FIFRA after December 31, 1999, except for the purposes of producing (e.g., repackaging or relabeling) new manufacturing-use and end-use products that conform with the terms of the Agreement. Persons applying such existing stocks as part of a service of applying methyl parathion products prior to December 31, 1999, shall not be considered to be engaged in the distribution or sale of pesticides, unless such persons also deliver unapplied methyl parathion pesticides. Any use of existing stocks of canceled product prior to January 1, 2000, must be in accordance with either the directions for use contained in the Agreement or the existing labeling of that product.

B. Notification of Possession of Canceled Products

No later than November 1, 1999, and pursuant to section 6(g) of FIFRA, any producer or exporter, registrant, applicant for a registration, applicant or holder of an experimental use permit, commercial applicator, or any person who distributes or sells any pesticide, who after the publication of this Notice possesses any stocks of the pesticide products identified on Table 2 of this notice, shall notify EPA and appropriate State and local officials of: (1) Such possession; (2) the quantity of canceled methyl parathion pesticide product possessed; and (3) the place at which the canceled methyl parathion pesticide product is stored.

List of Subjects

Environmental protection.

Dated: October 12, 1999.

Lois Rossi,

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

[FR Doc. 99–27800 Filed 10–26–99; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPP–00569B; FRL–6388–2]

Pesticides; Policy Issues Related to the Food Quality Protection Act

AGENCY: Environmental Protection Agency (EPA).
ACTION: Notice of availability.

SUMMARY: EPA is announcing the availability of the revised version of the pesticide science policy document entitled ''Threshold of Regulation (TOR) Policy—Deciding Whether a Pesticide With a Food Use Pattern Requires a Tolerance.'' This notice is the twelfth in a series concerning science policy documents related to Food Quality Protection Act and developed through the Tolerance Reassessment Advisory Committee.

FOR FURTHER INFORMATION CONTACT: Vivian Prunier, Environmental Protection Agency (7506C), 401 M St., SW., Washington, DC 20460; telephone number: (703) 308-9341; fax: (703) 305-5884; e-mail address: prunier.vivian@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture or formulate pesticides. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of potentially affected entities
Pesticide producers	32532	Pesticide manufacturers Pesticide formulators

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 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 affects certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under ''FOR FURTHER INFORMATION CONTACT.''

B. How Can I Get Additional Information, Including Copies of this Document or Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, the science policy documents, and certain other related documents that might be available electronically, from the Office of Pesticide Programs' Home Page at http://www.epa.gov/pesticides/. On the Office of Pesticide Programs' Home Page select ''FQPA'' and then look up the entry for this document under ''Science Policies.'' You can also go directly to the listings at the EPA Home Page at http://www.epa.gov/. On the Home Page select ''Laws and Regulations'' and then look up the entry to this document under ''**Federal Register**--Environmental Documents.'' You can go directly to the **Federal Register** listings http://www.epa.gov/fedrgstr/.

2. *Fax on demand*. You may request a faxed copy of the revised science policy paper, as well as supporting information, by using a faxphone to call (202) 401–0527. Select item 6042 for the paper entitled ''Threshold of Regulation (TOR) Policy—Deciding Whether a Pesticide With a Food Use Pattern Requires a Tolerance.'' You may also follow the automated menu.

3. *In person*. The Agency has established an official record for this action under docket control number OPP-00569B. In addition, the documents referenced in the framework notice, which published in the **Federal Register** on October 29, 1998 (63 FR 58038) (FRL–6041–5) have also been inserted in the docket under docket control number OPP–00557. 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.

II. Background for the Tolerance Reassessment Advisory Committee (TRAC)

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. Effective upon signature, the FQPA significantly amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Among other changes, FQPA established a stringent health-based standard (''a reasonable certainty of no harm'') for pesticide residues in foods to assure protection from unacceptable pesticide exposure; provided heightened health protections

for infants and children from pesticide risks; required expedited review of new, safer pesticides; created incentives for the development and maintenance of effective crop protection tools for farmers; required reassessment of existing tolerances over a 10-year period; and required periodic re-evaluation of pesticide registrations and tolerances to ensure that scientific data supporting pesticide registrations will remain up-to-date in the future.

