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THE AGENCY'S RESPONSES TO PUBLIC COMMENTS ON THE DRAFT FQPA SCIENCE POLICY DOCUMENT:

"Proposed Threshold of Regulation When a Food Use Does Not Require a Tolerance"
(Announced December 4, 1998; 63 FR 67063)

(October 18, 1999)

The Agency reviewed all comments pertaining to this document that were submitted specifically under this docket (OPP-00569). A listing of the names and affiliations of the individuals submitting comments is provided at the end of this document. The Agency would like to thank these organizations for critically reviewing the document, and for providing recommendations to improve the document. EPA has incorporated many of these recommendations into the revised document. 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 and summarized similar comments together.

Unit I of this document is the Agency's response to comments. The numbers used in the discussion below correspond to specific commenters listed in unit II of this document.

Before turning to the public comments, an explanation of terminology will be helpful to an understanding of EPA's responses. EPA has typically used the term "food use" to categorize pesticide uses for the purpose of data requirements and for determining, in general, whether a tolerance is necessary. By "food use" EPA means a use of pesticide in, on, or near food such that there is a possibility of residues in food. Where no such possibility exists or where data have shown that a use otherwise considered a food use does not result in residues, such use would be considered a "non-food use" and the use would generally trigger fewer data requirements and no tolerance would be deemed necessary. Traditionally, however, EPA has not treated all "food-uses" as needing a tolerance. For pesticide uses in connection with crops that serve in whole or in part as animal feeds, EPA has determined that tolerances are not needed for the food products from the animal (e.g., meat and milk) when "it is not possible to determine with certainty whether finite residues will be incurred in milk, eggs, meat, and/or poultry but there is no reasonable expectation of finite residues in light of data . . . ." 40 C.F.R. § 180.6(b). The "no reasonable expectation of finite residue" finding is not a determination that there is no expectation of residue but that if there is any residue present, it will be at levels so low as to be unmeasurable. The Threshold of Regulation (TOR) approach outlined in this policy expands slightly the number of pesticide food uses for which a tolerance is not necessary beyond those uses for which there is no reasonable expectation of finite residue. Under TOR, if a pesticide use results in undetectable residue levels using reliable and appropriately sensitive analytical procedure, EPA will take into account both the measurability of any expected residue and the risk posed by such residue in

deciding whether a tolerance is needed.

I. EPA's Response to Comments on the December 1998 Proposed Threshold of Regulation Policy

EPA received 22 comments on this notice. The commenters included pesticide manufacturers, grower groups, food processors, industry task forces, trade associations, and State and foreign governments.

A. Is the Proposed TOR Policy Reasonable?

1. Yes, the proposed policy is reasonable.

a. Registrants and agricultural interests generally liked the proposal because it could help certain uses survive reregistration or facilitate registration of new uses of certain pesticides.

Agency Response: EPA believes that the TOR Policy, if properly designed and implemented, can identify pesticide uses for which tolerances are not needed. Pesticide uses that might qualify as TOR uses are uses of pesticides on or near growing crops, livestock, or food. The Agency believes that this policy will help provide a reasonable transition for agriculture as EPA fully implements the Food Quality Protection Act.

b. Two commenters (6, 20) liked the policy because they interpreted it to mean that if a pesticide use results in no detected residues, using an analytical method that has a Limit of Quantitation (LOQ) of 10 ppb or lower, EPA would not need to regulate the residues from the use.

Agency Response: EPA finds that the commenters (6, 20) have misinterpreted EPA's policy statement. Neither approach that EPA proposed for TOR determinations would establish a default level of 10 ppb for regulating pesticide residues in food. A proponent of an "essentially zero risk" determination should establish that there are no residues detected using an analytical method with an LOQ no greater than 10 ppb **AND**, even if residues were present at levels of ½ the LOD, the risk posed by such residues would be of no concern. Under the December 1998 proposal, a proponent of an "essentially zero exposure" determination would need to establish, through special residue chemistry studies, that "there is no reasonable expectation of finite residues in the food." Generally, this means that there would be no detected residues at a level corresponding to 1/10 the LOQ for the analytic method. If the analytical method has an LOQ no greater than 10 ppb, a level corresponding to 1/10 the LOQ would be no greater than 1 ppb. Accordingly, the December 1998 proposal would have used 1 ppb as a threshold for regulating pesticide residues in food, not 10 ppb, as asserted in the comments. However, as explained in unit I.C., the essentially zero exposure approach is not being pursued.

US EPA ARCHIVE DOCUMENT

c. The proposal could significantly reduce costs for developing toxicity data.

