area in the **Federal Register** on April 16, 1999 (64 FR 18864).

**DATES:** Comments must be received on or before July 6, 1999.

**ADDRESSES:** Written comments on this action should be addressed to Mr. Thomas H. Diggs, Chief, Air Planning Section, at the EPA Regional Office listed below. Copies of the documents relevant to this action are available for public inspection during normal business hours at the following locations. Persons interested in examining these documents should make an appointment with the appropriate office at least 24 hours before the visiting day. Environmental Protection Agency, Region 6, Air Planning Section (6PD–L), 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733. Texas Natural Resource Conservation Commission, 12124 Park 35 Circle, Austin, Texas 78753.

**FOR FURTHER INFORMATION CONTACT:** Lt. Mick Cote, Air Planning Section (6PD-L), Environmental Protection Agency, Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, telephone (214) 665–7219.

### List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, Area designations and classifications, National parks, Wilderness areas.

**Authority:** 42 U.S.C. 7401 *et seq.*

Dated: May 20, 1999.

**Gregg A. Cooke,**

*Regional Administrator, Region 6.*

[FR Doc. 99–14064 Filed 6–2–99; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 176

**[OPP–181051; FRL–5750–1]**

**RIN 2070–AD15**

## Tolerances for Pesticide Emergency Exemptions

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing procedures and criteria under which EPA would establish tolerances for residues of pesticide chemicals resulting from emergency uses of pesticide chemicals authorized by EPA under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This regulation is required by the Federal Food, Drug, and Cosmetic Act (FFDCA), which was amended by the Food Quality Protection Act (FQPA) of 1996. FQPA established a new safety standard with special protections for infants and children and extends this new protection to the emergency use of pesticide chemicals. Specifically, FQPA requires EPA to establish time-limited tolerances, or an exemption from the requirement for a time-limited tolerance, for any pesticide uses authorized by EPA under section 18 of FIFRA that may result in residues in or on food (including animal feed). EPA actions under section 18 of FIFRA are taken in response to a petition submitted by a Federal or state agency. These proposed procedures and criteria will ensure that the Agency is able to address more quickly any tolerance related issues in conjunction with any decision made on the petition. EPA believes that the procedures proposed in this document will be protective of public health, while continuing to ensure availability of pesticides in emergency situations.

**DATES:** Written comments, identified by the docket control number OPP–181051, must be received on or before August 2, 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 of this notice.

**FOR FURTHER INFORMATION CONTACT:**

Joseph E. Hogue, Policy and Regulatory Services Branch, Field and External Affairs Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, telephone number: (703) 308–9072, e-mail address: hogue.joe@epa.gov.

**SUPPLEMENTARY INFORMATION:**

### I. Important Information

*A. Does This Proposed Rule Apply to You?*

You may be potentially affected by this proposed rule if you are the Federal Government or a State or territorial government agency charged with pesticide authority. Regulated categories and entities may include, but is not limited to:

| Category | Examples |
|---|---|
| Federal Government | Agencies that petition EPA for section 18 pesticide use authorization. |
| State and territorial government agencies charged with pesticide authority. | State that petition EPA for section 18 pesticide use authorization. |

This table is not all inclusive, but is intended as a guide for entities likely to be regulated by this action. To determine whether this proposed rule applies to you, carefully read the applicability criteria in a proposed § 176.1. If you have any 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 or Copies of Support Documents?*

*1. Electronically.* You may obtain electronic copies of this document and various support documents are available from the EPA Home page at the **Federal Register**—Environmental Documents entry for this document under ''Laws and Regulations'' (http://www.epa.gov/fedrgstr/).

*2. In person.* The official record for this proposed rule, as well as the public version, has been established under docket control number OPP–181051, (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of any electronic comments, which does not include any information claimed as CBI, is available for inspection in 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.

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

You may submit comments through the mail, in person, or electronically:

*1. By mail.* Submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460.

*2. In person.* Deliver written comments to: Public Information and

Records Integrity Branch, in Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

*3. Electronically.* Submit your comments and/or data electronically to: ''opp-docket@epamail.epa.gov.'' Please note that you should not submit any information electronically that you consider to be CBI. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number OPP–181051. Electronic comments on this proposed rule may also be filed online at many Federal Depository Libraries.

*D. How Should I Handle Information That I Believe Is Confidential?*

You may claim information that you submit in response to this document as confidential 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. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice.

## II. Authority

This action is issued under the authority of the Federal Food, Drug, and Cosmetic Act as amended by the Food Quality Protection Act of 1996.

## III. Background

The Food Quality Protection Act of 1996 (FQPA) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 201 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* Among other things, FQPA amends FFDCA to bring all pesticide tolerance-setting activities conducted by EPA under a new section 408 with a new safety standard and new procedures. FQPA also amends FFDCA by directing EPA to establish time-limited tolerances for any pesticide use authorized by EPA under section 18 of FIFRA that may result in residues in or on food (including animal feed). The FQPA amendments went into effect immediately.

EPA is proposing regulations to govern the establishment of time-limited tolerances for pesticide uses authorized by EPA under section 18 of FIFRA. This proposed rule pertains only to regulatory changes resulting from enactment of FQPA.

## IV. Emergency Exemptions under Section 18

Section 18 of FIFRA authorizes EPA to exempt any Federal or state agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166. Generally, these regulations allow a Federal or state agency to apply for an exemption to allow a use of a pesticide that is not registered when such use is necessary to alleviate an emergency condition. A state, as defined by FIFRA section 2(aa), means a state, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands and the American Samoa. The regulations set forth information requirements, procedures, and standards for EPA's approval or denial of such exemptions.