Subsequently, the Agency established the Food Safety Advisory Committee (FSAC) as a subcommittee of the National Advisory Council for Environmental Policy and Technology (NACEPT) to assist in soliciting input from stakeholders and to provide input to EPA on some of the broad policy choices facing the Agency and on strategic direction for the Office of Pesticide Programs. The Agency has used the interim approaches developed through discussions with FSAC to make regulatory decisions that met FQPA's standard, but that could be revisited if additional information became available or as the science evolved. As EPA's approach to implementing the scientific provisions of FQPA has evolved, the Agency has sought independent review and public participation, often through presentation of many of the science policy issues to the FIFRA Scientific Advisory Panel (SAP), a group of independent, outside experts who provide peer review and scientific advice to OPP.

In addition, as directed by Vice President Albert Gore, EPA has been working with the U.S. Department of Agriculture (USDA) and another subcommittee of NACEPT, the TRAC, chaired by the EPA Deputy Administrator and the USDA Deputy Secretary, to address FQPA issues and implementation. TRAC comprises more than 50 representatives of affected user, producer, consumer, public health, environmental, states and other interested groups. The TRAC has met six times as a full committee from May 27 through April 29, 1999.

The Agency has been working with the TRAC to ensure that its science policies, risk assessments of individual pesticides, and process for decision making are transparent and open to public participation. An important product of these consultations with TRAC is the development of a framework for addressing key science policy issues. The Agency decided that the FQPA implementation process and related policies would benefit from initiating notice and comment on the major science policy issues.

The TRAC identified nine science policy issue areas it believes were key to implementation of FQPA and tolerance reassessment. The framework calls for EPA to provide one or more documents for comment on each of the nine issues by announcing their availability in the **Federal Register**. In accordance with the framework described in a separate notice published in the **Federal Register** of October 29, 1998 (63 FR 58038) (FRL–6041–5), EPA is announcing through the **Federal Register** the availability of a series of draft documents concerning nine science policy issues identified by the TRAC related to the implementation of FQPA. After receiving and reviewing comments from the public and others, EPA is also issuing revised science policy documents which reflect changes made in response to comments. In addition to comments received in response to these **Federal Register** notices, EPA will consider comments received during the TRAC meetings. Each of these issues is evolving and in a different stage of refinement. Accordingly, as the issues are further refined by EPA in consultation with USDA and others, they may also be presented to the SAP.

III. Summary of Revised Science Policy Guidance Document

This **Federal Register** notice announces the availability of a revised version of the EPA pesticide science policy guidance document that has been retitled ''Threshold of Regulation (TOR) Policy—Deciding Whether a Pesticide With a Food Use Pattern Requires a Tolerance.'' The guidance document describes the approach that EPA will use for determining when a food use pattern does not produce residues in or on food that require establishment of a tolerance or tolerance exemption. Specifically, the guidance document describes:

A. EPA's authority for determining whether a tolerance or tolerance exemption is, or is not, required.

B. The criteria that EPA will use for determining whether a tolerance is required for a pesticide use in, on, or near food that produces no detected residues in the food.

C. The data, including toxicology and residue chemistry studies, that EPA will rely upon when deciding whether a tolerance is required.

D. Procedures that EPA will follow for evaluating new or existing pesticide uses that meet the criteria of the TOR policy.

E. Procedures that EPA will follow to establish a regulation in title 40 of the Code of Federal Regulations (CFR) for each use that meets the criteria of the TOR policy.

The Agency plans to use this guidance during tolerance reassessment to determine whether a tolerance is needed for existing uses. The Agency expects to use this guidance to evaluate proposed pesticide uses that could replace pesticide uses that are being discontinued. EPA believes that this policy will promote a reasonable transition for agriculture.

IV. Issues Raised in Comments

EPA published a draft version of the document described in Unit III. in the **Federal Register** on December 4, 1998 (63 FR 67063) (FRL–6048–2) and comments were filed under docket control number OPP–00569. The original public comment period ended on February 4, 1999, but was extended to February 18, 1999, in a **Federal Register** document published on February 5, 1999 (64 FR 5795) (FRL–6061–5). The Agency received comments from 22 different organizations. All comments were considered by the Agency in revising the document. The comments and the Agency's responses to these comments are briefly summarized in this Unit.