A producer of pesticides for seed treatment (14) commented that the adoption of a TOR policy would result in considerable savings in data generation costs. The commenter interpreted the December 1998 proposal to mean that EPA would not require toxicology data ordinarily required to support a potential food use if the pesticide use met the criteria for a TOR determination based upon "essentially zero exposure." The commenter believed that a proponent of such a TOR use would be responsible for providing the more limited toxicity database required to support non-food uses. Producers of pesticides for seed treatment would incur lower costs to develop their products and would be able to get their products on the market sooner if EPA adopts the TOR policy as proposed.

Agency Response: As explained below in unit I.C., EPA has clarified the TOR policy to indicate that toxicity data that are ordinarily required to support the registration of food uses of pesticides are still required to evaluate whether a potential food use qualifies for TOR status. The Agency acknowledges that this approach does not offer the potential savings in product development costs that the commenter inferred from the proposed TOR policy. The Agency recognizes that generating a full toxicity data set to support a TOR determination may be expensive, especially if the pesticide has no uses other than the use being proposed for a TOR decision. The data requirements could discourage development of new products. The Agency is willing to consider, on a case-specific basis, waiving some of its toxicity data requirements.

The Agency also emphasizes that some seed treatment uses may qualify as non-food uses, which require substantially less data than food uses. EPA will consider developing a separate policy specifically addressing seed treatment uses.

2. No, the proposed TOR policy is not reasonable.

a. The TOR policy does not conserve resources

One commenter (7) believes that the proposed policy does not save resources because industry must generate data to support the TOR request and EPA must allocate resources to review these data.

Agency Response: EPA agrees that the TOR policy does not relieve proponents of a pesticide use from their obligation to provide data in support of the proposed use. However, EPA would not perform an aggregate risk assessment, so EPA would use fewer resources to review a proposed TOR use than it would if it were establishing a tolerance or exemption for the use.

US EPA ARCHIVE DOCUMENT

b. Risks from a TOR use may not be "of no concern."

One commenter (6) remarked that if the analytical method used to support the registration of a TOR use is very sensitive, but the method used by the Food and Drug Administration (FDA) for compliance monitoring is less sensitive, misuse could occur and not be detected. Actual exposure could be much higher than anticipated in the TOR decision. Risk from such exposure could be higher than "risk of no concern."

Agency Response: While the situation described by the commenter is theoretically possible, EPA believes that it is unlikely to occur, and – even if it does – would not pose a significant hazard to the public. Although misuse is a possibility, legal restraints, i.e., the threat of enforcement action under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA), discourage pesticide users from applying more of a pesticide than the product labeling allows. Moreover, economic considerations encourage users to apply less pesticide than allowed by the product labeling. Given the very conservative assumptions used in EPA's calculation of the potential risk of TOR-eligible uses, the Agency believes that the incremental increase in exposure resulting from possibly undetected misuse would contribute very little to the overall exposure and risk. Therefore, the Agency does not believe that the comment provides adequate reason to abandon or significantly modify the TOR policy.

c. TOR policy may discourage development of more sensitive methods.

One commenter (17) observed that the TOR could discourage registrants of TOR uses from developing new, more sensitive analytical methods for pesticides in foods. A more sensitive method might be capable of detecting residues in food resulting from a TOR use. Under the proposed TOR policy, the use would no longer qualify as a TOR use if residues were detected.

Agency Response: EPA believes that adoption of a TOR policy will not have a significant effect on the continued advance of the frontiers of chemistry. There are many individuals and organizations who are interested in improving analytical methods. So, even if a registrant is unwilling to develop a new analytical method because the new method might theoretically jeopardize the status of a product registration, there may be others who are willing to do this work.

d. The TOR Policy would undercut other risk reduction efforts.

One association (17) commented that EPA's statement that analytical methods with levels of detection of 10 ppb are "sufficiently sensitive" has the effect of setting 10 ppb as the target for analytic methodologies. By so doing, EPA is undercutting risk reduction efforts in other areas. For example, EPA's water programs frequently establish Maximum Contaminant Levels (MCL) below 10 ppb and the National Institute of Occupational Safety and Health (NIOSH) recommends

US EPA ARCHIVE DOCUMENT

managing contaminants in workplace air at levels below 10 ppb. The commenter asserted that EPA's proposed action would not support efforts to understand human health risks associated with exposure to chemicals at very low concentrations, such as those that may occur in drinking water.