Federal and state agencies may petition EPA for a section 18 emergency exemption from FIFRA due to a public health emergency, a quarantine emergency, or a ''specific'' emergency. Most exemptions from FIFRA petitioned for or granted under section 18 fall under the category of ''specific exemptions.'' Typical justifications for specific exemptions include, but are not limited to, the introduction of a new pest; the expansion of the range of a pest; the cancellation or removal from the market of a previously registered and effective pesticide product; and the development of resistance in pest to a registered product, or loss of efficacy in available products for any other reasons. Additionally, an emergency situation is generally considered to exist when no other viable (chemical or non-chemical) means of control exist, and where the emergency situation will cause significant economic losses to affected individuals if the exemption is not granted.

When a Federal or state agency petitions EPA under section 18, it must submit a request in writing that documents the emergency situation, the chemical(s) proposed for the use, the target pest, the crop, the rate and number of applications to be made, the geographical region where the chemical(s) would be applied, and a discussion of risks which may be posed to human health or to the environment as a result of the pesticide use (40 CFR 166.20). EPA conducts an expedited review of the request, verifying the existence of the emergency, assessing risks posed to human health through dietary exposure, assessing risks posed to farmworkers and other handlers of the pesticide, assessing any adverse effects on non-target organisms (including federally listed endangered species), and assessing the potential for contamination of ground and surface water. If an application for the requested use has been made in previous years, EPA does an assessment of the progress toward registration for the use of the requested chemical on the requested crop, and considers this status in the final determination to grant or deny the exemption. If EPA's review concludes that the situation is an emergency, and that the use of the pesticide under the exemption will not cause unreasonable adverse effects on human health or the environment, then EPA may authorize the pesticide to be used under section 18.

Section 18 pesticide uses for specific and public health exemptions can be authorized for periods not to exceed 1 year; uses under quarantine exemptions can be authorized for up to 3 years. Since actions taken under section 18 are intended to address a time-specific crisis or emergency need for temporary relief, most section 18 exemptions are specific exemptions which are granted for just one growing season. Such actions should not, therefore, be reviewed as an alternative to registering the use(s) needed for longer periods. If the situation addressed with the section 18 exemption persists, or is expected to persist, affected entities must take the proper steps to amend the existing or seek a new registration to address that future need.

In general, EPA attempts to form and communicate decisions on section 18 requests within 50 calendar days of receipt of an exemption application; in fiscal year 1998 (October 1, 1997—September 30, 1998), EPA's average response time was 56 days. During FY98, EPA received requests for 601 exemptions, of which 410 were approved (27 requests were denied, 67 requests were withdrawn by states, and 97 requests were still pending at the end of the fiscal year).

EPA maintains lines of communication with the State Departments of Agriculture (or applicant) during the application review period so they may keep growers informed on the status of the request. The Agency works with the State Departments of Agriculture so that in case a request might be denied, the affected growers may be able to find alternative solutions. In the early stages of the development of this proposed rule, EPA consulted with

representatives from the States of North Carolina and Washington on behalf of the State's FIFRA Issues Research and Evaluation Group (SFIREG). SFIREG identifies, analyzes and provides State comments to the Office of Pesticide Programs on matters relating to pesticide registration, enforcement, training and certification, water quality, disposal and other areas of environmental concern related to pesticide manufacture, use and disposal. In addition, SFIREG provides a mechanism for EPA to keep the states informed and up-to-date on its pesticide regulatory programs.

In September 1997, the Office of Pesticide programs formed a minor use office which focuses on the special needs of growers of minor use crops. EPA has expanded work in this respect with Interregional Research Project No. 4 (IR–4), a U.S. Department of Agriculture (USDA) program which provides national leadership and coordination for information on the clearance of minor use pesticides and generates data to support minor-use registrations. IR–4 will often help support minor use emergency exemptions petitions.

The section 18 program can be an important part of developing reasonable transition approaches for certain crops, especially minor use crops, in moving to safer pest control methods. For example, in certain situations, a pesticide needed for emergency use on minor use crops might be registered for other use sites which have already filled the ''risk cup.'' In order to address the needs of minor use farmers, the Agency might work with pesticide registrants and growers to cap the existing use on registered crops at a level that allows room in the risk cup for use of the pesticide in combating an emergency. Under this offset approach, the Agency could achieve either no risk increase or a risk reduction and at the same time facilitate and permit critical emergency exemptions.

In continuing efforts to implement FQPA, EPA is working together with USDA to ensure that implementation of FQPA is informed by a sound regulatory approach, by appropriate input from affected members of the public, and by due regard for the needs of our Nation's agricultural producers and other pesticide users.

## V. Legal Basis of EPA Action

### *A. Residues in Food Prior to FQPA*

Prior to enactment of FQPA, when EPA granted an emergency exemption under section 18 for use of a pesticide that could result in residues in or on food, EPA did not establish a tolerance or exemption from the requirement for a tolerance under FFDCA. rather, EPA advised the Food and Drug Administration (FDA) of the emergency exemption and the level of residues that EPA concluded would be present in or on affected foods as a result of the emergency use, and requested that FDA refrain from enforcing against foods which contained residues of the pesticide due to use under the exemption. Similarly, EPA informed the USDA of pesticide use under an emergency exemption where residues would result in meat, milk, or eggs.