Many of the comments were similar in content, and pertained to general issues concerning the proposed policy or specific sections within the draft document. To facilitate review and consideration of the comments for purposes of revising the document, the Agency grouped the comments in accordance to nature of the comment, or issue or section of the document with which they addressed. Hence, comments were grouped as follows:

A. The purpose and effects of the policy.

B. Residue chemistry data requirements.

C. Toxicity data requirements.

D. Risk criteria for TOR decisions.

E. Registration criteria for pesticide uses that meet the criteria of the TOR policy.

F. Procedural issues, including publication of decisions made under the policy, enforcement, and assessment of fees.

The full text of the Agency's comments and response to the comments document is available as described in Unit I.B.1.

The comments raised several significant issues including:

1. What is EPA's authority for deciding that a tolerance is not required for a pesticide use in, on, or near food?

EPA has interpreted section 402 of the Federal Food, Drug and Cosmetic Act (FFDCA) as meaning that any use of a

pesticide in, on, or near growing crops, livestock, or food will result in residues in the food that are subject to section 408 of the Act unless the EPA decides otherwise. The TOR policy would establish criteria to decide whether additional food use patterns, in addition to those identified in 40 CFR 180.6, do not produce residues in food for which a tolerance or tolerance exemption is required. EPA finds that sections 408(e) and 701(a) of the FFDCA give EPA authority to issue regulations necessary to interpret the Act.

2. How will EPA implement, publish, and compile TOR decisions? How will FDA enforce TOR decisions?

Commenters asked EPA to publish notices of TOR policy decisions that specify the conditions of use and analytical method used to support each TOR decision and to maintain a list of TOR decisions in the CFR.

EPA has decided to issue each TOR decision as a regulation. The TOR regulation will identify the pesticide, conditions of use of the pesticide, and the analytic method that the Agency relied on in determining that the use of the pesticide would not produce detectable residues. This information will guide growers or other pesticide users who wish to employ a pesticide for a TOR use and should enable them to avoid misusing the pesticide.

This policy does not alter FDA's enforcement in any way. FDA monitors food for pesticide residues. FDA will continue to monitor food in interstate commerce for pesticide residues. To detect and quantify pesticide residues in a food, FDA may use either the analytical method that EPA relied upon in making the TOR decision or another method. Because the TOR policy is based on the premise that no residues will be found in a food following the use of a pesticide, FDA will continue to regard any residue finding for which there is no tolerance or tolerance exemption as a violation of the FFDCA and would deem the food as adulterated under section 402(a)(2)(B) of the FFDCA.

3. What would happen to a TOR use if a more sensitive analytical method is developed?

Food processors were concerned that FDA would eventually develop more sensitive enforcement methods and would be able to detect residues from TOR uses.

EPA agrees that advances in the science of analytical chemistry may eventually produce methods that are capable of detecting pesticide residues from TOR uses. If FDA adopts a new enforcement method that is more sensitive than the method described in the TOR regulation and subsequently detects residues in a food, it could deem the food to be adulterated under section 402 of the FFDCA. However, FDA generally provides the public ample notice when it is considering adopting a new analytical method for enforcement purposes. A person who is relying on a TOR approval to support a pesticide use would have opportunity to evaluate the new analytical method before FDA adopts it.

4. Several commenters asserted that EPA should expand the TOR Policy criteria to include detected residues that pose risks that are so inconsequential that they are ''*de minimis*'' and should not be regulated.

Under this principle, an agency may decide that some violations of the law are so trivial that they are not worth regulating. The commenters argued that, if EPA applies this principle, it would be able to find that a residue does not need to be regulated under FFDCA section 408 if a given level of a particular pesticide based on the hazard characteristics of the pesticide poses a ''*de minimis*'' risk. Detected residues of a pesticide could also be eligible for consideration under a ''*de minimis*'' policy.

EPA's approach does not attempt to write an exception to the statutory language as does the *de minimis* principle; rather, EPA has relied upon the less controversial legal approach of fashioning a reasonable interpretation of existing statutory language -- here, ''any pesticide chemical residue in or on a food.'' EPA's policy describes criteria that will be taken into account in determining when a pesticide can be deemed to be ''in or on food'' when the pesticide is NOT detectable on the food. EPA's approach of focusing on the risk posed by potential residues is a reasonable interpretation of when zero detected residues means the pesticide is not in or on food.