Agency Response: The commenter makes a valid point. EPA has clarified the TOR Policy to specify that analytical methods with levels of quantitation of 10 ppb *in food* are "sufficiently sensitive" for purposes of making TOR determinations for pesticide residues in food. EPA is aware that it is generally possible to measure pesticide concentrations in air or water at much lower levels than is feasible in complex organic matrices such as food. However, because the TOR policy applies to measurement of pesticide residues in food, and not in any other matrix, the criterion for selecting an LOQ for the proposed TOR policy was the level of quantitation that can be achieved in measuring pesticide residues in food.

3. Yes, the policy is reasonable but there are concerns.

a. The proposed TOR policy blurred the distinction between a food use that is subject to FFDCA and a "non-food" use that is not subject to FFDCA.

Agency Response: EPA has revised the TOR guidance to clarify its applicability. EPA did not intend the TOR policy to affect pesticide uses that are classified as "non-food" uses. Rather, EPA intends the TOR policy to apply to "food uses" of pesticides, that is, the types of uses of a pesticide in, on or around growing crops, livestock or food that may -- at least theoretically -- result in measurable residues in food. The TOR Policy applies to pesticide uses that produce no detected residues in food and is intended to establish criteria for judging whether the potential risk from residues that could theoretically occur in food is so low that it is insignificant. If a particular pesticide use meets the criteria, a tolerance will generally not be deemed necessary under section 408 of the FFDCA.

It appears, however, 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). This regulation specifies that EPA may use special chemistry studies to support a finding that pesticide-treated livestock feed or direct treatment of an animal results in "no reasonable expectation of finite residues" in milk, meat, poultry or eggs and that no tolerances are needed for the human food items. 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.

b. How will users, FDA and other interested parties find out about

US EPA ARCHIVE DOCUMENT

decisions made under the TOR policy?

The December 1998 proposal indicated that EPA must be able to document TOR decisions and retrieve this information later. However, the proposal did not indicate what information about a TOR decision would be made public or what form any announcement would take. Some commenters (6, 11) were concerned that pesticide users would be confused if a use on a pesticide product label did not have a corresponding tolerance or tolerance exemption. Trade associations and registrants (11, 14, 18, 20) suggested that EPA issue a kind of "tolerance" to inform the public of TOR decisions and the sensitivity of the method used to demonstrate the absence of residues. Many commenters stated that EPA should maintain a published compendium of TOR decisions. Government agencies informed EPA of their preference that each TOR decision be published as a rule.

Agency Response: The Agency agrees that it should publicly announce TOR decisions and publish a compendium of TOR decisions. The published information will specify the conditions of use and the analytic method used to establish that the use does not result in detectable residues in the food. For reasons discussed below (in unit I.A.3.c) EPA has decided that the TOR decisions will be issued as rules in order to clarify the regulatory status of the use.

c. What is EPA's authority for making TOR decisions?

Several commenters (e.g., L6) stated that EPA should identify the statutory authority it will rely on for establishing TOR decisions. Some commenters (e.g., 18) cited the Agency's procedural regulations for pesticide registration in 40 CFR 152.112(g) to show that FIFRA requires EPA to determine that all "necessary" tolerances or exemptions have been issued before registering a pesticide for a food use. Other commenters (11) believe that section 24(c)(2) of FIFRA also gives EPA authority to determine that a tolerance is not required.

Agency Response: EPA would agree that TOR decisions are an application of 152.112(g) which is a longstanding regulation coordinating EPA's authorities under FIFRA and FFDCA. Authority for issuing TOR decisions as rules is found in section 701(a) of FFDCA and section 408(e). Section 701 states, "The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary." The term "Secretary" means "Administrator" with respect to those provisions of FFDCA for which the Administrator of EPA, rather than the Secretary of Health and Human Services, has responsibility. Section 408(e) authorizes EPA to establish by regulation general procedures and requirements to implement this section. EPA interprets this section as authority to issue guidance for making TOR decisions and to establish TOR decisions as rules.

US EPA ARCHIVE DOCUMENT

d. How will FDA respond if it finds residues in food that appear to result from a TOR use?

Comments from trade associations and food processors (18, 20) expressed great concern about the status of food that contains detected residues resulting from a TOR use. This circumstance could arise if a TOR use produces higher residues than expected or if the analytical methods used for compliance monitoring are more sensitive than the method considered in the TOR decision. In the December 1998 proposed policy, EPA had indicated that such foods would be considered to be adulterated under section 402 of the FFDCA and would be subject to seizure. Comments from the food industry said that they would not use a pesticide for a TOR use because they cannot risk seizure of the treated food if residues were found in the food. They requested that EPA find a way to establish a "safe harbor" for foods treated with a pesticide in accordance with a TOR decision. Some commenters suggested that EPA rely on FFDCA section 408(l)(5) to legitimize residues that may be found in food as a result of a TOR use.