### *B. FQPA Requirements*

New section 408(l)(6) requires EPA to establish a tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in or on food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA, and requires that the tolerances be consistent with sections 408(b)(2) and (c)(2) and FIFRA section 18. Section 408(l)(6) also requires EPA to promulgate regulations governing the establishment of tolerances and exemptions under section 408(l)(6). New FFDCA section 408(b)(2)(A)(i) allows EPA to establish a tolerance (the maximum legal limit) for a pesticide chemical residue in or on a food in accordance with the following:

1. EPA must determine that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' Aggregate exposure includes exposure through food and drinking water, as well as all non-occupational, non-dietary exposure, such as through residential uses.

2. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.* * *''

3. Section 408(b)(2)(D) specifies certain factors EPA is to consider in establishing a tolerance. These factors include the use of reliable data, nature of toxic effects, human risk involved, dietary consumption patterns, cumulative effects of a pesticide residue with other substances that have a common mechanism of toxicity, aggregate exposure levels, variability of the sensitivities of subgroups of consumers, endocrine disrupting effects, and appropriate safety factors.

4. Section 408(b)(3) requires that there is a practical method for detecting and measuring levels of the pesticide chemical residue in or on food. A tolerance may only be established at a level at or above the limit of detection of the designated method.

5. Section 408(c) governs EPA's establishment of exemptions from the requirement for a tolerance using the same safety standard as section 408(b)(2)(A) and incorporating the provisions of sections 408(b)(2)(C) and (D). In this preamble, EPA will use the terms ''tolerance'' to refer to exemptions from the requirement for a tolerance as well.

Section 408(l)(6) requires EPA to establish tolerances in connection with EPA's granting of FIFRA section 18 emergency exemptions. When EPA establishes a tolerance under section 408(l)(6), it may do so without providing notice or a period for public comment. Tolerances established under section 408(l)(6) must also be consistent with the safety standards in section 408(b)(2) and (c)(2) that are applicable to all tolerances under section 408, and with FIFRA section 18. Section 408(l)(6) specifies that such tolerances shall have an expiration date, but does not specify the duration of the tolerance.

## VI. Interim Section 18 Practices

Since August 3, 1996, EPA has been acting on requests for section 18 exemptions and has been issuing associated tolerances on a case-by-case basis under the new safety standard mandated by FQPA. The Agency sent a letter to Federal and state agencies in September 1996, informing them of the new procedures and issued guidance on interim procedures in Pesticide Regulation Notice 97–1 (January 31, 1997). In establishing section 18-related tolerances during this interim period before issuing the section 408(l)(6) procedural regulation and before making broad policy decisions concerning the interpretation and implementation of the new section 408, EPA does not intend to set precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Rather, these early section 18 tolerance decisions are being made on a case-by-case basis and will not bind EPA as it proceeds with further rulemaking and policy development.

## VII. EPA Proposal

### *A. Scope*

This proposal deals exclusively with procedures for setting time-limited tolerances for pesticide chemical residues associated with FIFRA section 18 emergency exemptions. The proposal does not modify any regulatory policies or procedures associated with the issuance of an emergency exemption itself, nor does it affect tolerance procedures which fall under other sections of FIFRA or FFDCA.

### *B. Definitions*

The terms defined in proposed § 176.3 of the regulatory text have the same meaning as FIFRA section 2, FFDCA section 201, and 40 CFR part 166.

### *C. Request for a Section 18 Tolerance*

Proposed § 176.5 specifies that EPA will review data to establish a time-limited tolerance for a pesticide to be used in an emergency or crisis situation under section 18 only after it has received the emergency exemption request or a crisis situation has been declared.

### *D. Determining Reasonable Certainty of No Harm*

In developing these proposed regulations, EPA considered several approaches for assuring timely access to information adequate to ensure that a section 18 tolerance, taking into account its limited duration and emergency nature, meets the new FFDCA safety standard of reasonable certainty of no harm.

For a number of reasons, EPA proposes to implement the new provisions of FFDCA related to section 18 tolerances in § 176.7 by evaluating each submission on a case-by-case basis to determine if adequate reliable data are available to make the ''reasonable certainty of no harm'' finding mandated under section 408 of FFDCA. EPA believes that timeliness of review in a manner responsive to the requirements of the situation is of critical importance. EPA must be able to conclude rapidly whether it has enough reliable data readily available to make a safety finding under FFDCA for the requested use. Even if EPA concludes that it is unable to establish a time-limited tolerance for the requested use, the Agency will strive to make that conclusion in sufficient time for the applicant to search for some additional method to control the emergency pest situation. This case-by-case evaluation is consistent with EPA's traditional approach to section 18 exemption requests and with the statutory mandate of FFDCA section 408(l)(6).

In addition to the practical limits on the time available for decision-making, EPA believes it is reasonable to rely on available data for several other reasons, even though those data will generally be less than those required for the establishment of a permanent tolerance. Dietary exposures to pesticide chemical residues from use under a section 18 exemption are generally less than those associated with permanent tolerances because section 18 uses are of limited duration, and because section 18 uses generally do not involve the entire U.S. production of any crop since they are granted on a state-by-state basis. Moreover, substantial hazard and exposure data are usually available. Many section 18 exemption requests are for new use sites of currently registered pesticides or for uses of previously registered pesticides which are no longer in use. Consequently, EPA may already have an extensive data base readily available to make the reasonable certainty of no harm determination to set the tolerance. Using available data is less likely to require significant increases in the resources necessary to support exemption requests. It would not significantly increase the regulatory burden on applicants by creating new data requirements for section 18 exemptions nor significantly increase costs to EPA for evaluating the requests. It is important to limit the resource requirements of the section 18 program so that both the Agency and applicants have sufficient resources to carry out their other responsibilities under FIFRA and FFDCA.

