State inspection. Violations might be discovered after receiving compliance assistance, conducting an environmental audit or participating in mentoring programs. Other activities that may be useful in discovering violations include establishing compliance management systems (CMS), using compliance checklists, reading materials on complying with environmental requirements, using compliance assistance center web sites, and attending training classes.

The violation must be identified voluntarily, and not through a legally mandated monitoring or sampling requirement prescribed by statute, regulation, permit, judicial or administrative order, or consent agreement. These include emissions violations detected through a continuous emissions monitor (or alternative monitor established in a permit), violations of National Pollutant Discharge Elimination System (NPDES) discharge limits detected through required sampling or monitoring; or violations discovered through a compliance audit required to be performed by terms of a consent order or settlement order.

2. Disclosure Period Is Met

a. The small business must fully disclose a specific violation in writing to EPA or the State within 21 days after it has discovered that the violation has occurred, or may have occurred. Prompt disclosure is evidence of the regulated entity's good faith in wanting to achieve or return to compliance as soon as possible. The time at which discovery that a violation may have occurred begins when any officer, director, employee or agent of the facility becomes aware of any facts that constitute a possible violation. Where there is some doubt about whether a violation has occurred, the recommended course is for the facility to disclose and allow the regulatory authorities to make a definitive determination. This will insure that the

[1] The number of employees should be considered as full-time equivalents on an annual basis, including contract employees. Full-time equivalents means 2,000 hours per year of employment. For example, see 40 CFR 372.3.

facility meets the disclosure period requirement.

b. The disclosure of the violation must occur before the violation was otherwise discovered by, or reported to EPA, the appropriate state or local regulatory agency. See section F.1 of the Policy below. Good faith also requires that a small business cooperate with EPA and provide such information requested by EPA to determine applicability of this Policy.

c. If a small business wishes to obtain a corrections period after receiving compliance assistance from a confidential assistance program, the business must disclose the violations to the appropriate regulatory agency within 21 days of discovery.

3. This is the small business's first violation of this requirement in three years. This Policy applies unless the business has:

a. Previously been subject to a warning letter, notice of violation, field citation, citizen suit, or any other enforcement action by a government agency for a violation of the same requirement within the past three years.

b. Used this Policy for a violation of the same or a similar requirement within the past three years.

c. Been subject to two or more enforcement actions for violations of environmental requirements in the past five years, even if this is the first violation of this particular requirement.

4. The business corrects the violation within the corrections period set forth below.

Small businesses are expected to remedy the violations within the shortest practicable period of time. Correcting the violation includes remediating any environmental harm associated with the violation, as well as implementing procedures to prevent a recurrence of the violation.

a. For any violation that cannot be corrected within 90 days of detection, the small business should submit a written schedule, or the agency should issue a compliance order with a schedule, as appropriate. The corrections are to be completed not more than 180 days following the date that the violation was detected.

b. If the small business intends to correct the violation by implementing pollution prevention measures, they may take an additional period of 180 days, *i.e.*, up to a period of one year from the date the violation is detected, only if necessary.

5. The Policy does not apply if:

a. The violation has caused actual serious harm to public health, safety, or the environment;

b. The violation is one that may present an imminent and substantial endangerment to public health or the environment; or

c. The violation involves criminal conduct. Businesses wishing to pursue penalty mitigation for a violation that does involve criminal conduct should refer to the Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations Policy of December 1995 (60 FR 66706, 12/22/95).

E. Penalty Mitigation Guidelines That EPA Will Follow

EPA will exercise its enforcement discretion to eliminate or mitigate civil penalties as follows.

1. EPA will waive the civil penalty if a small business satisfies all of the criteria in section D. If, however a small business has obtained a significant economic benefit from the violation(s), EPA will waive 100% of the gravity component of the penalty, but may seek the full amount of the significant economic benefit associated with the violations.[2] EPA anticipates that such a significant economic benefit will occur infrequently. However, EPA retains this discretion to ensure that small businesses that comply with public health protections are not put at a serious marketplace disadvantage by those who have not complied.

2. If a small business does not fit within the guideline immediately above, this Policy does not provide any special penalty mitigation. However, if a small business has otherwise made a good faith effort to comply, EPA has discretion, pursuant to its applicable enforcement response or penalty policies, to waive or mitigate civil penalties.[3]

3. Further, these policies allow for mitigation of the penalty where there is a documented inability to pay all or a portion of the penalty, thereby allowing the small business to continue operations and to finance compliance. See Guidance on Determining a Violator's Ability to Pay a Civil Penalty of December 1986. Penalties also may be mitigated pursuant to the Final EPA Supplemental Environmental Projects Policy of May 1998 (63 FR 24796, 5/5/98) and Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations Policy of December 1995 (60 FR 66706, 12/22/95).

4. This Policy sets forth how the Agency expects to exercise its enforcement discretion in deciding on an appropriate enforcement response and determining an appropriate civil penalty for violations by small businesses. It states the Agency's views as to the proper allocation of enforcement resources. This Policy is not final agency action and is intended as guidance. It does not create any rights, duties, obligations, or defenses, implied or otherwise, in any third parties.

F. Enforcement

To ensure that this Policy enhances and does not compromise public health and the environment, the following conditions apply:

1. Violations detected through inspections, field citations, reported to a federal, state or local agency by a member of the public or a ''whistleblower'' employee, identified in notices of citizen suits, previously reported to an agency, or required to be reported to an agency by applicable regulations or permits, remain subject to enforcement.

2. A business is subject to all applicable enforcement response policies (which may include discretion whether or not to take formal enforcement action) for all violations that were not remedied within the corrections period. The penalty in such action may include the time period before and during the correction period.

G. Applicability to States and Tribes

EPA recognizes that states and tribes are partners in enforcement and compliance assurance. Therefore, EPA will defer to state and tribal actions in delegated or approved programs that are consistent with the criteria set forth in this Policy. Whenever a State agency or Tribe provides a correction period to a small business pursuant to this Policy or a similar policy, the agency should notify the appropriate EPA Region. This notification will enable EPA to apply this Policy in coordination with similar state policies. Similarly, EPA will notify the appropriate State agency whenever EPA applies this policy and requests that such States defer to EPA's action under the Policy. Regional contacts will be listed at the EPA web page with this Policy.

H. Public Accountability

Within three years of the effective date of this Policy, EPA will compile data on the use of this Policy in promoting compliance among small businesses. EPA will make this data available to the public.

[2] The ''gravity component'' of the penalty includes everything except the economic benefit amount.

[3] For example, in some media specific penalty policies, the penalty calculation is reduced to account for good faith efforts to comply.

[FR Doc. 99–19437 Filed 7–28–99; 8:45 am]

BILLING CODE 6560–50–P