In its discussions with the Agency, FDA noted the effect that the Community Nutrition Institute v. Young decision (Community Nutrition Institute v. Young, 818 F.2d 943 (D.C. Cir. 1987) has had on that agency's practices. This decision involved an FDA action level, a level that FDA may establish for a contaminant in food to guide it in an enforcement action. Prior to this decision, an "action level" was an enforcement directive that established a level of contamination below which FDA considered enforcement action to be unnecessary. Foods that contained these contaminants at levels above the "action level" were deemed to be adulterated. In Community Nutrition, the court ruled that FDA could not substitute informal "action levels" for rules that set limits on the levels of contaminants in food. In the absence of a rule that established a permissible level for a contaminant, FDA could not use an action level as a binding regulation.

FDA explained that a TOR decision, absent rule-making, is similar to an action level in that: 1) it is an enforcement policy rather than a rule; and 2) it would establish the LOD of the analytical method for a pesticide as the level of pesticide in a food below which EPA considers enforcement of FFDCA section 408 to be unnecessary. As the court ruled in Community Nutrition, a regulatory agency may not use action levels as binding rules without notice and comment rulemaking. If FDA detected any pesticide in a food treated with a pesticide in accordance with a TOR decision, FDA would be obliged to consider the food to be adulterated under section 402(a)(2)(B) of the FFDCA.

Agency Response: EPA has decided that a TOR decision will be based on a finding that FFDCA section 408 does not apply because the available evidence shows that the use will not result in residues in or on the food. If improved analytical methods show that the use does produce residues in or on the food, sections 402(a)(2)(B) and 408 of the FFDCA would apply to such residues.

EPA has considered whether it should establish a rule for each TOR use to exempt pesticide residues from regulation under section 408 of the FFDCA provided that residues

US EPA ARCHIVE DOCUMENT

resulting from a TOR use are present at levels at or below the level of detection for the analytical method used to establish whether a particular use food results in detectable residues in the food. Such a rule would have to rely on the de minimis principle as its primary justification. As outlined below, EPA has certain concerns about relying on the de minimis principle as its primary justification for the TOR policy. (See discussion in Unit I.A.3.e.).

Moreover, EPA believes that the commenters may be overly concerned about the possibility that TOR uses will result in residues that are detected by FDA. The TOR use will be supported by data to demonstrate that the use does not result in residues that are detectable with state-of-the-art analytical methods. EPA is confident that it has sufficient expertise, based upon years of experience in evaluating residue chemistry data, to judge the reliability, representativeness and validity of the data supporting a TOR use. Each TOR decision will be published as a rule that specifies the pesticide, the food, the conditions of use, and the analytic method used to establish that the use does not result in detectable residues in the food. Therefore, EPA believes that if FDA finds residues in a food that has been treated with pesticides under a TOR approval, either FDA used an analytical method that is even more sensitive than the method evaluated by EPA or the pesticide user did not carefully adhere to the conditions of the TOR approval (i.e., the pesticide product label). 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.

FFDCA section 408(l)(5) ("safe harbor" provision) does not apply in this situation. This provision applies when residues are found after EPA has revoked a tolerance and the residues are below the level of the former tolerance.

e. The criterion that "There must be no residues detected in or on the food" is too restrictive.

(1) The proposed TOR excludes Section 18 uses that result in detected residues.

Some commenters (6, 18) noted that as proposed, the TOR policy would not apply to FIFRA section 18 uses that result in detected residues in or on food. They questioned whether EPA will apply the same criteria to FIFRA section 18 emergency exemptions as it would to FIFRA section 3 registrations, asserting that different criteria could be used for the time-limited and geographically limited FIFRA section 18 uses. An industry task force (18) asserted that EPA had authority to determine that a tolerance or exemption is not required under FFDCA section 408 (l)(6) for a FIFRA section 18 food use. This determination could be based on criteria that consider only the incremental risk posed by the proposed use.

Agency response: There is no basis for including in the TOR policy FIFRA section 18 uses that result in detected residues. A fundamental element of the TOR policy is that a use

US EPA ARCHIVE DOCUMENT

results in no detected residues. Therefore, the TOR policy cannot be used to manage the risk posed by FIFRA section 18 uses that result in detected residues.

The Agency will not address in this document whether it may use different criteria for judging FIFRA section 18 uses than it uses to judge FIFRA section 3 or Section 24(c) uses. EPA addressed this issue in the preamble of the recently published FIFRA Section 18 proposed rule (64 FR 29823; June 3, 1999). As part of that rule-making, EPA requested comment on an "incremental risk" option for managing the risk posed by FIFRA Section 18 uses.