*1. Data requirements.* Under this approach, EPA will review data that has been submitted as required in 40 CFR part 158 for FIFRA section 18 requests and whatever additional useful data it has available in order to make the safety determination required under FFDCA for establishment of a time-limited tolerance for an emergency exemption. Pesticide Registration (PR) Notice 97–1, issued January 31, 1997, provides additional guidance on what data to submit to the Agency to enable EPA to make a ''reasonable certainty of no harm'' determination in order to issue a tolerance (for a copy of PR Notice 97–1, please contact the OPP docket, address above, or visit the EPA web site). Because EPA already has in its files much of the data it will review to make a determination on a section 18 tolerance, the Agency does not expect such data to be submitted routinely with an exemption request. EPA will exercise its best scientific judgment and rely on data submitted to support past and pending registration actions for the subject or closely related chemical, or data submitted to EPA as part of the reregistration process. When possible, applicants should cite studies previously reviewed, and found acceptable by EPA, that pertain to the requested use. EPA will not, however, conduct expedited reviews of data submitted for permanent tolerances, or for registration or reregistration actions, solely in order to ascertain the viability of establishing a tolerance for a section 18 exemption request.

In all cases, applicants must include the earliest anticipated harvest date of crops for which the section 18 exemption is being requested. This information is useful for EPA to allocate the necessary resources to establish the time-limited tolerances in time for the harvest, and will also be useful to FDA and USDA in enforcing the tolerances.

*2. Agency review under a case-by-case approach.* In order to determine whether EPA will be able to establish a time-limited tolerance for a requested section 18 use, EPA will consider available information relevant to the factors listed in FFDCA section 408(b)(2)(D), including:

a. Aggregate exposure to the pesticide chemical residue through:

i. Dietary exposure, including drinking water.

ii. Non-dietary, non-occupational residential exposure [indoor and outdoor].

b. Cumulative effects of the pesticide chemical residue and other substances that have a common mechanism of toxicity.

c. Extra sensitivity of infants and children.

d. Potential to produce endocrine effects.

Because there is a significant scientific uncertainty at this time about how to aggregate non-dietary risk factors with dietary risk, and because generally EPA has limited data with which to evaluate common mechanism of toxicity and endocrine disruption capacities of chemicals, EPA will make its ''reasonable certainty of no harm determination'' based on available and reliable information coupled with best scientific judgment as necessary. If EPA concludes that establishment of the appropriate tolerance would result in ''a reasonable certainty of no harm'' as defined in FFDCA section 408(b), then a tolerance may be established for the requested use.

EPA will be unable to establish a time-limited tolerance for the proposed emergency exemption use, and therefore will deny the exemption request, if: (1) The Agency finds that the tolerance

does not meet the safety standard of reasonable certainly of no harm as defined in FFDCA section 408, or (2) the Agency does not have enough reliable data to make a determination that the safety standard is met.

*3. Alternative approaches considered.* EPA has identified other possible approaches to establishing section 18 tolerances which it could pursue. One approach was to require a full data set to support section 18 tolerances as is required in 40 CFR part 158, subparts D and F, for the establishment of permanent tolerances. However, the Agency recognized that adhering rigidly to all data specified in 40 CFR part 158, as they currently exist and as they may be modified in the future, would effectively remove section 18 as a mechanism to address emergency pest situations. Review and decisions would not be made in a timely or responsive fashion, and the process of data collection, submission and review would be equivalent to that required to establish a permanent tolerance. This would be unduly burdensome to the applicants that request emergency exemptions. They generally do not have resources to develop the data themselves and so would have to rely upon data developed by the producers of pesticide products. In sum, this approach does not consider the emergency nature or short duration of most exemption requests. Therefore, EPA believes that it would be impractical, given the urgent nature of emergency conditions.

EPA also considered a minimum data set approach in which the applicant would be required to provide a specific subset of the data normally required to establish a full tolerance which would be sufficient to support a safety determination given the time-limited nature of section 18 tolerances and the urgent nature of emergency situations. Under this approach, EPA would consider only those defined data requirements in making a safety finding. If EPA chose to implement the new provisions of FFDCA in this fashion, applicants would likely have to provide specific data to EPA to support a section 18 tolerance in addition to data which must already be submitted for emergency exemption requests in general, outlined in 40 CFR 166.20.

EPA believes that both the creation of a new, specific minimum data set to support section 18 time-limited tolerances, and the practical implementation of those requirements, would result in significant disruption to the availability of section 18 as a viable response to emergency situations requiring use of pesticide products. EPA believes that many applicants would have difficulty complying with a minimum data set because these requirements would still represent levels of technical data which most states do not have access to and currently are unable to develop. As EPA's data requirements evolve, a defined minimum data set might also require revision. Because a prescribed data set is not necessary for the Agency to conclude that a tolerance is safe and because it is EPA's belief that the amendments to FFDCA were not intended to eliminate or significantly disrupt the availability of emergency exemptions, EPA is not proposing to establish a minimum data set required for tolerances associated with section 18 requests.