EPA chose not to rely on the *de minimis* doctrine as its primary justification for several reasons. First, despite the fact that the *de minimis* principle is well-established, there is always some legal risk when an agency asks a court to disregard the plain language of the statute. In the event that a court concludes that potential risk is not an appropriate consideration in determining when undetected residues qualify as residues ''in or on food,'' the *de minimis* principle provides a secondary justification for EPA's approach. Second, reliance on a *de minimis* theory as a primary justification is only necessary if EPA's policy extends to pesticide residues that are detectable. However, EPA is uncertain whether an expansion of TOR to detected residues posing insignificant risks is necessary to meet the concerns that motivated EPA to formulate the TOR policy. If, at some later date, EPA decides to explore an expansion of TOR, EPA would at that time evaluate the application of the *de minimis* doctrine as the primary justification for the TOR policy. Finally, EPA does not need to rely on the *de minimis* principle in order to apply the policy. As outlined in the policy, EPA has already been making this type of determination as to a considerable range of pesticide uses.

5. The criteria in the ''essentially zero'' exposure approach proposed in the draft TOR policy blurred the distinction between a food use pattern that is subject to FFDCA and a non-food use that is not subject to FFDCA.

It appears that the proposed ''essentially zero'' exposure approach for a TOR determination could be interpreted as applying both to food uses e.g., uses that result in a reasonable expectation of no finite residues in milk, meat, poultry or eggs and to uses that are likely to be classified as ''non-food'' uses.

EPA modified the policy to make clear that it applies to the uses of pesticide in, on, or near growing crops, livestock, or food and not to uses that have been classified as ''non-food'' uses.

EPA found that the proposed ''essentially zero'' exposure approach for a TOR determination could be interpreted as applying to certain food uses e.g., uses that result in no finite residues in milk, meat, poultry, or eggs. EPA already has procedures for handling ''essentially zero'' residues in some foods in 40 CFR 180.6(a)(3) and 180.6(c)(3). Because a mechanism already exists for managing certain pesticide uses that result in ''essentially zero'' residues in food, EPA believes that the ''essentially zero'' exposure approach proposed in the TOR policy is redundant and potentially confusing. To eliminate this confusion, EPA will not use the ''essentially zero'' exposure approach in its TOR policy.

6. Should EPA make TOR decisions in the absence of data to characterize a pesticide's hazard?

A government Agency advised EPA to continue to require toxicity information for all food use patterns, including uses that meet the criteria of the TOR policy.

When EPA originally proposed ''essentially zero'' exposure criteria for TOR decisions, it reasoned that if exposure is ''essentially zero,'' risk would also be ''essentially zero.'' EPA has reconsidered this position, however, because it cannot conclude with certainty that very low exposures are

without risk if there is no relevant information about the biological activity of the pesticide. Accordingly, EPA expects to evaluate the array of toxicity data that are normally used in a dietary risk assessment in order to identify health hazards and quantify a dose response. The Agency will normally perform a quantitative risk assessment before concluding that a specific use poses ''essentially zero'' risk from dietary exposures. Therefore, proponents of a TOR use should provide a full set of toxicity data, as specified in 40 CFR 158.340.

7. What criteria will be used to define ''essentially zero'' risk for infants and children?

EPA should explain what ''acceptable risk'' means with respect to risks to infants and children or other subpopulations when the Agency states that food risks from a TOR use must be less than 0.1% of acceptable risks.

EPA will separately evaluate the incremental dietary risk (i.e., risks from food) posed by a proposed TOR use to each population subgroup, particularly infants and children. If EPA has already determined the appropriate FQPA safety factor for a particular pesticide, EPA will use this safety factor in its evaluation of the proposed TOR use. If EPA has not established an FQPA safety factor, EPA will, as a matter of policy, decide whether the FQPA safety factor is appropriate, and if so, the Agency will use it when evaluating the potential risk posed by the proposed TOR use to infants and children.

8. The risk criteria in the TOR policy represent ''risk management policy,'' not ''science policy.'' Furthermore, the definition of ''essentially zero'' risk is so restrictive that few pesticide uses will qualify.