(2) A de minimis policy would be more inclusive than the proposed TOR.

Several comments (7, 16, L6, L7) urged EPA to consider a de minimis policy for uses that pose inconsequential risks. According to one commenter (L6), the Agency has underutilized the de minimis principle embodied in Monsanto v. Kennedy, 613 F.2d 947 (D.C. Cir. 1979). This commenter noted that Monsanto had both defined the legal limit of which substances qualified as "food additives" under the FFDCA, and advised that FDA might use the de minimis principle to decline to regulate some substances that did qualify as food additives. According to this commenter, the de minimis principle would be more simple to implement in practice. This comment also contained considerable discussion regarding how the legal principle of "de minimis non curat lex" can be applied to FFDCA section 408(b). This principle means that an Agency may decide 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.

Agency Response: The TOR policy does not rely on the de minimis doctrine as its primary justification. This was a conscious choice by EPA 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. 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. 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

US EPA ARCHIVE DOCUMENT

the concerns that have 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, reliance on the de minimis principle is not needed to meet the practical concerns raised by the commenter. EPA does not believe it will be difficult to apply the criteria in the policy to decide when a pesticide is in or on food. As outlined in the policy, EPA has already been making this type of determination as to a considerable range of pesticide uses.

(3) EPA should adopt a single level of exposure as the threshold of regulation

One comment (L6) urged EPA to abandon its proposed TOR approach in favor of either (1) a single level of exposure, such as 0.5 ppb per day, as the threshold of regulation for any pesticide residue in foods or (2) a level of exposure that is specific for each pesticide, e.g., a fraction of the reference dose (RfD)[1] for the pesticide, as the threshold of regulation for each pesticide. Under this approach, the TOR residue level in a particular food would depend on the relative importance of the food in a person's daily diet. A pesticide residue in a food would be below the threshold of regulation if exposure to the pesticide that is attributable to residues in that food comprised less than either 0.5 ppb in a person's total daily food intake or the pesticide-specific level of daily exposure. Uses that produce measurable pesticide residues would be covered under each of the suggested approaches.

Agency Response. EPA does not agree that a single level of exposure should be used as a threshold of regulation for all pesticides. Many pesticides are inherently toxic; it is likely that a the level of exposure selected by FDA in its TOR policy for certain food additives would not be protective enough for pesticides. EPA reasoned as follows: assuming that the average American adult weighs 70 kg and consumes 1.6 kg of food per day[2], a concentration of 0.5 ppb of pesticide residue in the diet corresponds to a daily dose, expressed in mg/kg/body weight, of 0.000011 mg/kg/day. If a dose of 0.000011 mg/kg/day is to be of no consequence, it should be at least 1000 times lower than the population-adjusted reference dose for the pesticide (see discussion in unit I.D.3). EPA then referred to a compilation of RfDs for 377 pesticides. The RfDs ranged from 4.5 mg/kg/day (least toxic) to 0.00001 mg/kg/day (most toxic). For 197 of these pesticides 0.000011 mg/kg/day is greater than 0.1% of the RfD. This means that for 52% of pesticides, the exposures that would be received by the average adult under the "single level of exposure" approach would pose risks that are greater than inconsequential.

EPA did not perform this analysis for children's risk because children's food consumption

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[1] A reference dose is the amount of a substance that a person can consume every day on a continuous basis without appreciable risk.

[2] Average food consumption as reported in Exposure Factors Sourcebook, American Industrial Health Council, May 1994.

US EPA ARCHIVE DOCUMENT

is more variable than that of adults and because population-adjusted RfDs are not available for all 377 pesticides. However, because the ratio of food consumption per unit body weight is generally higher for children than for adults, children would receive a larger dose of pesticide residue in the diet than adults receive when pesticide is present in the diet at a level of 0.5 ppb. Accordingly, for more than 197 pesticides, a daily exposure of 0.5 ppb in children's diets would pose risks that are greater than inconsequential.

The other suggested approach resembles EPA's TOR policy in that it considers the toxicity of each pesticide in establishing a threshold of regulation and expresses the TOR as a percentage of the acceptable exposure for the pesticide. However, as explained above, EPA is not willing to consider a TOR policy that would allow measurable residues to be eligible for a TOR decision.

The commenters further proposed that EPA grant FIFRA registration to any pesticide use that could theoretically result in human dietary exposures that are below the TOR. However, this proposal overlooks key elements of pesticide registration procedure. In evaluating a pesticide use, EPA considers the conditions of the pesticide use and reviews data that characterize the hazards and risks posed by the pesticide. Under FIFRA section 3(c)(5) or 3(c)(7), EPA must determine whether the use of the pesticide meets the FIFRA standard for registration. The commenters' proposal does not appear to contemplate submission of information regarding the conditions of use that would produce residues on the food that are below the TOR. In the absence of specific information about how the pesticide is to be used, EPA would not be able to make the required findings under FIFRA section 3(c)(5) or 3(c)(7).