A fourth approach to setting tolerances under section 18 has been suggested to the Agency. This approach was initially presented in a paper developed by a work group of the Pesticide Program Dialogue Committee and subsequently through a petition submitted by the National Food Processor's Association. Under this approach, the Agency would not conduct a full risk assessment under FQPA but would assess the incremental risk of the proposed section 18 use. If the Agency were to find the incremental risk insignificant, it would establish a time limited tolerance and grant the section 18 use without conducting a full aggregate risk assessment for the existing uses of the pesticide chemical. This approach would take into account the limited scope and duration of the emergency use of the pesticide. The NFPA petition assets that limiting the Agency's review of a section 18 tolerance to an incremental risk assessment might decrease the amount of time it takes for the Agency to review the emergency exemption application, thus taking into account the emergency nature and time sensitivity of the use and potentially allowing Agency resources to be used in other areas. In addition, the petitioners believe that the use of an incremental risk assessment may reduce the time needed to establish a tolerance after granting an emergency exemption. Although the Agency is proposing to use a case-by-case approach including aggregate risk assessment based on available data, the Agency is accepting comments on all of these alternative approaches.

### *E. Publication of Tolerances*

Tolerances established to support emergency exemption uses of pesticide products would become effective upon publication of a final rule under proposed § 176.9. Shortly after promulgation of a tolerance, EPA would publish a final rule in the **Federal Register** establishing the tolerance and specifying the duration of the tolerance. Section 408(l)(6) of the FFDCA allows EPA to establish a tolerance without prior public notification or comment period. Additionally, EPA intends to make tolerances established under FFDCA section 408(l)(6) available electronically, so that there can be a record of the most up-to-date tolerances, their expiration dates, and any other information that can be of practical use to growers, states, and other various enforcement agencies.

### *F. Duration of Tolerances*

Section 408(l)(6) of FFDCA provides that tolerances for emergency exemptions shall have an expiration date. Proposed § 176.11 specifies that tolerances would expire and be revoked automatically at such a time as determined by the Administrator. Timing of expiration and revocation of the tolerance would be identified at the time of establishment of the tolerance.

EPA anticipates that, typically, tolerances would not be established for a period longer than 24 months. In its discretion, and at its own initiative or at the request of an applicant, EPA may establish a section 408(l)(6) tolerance for longer periods when conditions merit such an extended time-frame. If an applicant requests a longer time-limited tolerance for a section 18 pesticide use, the applicant must adequately justify the requested duration when making its emergency exemption request, and EPA would have to consider whether the extended tolerance could pose higher risks.

### *G. Lawful Residues After Expiration of Tolerances*

Section 408(l)(5) of FFDCA specifies that, if a tolerance for a pesticide chemical residue in or on a food has been revoked under section 408, food containing the residue is not unsafe if ''the residue is present as the result of an application or use of a pesticide at a time and in a manner that was lawful'' under FIFRA and ''the residue does not exceed a level that was authorized at the time of the application or use to be present on the food under a tolerance * * * then in effect under [FFDCA]. * * *''

Taking sections 408(l) (5) and (6) together, EPA has concluded that the best way to effect an ''expiration date'' for a tolerance established in connection with EPA's granting of a FIFRA section 18 emergency exemption is to specify that the tolerance will expire and be revoked automatically, without further

action by EPA, as of a specified date. That date will generally be 24 months or less from the date of issuance of the emergency exemption. After a tolerance is automatically revoked, food that contains residues of a pesticide chemical will still be legally marketable so long as the residues are the result of lawful use of the pesticide under the terms of the section 18 emergency exemption and are at levels within the tolerance established under section 408(l)(6).

Occasionally, use of the pesticide might occur before EPA actually establishes the necessary time-limited tolerance, such as in the case of a crisis exemption. When a time-limited tolerance is established after the time that use of the pesticide product is authorized, the residues on the subject commodity are only legal during the period of time prior to the expiration and revocation of the tolerance. In other words, there would be no ''pipeline'' provision for treated commodities if use occurred before a tolerance was set. In case of such a gap, EPA will consider setting a longer duration for the time-limited tolerance to ensure that the commodity will leave channels of trade before the tolerance expires.

EPA believes that handling the section 18-related tolerances in this manner will allow EPA to respond promptly to emergency conditions and will ensure that food containing pesticide residues as a result of use under an emergency exemption will not be considered adulterated.

*H. Limitations of 408(l)(6) Tolerances*

Time-limited tolerances established under the authority of FFDCA section 408(l)(6) apply to pesticide chemical residues resulting from pesticide applications authorized by EPA under provisions of FIFRA section 18. In addition, time-limited tolerances established under this section will cover commodities imported into the United States during the duration of the tolerance.

The previous establishment of a 408(l)(6 ) tolerance does not alter the requirement for applicants to submit formal emergency exemption requests to EPA for review. Issuing a tolerance does not grant authority to use a pesticide, but rather provides a legal limit on residues of the pesticide on food shipped in interstate commerce. Even if a time-limited tolerance for a pesticide has been established in response to one applicant's (a state, U.S. territory, or Federal agency) emergency exemption, other applicants must obtain an emergency exemption for the use of that pesticide if they experience a pest emergency which requires the use of that pesticide.

## VIII. Additional Section 18 Concerns Not Addressed in This Proposed Rule

On November 21 and 22, 1996, EPA hosted a public workshop to discuss a range of issues related to emergency exemptions from FIFRA. The purpose of the meeting was to informally establish a dialogue amongst and solicit the opinions of a variety of individuals and groups affected by section 18 decisions. During this meeting, EPA encouraged discussion of various changes that may be made to regulations governing section 18. Although the meeting had been planned prior to the passage of FQPA because the new law had recently been enacted, some portions of the meeting were devoted to discussions of how implementation of FQPA could or would affect the section 18 process. Based on the November 21–22 meeting, there may be additional concerns regarding the section 18 program aside from the tolerance setting procedures set forth in this proposed rule that are of great interest to many section 18 stakeholders. EPA may, at a later date, prepare a formal proposal to make changes to the section 18 regulations.