Several commenters asked that EPA ease the risk criterion, recommending either a specific value such as 1% of acceptable risk for the pesticide or more subjective criterion such as ''an insignificant proportion of allowable risk'' be used as the risk threshold in the TOR policy.

EPA agrees that the selection of the risk criterion for the TOR policy is a risk management rather than a science policy decision. EPA intends that the exposures from TOR uses be so small that risk resulting from such exposures would be of no concern. Because selection of the risk criterion for TOR decisions is a risk management decision; the risk level itself should connote the triviality of the risk.

EPA conducted its own analysis to ascertain whether the selected risk criteria were so strict that no uses would qualify. The results suggest that many pesticides will qualify for a TOR for use on a food item that is a minor component of the diets of the general U.S. population or children aged 1 to 6 years.

9. Some interpreted the policy to mean that if there are no detected residues above 10 ppb, no tolerances are needed.

EPA finds that this interpretation is not accurate. Tolerances (or exemptions from tolerance) continue to be required for any use of a pesticide in, on, or near food unless EPA determines that the use meets TOR criteria.

10. EPA should adopt alternative criteria for deciding not to establish tolerances for potential residues resulting from the use of pesticides to treat seeds.

Registrants of seed treatment asserted that exposures from seed treatment uses would be even lower than exposures from other uses that may be eligible for TOR decisions. Accordingly, EPA should adjust data requirements and other criteria for making TOR decisions on seed treatment uses.

The Agency will apply the criteria in the revised TOR Policy to seed treatment uses. As discussed above, a proponent of a TOR use would normally be expected to submit the full toxicity data set for a food use. EPA will, however, consider waiving toxicity data requirements on a case-by-case basis.

11. EPA should not require tolerance fees for TOR requests because fees can be charged only for actions done under FFDCA 408.

TOR eligibility determinations involve application of FFDCA section 408. The decision whether FFDCA section 408 applies to a particular case is itself a section 408 action. Accordingly, EPA could require payment of a ''tolerance fee'' to cover the costs of evaluating a TOR eligibility request.

V. Policies Not Rules

The policy document discussed in this notice is intended to provide guidance to EPA personnel and decision-makers, and to the public. As a guidance document and not a rule, the policy in this guidance is not binding on either EPA or any outside parties. Although this guidance provides a starting point for EPA risk assessments, EPA will depart from its policy where the facts or circumstances warrant. In such cases, EPA will explain why a different course was taken. Similarly, outside parties remain free to assert that a policy is not appropriate for a specific pesticide or that the circumstances surrounding a specific risk assessment demonstrate that a policy should be abandoned.

List of Subjects

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

Dated: October 17, 1999.

Susan H. Wayland,

Deputy Assistant Administrator for Prevention, Pesticides and Toxic Substances.

[FR Doc. 99–28047 Filed 10–26–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[NCEA–CD–99–1072; FRL–6464–1]

Air Quality Criteria for Particulate Matter (External Review Draft)

AGENCY: Environmental Protection Agency.

ACTION: Notice of a Draft for Public Review and Comment.

SUMMARY: The Environmental Protection Agency (EPA), National Center for Environmental Assessment (NCEA), is today announcing the availability of an external review draft of the document, Air Quality Criteria for Particulate Matter. Required under sections 108 and 109 of the Clean Air Act, the purpose of this document is to provide an assessment of the latest scientific information on the effects of airborne particulate matter (PM) on the public health and welfare for use in the next periodic review of the National Ambient Air Quality Standards (NAAQS) for PM.

DATES: Anyone who wishes to comment on the draft document, Air Quality Criteria for Particulate Matter, must submit the comments in writing by no later than January 14, 2000.

ADDRESSES: Send the written comments to the Project Manager for Particulate Matter, National Center for Environmental Assessment-RTP Office (MD–52), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711.

A copy of the Air Quality Criteria for Particulate Matter (External Review Draft) is available on CD ROM from the OAO Corporation, which is under contract to the EPA. Contact Ms. Cindy Jenkins, OAO Corporation representative, at 919–541–4826, 919–541–1818 (fax), or jenkins.cindy@epa.gov to request the document. OAO will need the document's title, Air Quality Criteria for Particulate Matter (External Review Draft), as well as your name and address