B. Residue Chemistry Data Requirements for TOR Decisions

1. Some pesticides will not be eligible for TOR because analytical methods are not sensitive enough.

Several commenters (5, 11, 16, 18) objected to EPA's proposed recommendation that the analytical method for the pesticide be capable of quantifying levels of 10 ppb. They suggested that if a pesticide use otherwise met the criteria for "essentially zero" risk, the use should be granted TOR status. One commenter (5) remarked that some pesticides do not contain readily measured atoms such as chlorine, phosphorus or sulphur, so it is not possible to achieve such method sensitivities for all pesticides. The commenter believes that proponents of TOR decisions for pesticides that are difficult to measure are being penalized because their pesticides are not as easily measured as other pesticides.

Agency Response: The 10 ppb level is a recommended level given the current state of science. On a case-by-case basis, EPA will examine whether a higher or lower LOQ is needed.

US EPA ARCHIVE DOCUMENT

2. There are alternatives to using ½ LOD as the default residue value in "essentially zero" risk TOR decisions.

Most commenters (5, 11, 18, 19) agreed that it was reasonable to use ½ of the LOD as a surrogate for the potential residue level when estimating dietary exposures to undetected residues that theoretically could occur in pesticide-treated food. One commenter (5) suggested that EPA consider using data from studies of residue disappearance kinetics to predict concentrations that would be expected at harvest. The kinetics of residue disappearance would be established at application rates that result in measurable residues. When the pesticide is applied at lower rates so that no detected residues occur in the treated food, data from the kinetics studies could be used to extrapolate the residue level. This value would be used in the dietary risk assessment for the use. One commenter (7) did not agree with EPA's approach of using ½ LOD as a default residue value when no residues are detected, suggesting that EPA use either "0" or the LOD as the residue value instead. Another commenter (L5) observed that analytical methods are becoming increasingly sensitive and that at some point, methods will be able to detect such low levels of residues that EPA should be able to treat "non-detect" data as "zero residue" data.

Agency response: When estimating dietary exposures from proposed TOR uses, EPA will generally use ½ LOD as a default residue value for samples that show no detected residues. This approach follows Agency policy concerning the use of data showing no detected residues in a food (see 63 FR 67063, December 4, 1998). EPA will substitute other residue values for samples that show no detected residues if data such as the kinetic studies described above were available.

EPA agrees with the observation that methods for quantifying pesticide residues in food are becoming more sensitive and notes that a more sensitive method has, by definition, a lower LOD. However, the fact that no residue is detected – even with a method that is more sensitive than a method previously considered to be state-of-the-art – does not mean that no residues are present. As discussed above, other data may justify using a value (even "0") other than ½ LOD of the most sensitive available method.

EPA will address the objections raised to EPA's approach for handling samples that show no detected residues in its response to the paper "Exposure Assessment – Interpreting 'No Residues Detected'," announced December 4, 1998; 63 FR 67063.

3. Multiple rate studies for seed treatments

A developer of seed treatment products (14) commented on the feasibility of multiple rate studies. In the December 1998 proposal, EPA said that it would use multiple rate studies, performed at 10X the labeled rate, to make a finding that a seed treatment results in "essentially zero" residues in the mature plant. The commenter said that pesticides used in seed treatment are phytotoxic at high concentrations so it is not possible to treat seeds at 10X the labeled rate as EPA has recommended. The commenter wants EPA to accept multiple rate residue chemistry studies performed at 3-5X.

US EPA ARCHIVE DOCUMENT

Agency Response: As explained above, EPA is modifying the proposed TOR policy to eliminate the "essentially zero" exposure approach to TOR determinations. Accordingly, EPA will examine toxicology and residue chemistry data to determine if a pesticide use results in "essentially zero"dietary risk to qualify as a TOR use. Nonetheless, multiple rate studies -- including studies performed at 3-5X the labeled rate – would still be useful for demonstrating that the seed treatment use qualifies as a TOR use under the revised criteria.

4. TOR decisions for antimicrobial pesticides

One commenter (11) asked EPA to describe the models and assumptions that EPA will use to determine whether the use of an antimicrobial pesticide qualifies as a TOR use.