Although this proposed rule only addresses procedures for setting tolerances in connection with section 18 exemptions, the following recommendations were presented to EPA by the National Association of State Departments of Agriculture (NASDA) and the Association of American Pesticide Control Officials (AAPCO) in a letter dated February 28, 1997, addressed to Assistant Administrator for Prevention, Pesticides and Toxic Substances, Dr. Lynn R. Goldman, M.D. NASDA and AAPCO prepared this letter to capture the recommendations of their membership following EPA's November 1996 Section 18 Stakeholder Meeting. Specifically, NASDA and AAPCO recommend that EPA implement the following changes to the section 18 emergency exemption process:

1. Seek changes to current regulations which will allow EPA the flexibility to base decisions on crop yield as opposed to crop value (or profit loss) in situations where that is a better indicator of pest damage.
2. Provide states general guidance regarding the appropriate documentation of an ''urgent, non-routine situation'' and allow states to certify that the ''urgent, non-routine situation'' exists based on the guidance.
3. Implement a performance audit program to ensure compliance with the guidance and give states justification to resist pressure to certify an ''urgent, non-routine situation'' when it does not exist.
4. Delegate to the states authority to reissue the section 18 exemption for a second or third year, based on the state's confirmation/certification that the basis for an emergency continues to exist.
5. Actively support and coordinate regional section 18 requests.
6. Enter into discussions with the states to establish reasonable monitoring criteria and approaches for wildlife and endangered species.
7. Support specific exemptions for resistance management where there is documented scientific evidence of resistance to currently registered pesticide or where valid research demonstrates that a dynamic process of resistance is developing.
8. Amend 40 CFR 166.2 to include ''reduced risk'' as an acceptable basis for granting a section 18 exemption. The definition of ''reduced risk,'' and the requirements for this request should allow states the ability to request a section 18 to allow for a pesticide use that will result in a lower potential for an adverse impact on human health or any other non-target species, including but not limited to, pest predators, pollinators, endangered species, and other organisms of special concern. Requests should be limited to only those situations where the ''reduced risk'' request will not result in additional risk to any aspect of the environment. Such requests should only be permitted where the proposed use is highly effective so that the potential for an increase in pesticide applications is extremely low.

As stated above, by including the recommendations of NASDA and AAPCO in this document, the Agency is not proposing to alter existing regulations which govern implementation of FIFRA section 18, nor is the Agency prepared to take a position on the propriety of any of the recommendations. EPA will accept comments on the eight recommendations presented by NASDA and AAPCO, should individuals or organizations wish to comment at this time. Comments on these recommendations must be identified by the docket control number, OPP–181052, rather than the docket number for this proposed rule.

EPA does not expect to address any comments resulting from these eight issues in promulgating final rules establishing procedures for setting tolerances under FFDCA section 408(l)(6), nor does the Agency intend to allow these issues to delay implementation of the tolerance setting

regulations. EPA does intend to develop a proposed rule which would make various changes to the regulations governing section 18 exemptions at a later date. At that time, the Agency will describe in much greater detail these recommendations and any other changes it has considered, and comments will be officially solicited and addressed as part of that process.

The Agency is also seeking ideas on how to reduce the time from when the emergency exemption is granted to when the tolerance is established per the request of the NFPA petition.

## IX. Regulatory Requirements

### *A. Executive Order 12866*

Pursuant to Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993), it has been determined that this proposed action is not a ''significant regulatory action'' and is therefore not subject to review by the Office of Management and Budget (OMB). Applicants for section 18 emergency exemptions are the only parties, other than EPA, directly affected by this proposed action. According to the economic assessment conducted by the Agency, the direct costs of this action are insignificant to the applicants (Federal and state agencies) of section 18 emergency exemptions because additional data are not readily accessible under case-by-case approach of determining a reasonable certainty of no harm. A copy of the economic assessment is available in the public docket for this proposed rule.

### *B. Regulatory Flexibility Act*

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Agency has determined that this regulatory action does not impose any direct adverse economic impact on small entities. Applicants for section 18 emergency exemptions are U.S. states, territories, or Federal agencies which, by definition, are not small entities. Applicants for section 18 emergency exemptions are the only parties, other than EPA, directly affected by this proposed action. Therefore, pursuant to section 605(b), the agency hereby certifies that this action will not have a significant adverse impact on a substantial number of small entities. Information regarding this determination will be provided to the Chief Counsel for Advocacy of the Small Business Administration (SBA) upon request. Any comments regarding the impacts that this action may impose on small entities should be submitted to the Agency at the address listed above.

### *C. Paperwork Reduction Act*

This proposed regulatory action does not contain any new information collection requirements that would require additional approval by OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* The information collection requirements that are related to this proposed rule have already been approved by OMB under control No. 2070–0032 (EPA ICR No. 596) and control No. 2070–0024 (EPA ICR No. 597). Specifically, EPA regulations at 40 CFR part 166 allow a state, U.S. territory, or Federal agency to apply for an emergency exemption pursuant to section 18 of FIFRA, which would allow for a pesticide to be used for a use for which that pesticide is not registered when such use is necessary to alleviate an emergency condition. The regulations set forth information requirements, procedures, and standards for EPA's approval or denial of such exemptions. OMB has approved the information collection requirements contained in part 166 under OMB control No. 2070–0032 (EPA ICR No. 596). In addition, EPA regulations in 40 CFR part 180 described the process and informational needs for requesting that the Agency establish or provide an exemption for the establishment of a tolerance or maximum residue level for the use of a pesticide on food crops. OMB has approved the information collection requirements contained in part 180 under OMB control No. 2070–0024 (EPA ICR NO. 597).