Agency Response: The food uses of antimicrobial pesticides include direct use of antimicrobial pesticides in fresh fruit and vegetable rinses and uses in agricultural settings such as the use of disinfectants in irrigation water or algicides in drinking water for livestock. Residue chemistry studies that would be useful in estimating human dietary exposures from such uses are described in the Agency's Residue Chemistry Data Guidelines. For estimating human dietary exposure resulting from other uses, such as use of antimicrobial pesticides on food contact surfaces, EPA may use models developed by the FDA. These include "Recommendations for Chemistry Data for Indirect Food Additive Petitions," and "Sanitizing Solutions: Chemistry Guidelines for Food Additive Petitions."

5. Residue chemistry data requirements for Section 18 uses or minor uses

The December 1998 TOR policy proposal acknowledged that residue chemistry data needed for a TOR determination may not be available for Section 18 uses or minor crop uses and indicated that surrogate data may be acceptable. Several comments (11, L7) asked EPA to specify surrogate data that could be used to support a TOR decision for a Section 18 or minor crop use.

Agency Response: To make a TOR decision, EPA would need data to show that no residues are detected in the commodity as a result of the use and that the analytical method is suitably sensitive to detect residues if they were present. If there are no data to directly measure pesticide residues in the commodity or to characterize the performance of the analytical method, EPA may accept alternative data that show, or allow the Agency to extrapolate, the necessary information. As is presently done for establishing tolerances to support minor uses, the Agency may accept residue data from a related crop to establish eligibility under the Threshold of Regulation policy. EPA may also adopt the crop group concept from 40 CFR 180.41 when making TOR decisions. In other words, if residues are shown to be not detectable for the representative commodities of a crop group, it will be assumed residues are below the LOD in all other members of that crop group, provided that the conditions of use are comparable.

6. Performance requirements for the analytical method

US EPA ARCHIVE DOCUMENT

One commenter (17) suggested that EPA require that analytical methods used to support a TOR decision meet the following criteria: 1) the method should be fully characterized; 2) the method should be demonstrated in several laboratories before it is adopted; 3) the method performance should be appraised through peer reviewed literature or consensus method of the American Standards and Testing Methods (ASTM). The method should be usable by federal compliance monitoring laboratories.

Agency Response: The Agency agrees the methods should be thoroughly tested prior to acceptance and believes the present procedures ensure that. Analytical methods are required to be validated by the petitioner, an independent laboratory unfamiliar with the procedure, and by the Agency's own analytical laboratory. That same process will be followed for methods associated with TOR decisions.

C. Toxicity Data Requirements for TOR Decisions

A government agency (19) recommended that EPA require toxicity information for all food uses that are potential TOR uses, including seed-treatment uses. Under the "essentially zero" exposure approach described in the December 1998 proposal, a proponent of a TOR use would not be required to present any data for characterizing the hazard posed by dietary exposure to the pesticide.

Agency Response: 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, even "essentially zero" exposures, are without risk if there significant gaps in the information about the biological activity of the pesticide. The "essentially zero exposure" approach proposed in the December 1998 TOR Policy would have established a level in the range of 1 ppb as "essentially zero." If EPA were to adopt the "essentially zero exposure" approach for TOR decisions, the Agency would be concluding that risk from exposure to 1 ppb of any pesticide, regardless of toxicity and the crop which it would be used, would always pose risks of no consequence, or "essentially zero" risk.

Some pesticides, however, are so toxic that exposures of 1 ppb may pose risks greater than "inconsequential" or "essentially zero" risk. The Agency will perform a quantitative risk assessment before concluding that a specific use poses "essentially zero" risk from dietary exposures. 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. (See 40 CFR 158.340.) On a case-by-case basis, however, the Agency may waive specific toxicity data requirements, based upon a pesticide's known toxicity, structure-activity relationships, and estimated exposures.

D. Risk Criteria for TOR Decisions

US EPA ARCHIVE DOCUMENT

1. EPA's TOR risk criteria are overly stringent.

Several commenters (5, 8, 11, 13, 16, L6) asserted that few pesticide uses would meet the TOR criteria for the "essentially zero" risk approach and recommended that EPA ease the criteria for "essentially zero" risk so that more uses could qualify for TOR decisions. One commenter (5) observed that the EPA's proposed TOR policy, whereby dietary exposure to a pesticide at 0.1% of the acceptable level of risk is considered to be of no consequence, is "risk management policy," not "science policy."