The public reporting and recordkeeping burden for the collection of information related to a section 18 exemption is estimated to average 103 hours per response annually. This estimation is based on the number of requests for section 18 exemptions that the Agency received in fiscal year 1996 (October 1, 1995–September 30, 1996), and the estimated burden associated with submitting information related to a request for the establishment of a tolerance or an exemption for a tolerance. In FY 1996, EPA received requests for 478 emergency exemptions pursuant to section 18. According to EPA ICR No. 597, the Agency has estimated the annual burden to be 1,442 hours for providing information in support of a full tolerance request under section 3 of FIFRA.

In general, ''burden'' means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. The includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires approval under the PRA, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

Comments are requested on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques. Send comments on the ICR to EPA as part of your overall comments on this proposed action at the address provided above, or to the Director, OPPE Regulatory Information Division, Environmental Protection Agency (Mail Code 2137), 401 M St., SW., Washington, DC 20460, with a copy of any ICR comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St., NW., Washington, DC 20503, marked ''Attention: Desk Officer for EPA.'' Please remember to include the ICR number in any correspondence. In developing the final rule, the Agency will address any comments received regarding the information collection requirements contained in this proposal.

### *D. Environmental Justice Considerations*

Pursuant to Executive Order 12898 (59 FR 7629, February 16, 1994), entitled Federal Actions to Address—Environmental Justice in Minority Population and Low-Income Populations, the Agency has considered environmental justice related issues with regard to the potential impacts of this action on the environmental and health conditions in low-income and minority communities. The Agency has found that this proposed rule does not directly affect minority populations or low-income groups, but will be more protective of certain subpopulations such as infants and children.

### *E. Unfunded Mandates Reform Act*

Under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4), EPA has determined that this action does not contain a

Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. The costs associated with this action are described in the Executive Order 12866 section above. Therefore, this action is not subject to the requirements of sections 202 and 205 of the UMRA.

*F. Enhancing Intergovernmental Partnerships*

Under Executive Order 12875, entitled Enhancing Intergovernmental Parnterships (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. Today's proposal would implement requirements specifically set forth by the Congress in FFDCA section 408(l)(6) without the exercise of any discretion by EPA. EPA consulted with various state officials during the development of this proposal, including representatives from the States of North Carolina and Washington, who acted as representatives of SFIREG.

*G. Consultation and Coordination With Indian Tribal Governments*

Under Executive Order 13084, entitled Consulatation and Coordination with Indian Tribal Governments (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. Today's proposal would implement requirements specifically set forth by the Congress in FFDCA section 408(l)(6) without the exercise of any discretion by EPA. The proposal does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this proposal.

*H. Children's Health Protection*

This proposed rule is not subject to Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), because that is not an economically significant regulatory action as defined by Executive Order 12866 (see Unit IX.A.). In addition, this proposed rule is procedural in nature and does not involve decisions on environmental health risks or safety risks that may disproportionately affect children.

*I. National Technology Transfer and Advancement Act*

This proposed regulatory action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Section 12(d) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by voluntary consensus standards bodies. The NTTAA requires EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. EPA invites public comment on this conclusion.

**List of Subjects in 40 CFR Part 176**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 24, 1999.

**Carol M. Browner,**

*Administrator.*

Therefore, it is proposed that 40 CFR chapter I be amended by adding new part 176 to read as follows:

## PART 176—TIME-LIMITED TOLERANCES FOR EMERGENCY EXEMPTIONS

Sec.



**Authority.** 21 U.S.C. 346a and 371.

### § 176.1 Scope and applicability.

This part describes the procedures and criteria under which EPA will establish time-limited tolerances and exemptions from the requirement of a tolerance for pesticide chemical residues associated with emergency or crisis exemptions under FIFRA section 18. This part applies only to tolerances issued on the initiative of EPA as the result of the issuance of an emergency exemption or the declaration of a crisis exemption. This part does not cover time-limited tolerances in any other circumstances.

### § 176.3 Definitions.

Terms have the same meaning as in the Federal Insecticide, Fungicide, and Rodenticide Act section 2, and in the Federal Food, Drug, and Cosmetic Act section 201 and § 166.3 of this chapter. In addition, the following terms are defined for the purposes of this part.

*Agency* means the U.S. Environmental Protection Agency.

*Applicant* means a State, U.S. Territory, or Federal Agency that requests an emergency exemption under §§ 166.20 through 166.35 of this chapter or declares a crisis exemption under §§ 166.40 through 166.53 of this chapter.

*Crisis exemption* means an exemption authorized under FIFRA section 18, in accordance with §§ 166.40 through 166.53 of this chapter.

*Emergency exemption* means a specific, quarantine or public health exemption authorized under FIFRA section 18 and the regulations at §§ 166.20 through 166.35 of this chapter.

*EPA* means the U.S. Environmental Protection Agency.

*FFDCA* means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*)

*FIFRA* means the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*)

*Tolerance* means the maximum amount of a pesticide chemical residue that may lawfully be present in or on a raw agricultural commodity, or processed food, or animal feed, expressed as parts per million by weight of the pesticide chemical residue in the food or feed.

*Tolerance exemption* means a formal determination by the Agency pursuant to FFDCA section 408(c), 21 U.S.C. 346a(c), that no tolerance is needed for a given pesticide chemical residue in or on a particular food commodity. For purposes of this subpart, the term ''tolerance'' shall include an exemption from the requirement of a tolerance.

### § 176.5 Establishment of a time-limited tolerance or exemption.

EPA will establish a time-limited tolerance for pesticide chemical residues in or on raw or processed food

or feed resulting from the use of a pesticide chemical when EPA authorizes an emergency exemption or a crisis exemption. EPA will consider establishing such a tolerance only if an applicant under FIFRA section 18 either has requested an emergency exemption, or has stated its intention to declare a crisis exemption under FIFRA section 18 for a use that may result, directly or indirectly, in pesticide chemical residues in food or feed.

**§ 176.7 Information needed to establish a tolerance.**

(a) EPA will establish a time-limited tolerance only if EPA can determine that the tolerance is safe, that is, there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue. EPA will base its determination upon data submitted by the applicant and other readily available data. If, taking into account the limited duration and emergency nature of a section 18 application, the available data are not adequate to support a reasonable certainty of no harm determination, EPA will not establish a tolerance.

(b) Data and other relevant information to support the establishment of a time-limited tolerance may be submitted by the applicant, or by any other person, in support of the time-limited tolerance. The applicant may also cite relevant data previously submitted to the Agency.

**§ 176.9 Publication of a tolerance.**

(a) If EPA concludes that the tolerance will be safe, it may issue a regulation establishing the tolerance and publish a notice to that effect in the **Federal Register**.

(b) A tolerance under this part may be established without prior public notification of a proposed tolerance or comment period.

**§ 176.11 Duration of a tolerance.**

(a) Tolerances under this part become effective upon publication in the **Federal Register**, unless otherwise specified by the Administrator.

(b) Tolerances will automatically expire and be revoked, without further action by EPA, at the time set out in the **Federal Register** notice estabishing the tolerance.

(c) The Administrator may revoke a tolerance at any time if the Administrator determines that the tolerance is no longer safe.

**§ 176.13 Modification of a time-limited tolerance.**

If additional emergency or crisis exemptions are authorized that would extend use beyond the date of expiration or revocation of a time-limited tolerance, EPA may modify the time-limited tolerance by extending its duration. EPA will use the same criteria and procedures for modification as for establishing tolerances under this part.

**§ 176.15 Effect of a tolerance.**

The establishment of a tolerance under this part does not alter the requirement that any State, U.S. Territory, or Federal Agency comply with procedures established in part 166 of this chapter for emergency exemptions of FIFRA.

[FR Doc. 99–14070 Filed 6–2–99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 42 CFR Parts 5 and 51c

**RIN 0906–AA44**

### Designation of Medically Underserved Populations and Health Professional Shortage Areas

**AGENCY:** Health Resources and Services Administration, DHHS.

**ACTION:** Proposed rules; status.

**SUMMARY:** The Health Resources and Services Administration (HRSA) is announcing its intention to issue a second Notice of Proposed Rulemaking (NPRM) on Designation of Medically Underserved Populations (MUPs) and Health Professional Shortage Areas (HPSAs) following a period of evaluation of comments received, analysis of alternative approaches, and impact testing. This will involve a new 60-day public comment period for the revised proposal.

**FOR FURTHER INFORMATION CONTACT:** Richard Lee, 301–594–4280.

**SUPPLEMENTARY INFORMATION:** Proposed rules for designation of MUPs and HPSAs were published on September 1, 1998 (63 FR 46538). The original comment period was extended for an additional 60 days (until January 4, 1999) (63 FR 58679, November 2, 1998), and over 800 comments on the proposed rules were received. Given the large volume of thoughtful comments and the high level of concern that has been voiced about the potential impact of the proposal as published, HRSA believes it is imperative to conduct further analyses before proceeding. This will include a thorough, updated analysis of the impact of the proposal as published, applied to current data for all counties and currently designated MUPs and HPSAs, followed by testing of a number of possible revisions to the proposal, based on HRSA's analysis of the comments received. HRSA also plans to have one or more independent outside organizations verify its impact testing. A new NPRM will then be published for public comment, with a goal of publishing the revised proposal by the end of 1999. The decision to publish another NPRM with its associated public comment period means that new final regulations likely will not be implemented prior to the fall of 2000.

(Authority: 42 U.S.C. 254c and 42 U.S.C. 254e).

Dated: March 12, 1999.

**Claude Earl Fox,**

*Administrator, Health Resources and Services Administration.*

Approved: May 25, 1999.

**Donna E. Shalala,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 99–13951 Filed 6–2–99; 8:45 am]

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## DEPARTMENT OF TRANSPORTATION

### Office of the Secretary

### 49 CFR Part 40

**[OST Docket No. OST–99–5742; Notice 99–4]**

**RIN 2105–AC78**

### Drug and Alcohol Testing Procedures

**AGENCY:** Office of the Secretary, DOT.

**ACTION:** Advance notice of proposed rulemaking (ANPRM).

**SUMMARY:** This advance notice solicits public comments on a proposed procedure that organizations certifying substance abuse professionals (SAPs) could use to have members included in the Department of Transportation's substance abuse professional (SAP) definition. The Department proposes to require such organizations to obtain a National Commission for Certifying Agencies (NCCA) accreditation as a prerequisite for having the DOT review their petitions for inclusion of their members as SAPs in the Department's drug and alcohol testing program.

**DATES:** Comments should be submitted on or before August 2, 1999. Late-filed comments will be considered to the extent practicable.

**ADDRESSES:** Written comments should be sent to Docket Clerk, Att: Docket No. OST–99–5742, Department of Transportation, 400 7th Street, SW., Room PL401, Washington DC 20590.