Another commenter (13) provided an analysis to show that the proposed TOR risk criteria are much more protective than EPA realizes. Under the "essentially zero" risk approach for TOR, the level of detection (LOD) for a pesticide represents 1/500 of the acceptable risk (i.e., exposure to residues at a level of ½ LOD results in risk that is 1/1000 of acceptable risk). If the mean level of residues is ½ LOD and the Standard Error for the measurements is 0.7, the probability of detected residues would be 16%. Therefore, if there are no detected residues in a food treated with pesticides under a TOR use, the mean level of residues must be considerably below ½ LOD. According to this analysis, the probability of exposures resulting from a TOR use reaching a level of 1/10 of acceptable risk would be 2.4×10^{-11}. If the LOD for a pesticide represents 1/50 of the acceptable risk (i.e., exposure to residues at a level of ½ LOD results in risk that is 1/100 of acceptable risk), the probability of residues reaching a level of 1/10 of acceptable risk would be 5×10^{-4}. The commenter believes that the risk resulting from exposures of 1% of the acceptable risk level would be of no consequence.

One commenter (L6) speculated that EPA did not choose 1% of acceptable risk as the risk criterion for TOR decisions because EPA imagined that 100 TOR uses would fill the "risk cup," leaving no "room"in the risk cup for other uses. The commenter dismissed this reasoning as overly simplistic. The commenter supposed that another possible reason for EPA's rejection of 1% as the TOR risk threshold could be that EPA may believe a person could receive exposures from a multitude of TOR uses and that EPA may believe that the aggregate risk from these exposures could be significant. The commenter believed that it is not reasonable to suppose that a person could receive exposures from 100 sources each of which contains the maximum residues allowed under a TOR policy.

One commenter (16) stated that a TOR risk criterion of 1% of the RfD would be consistent with the risk criteria FDA uses in its threshold of regulation policy for indirect food additives and asked EPA to explain why 1% of the RfD was not selected. A comment from a state agency (L7) opined that there was no scientific basis for requiring a showing of "essentially zero" risk and asserted that sufficient protection would be achieved if the risk posed by the TOR use is "an insignificant proportion of allowable risk."

Agency Response: The Agency agrees with the commenter that the selection of risk criteria for the TOR policy is a risk management rather than a science policy decision. EPA

US EPA ARCHIVE DOCUMENT

intends that the exposures from TOR uses be so small that risk resulting from such exposures would be of no concern.

EPA would note that the commenter's assertions about the extreme improbability of receiving exposures above the LOD when TOR decisions are based on the proposed risk criterion of 1/1000 of acceptable risk related to exposure at a single meal. That, however, is not the only exposure scenario with which EPA is concerned.

Because selection of the risk criteria for TOR decisions is a risk management decision; the risk level itself should connote the triviality of the risk. With the caveat noted above, the commenter's analysis of the probability of exposure exceeding the acceptable risk from a single meal is supportive of the trivial nature of the risk of pesticide uses meeting the TOR policy. However, EPA does not rely on a statistical analysis of the probability of detected residues alone to justify its decision that exposures at a particular level pose inconsequential risks. The Agency must communicate TOR decisions to many audiences. Some people may have a very concrete understanding of the "risk cup" concept. To their minds, a use that occupies 1% of the risk cup does not pose an inconsequential risk, just as a penny does not pose an inconsequential part of a dollar. A person with a literal understanding of the risk cup concept may, however, accept the notion that 0.1% of acceptable risk is really of no consequence and can be dismissed. The Agency believes that a risk of 0.1% of the acceptable level of risk is of no consequence.

2. Few uses will meet the proposed criteria.

Many commenters expressed the opinion that EPA's criteria for "essentially zero" risk TOR decision are so strict that few uses would qualify.

Agency Response: Under the revised TOR policy, proponents of a TOR use should establish that the use meets two criteria to establish that the use poses "essentially zero" risk: 1) the use results in no detected residues, using a valid sufficiently sensitive analytical method; and 2) the risk posed by residues at levels of ½ LOD should generally be no greater than 0.1% of acceptable risk. EPA does not have the data to assess how many pesticides would qualify for the first criterion, but the Agency does have information to show that the second criterion is not overly restrictive.

EPA conducted its own analysis to see how many pesticide uses could qualify for TOR exemptions, using the following parameters and assumptions: The proposed TOR policy indicated that no residues be detected using a method capable of quantifying 10 ppb and that EPA would assume that residues to be present at ½ the LOD. For this analysis, residues were assumed to be present at ½ the LOQ, i.e., 5 ppb, instead of ½ LOD (½ LOQ is slightly higher than ½ LOD). EPA selected various dietary items that comprise either "large," "medium," or "small" components of the diet and calculated the dietary exposures to residues in or on each of the selected commodities for either the general U.S. population or children aged 1 through 6 years. EPA then referred to a compilation of reference doses (RfD) for 377 pesticides. The RfDs ranged

US EPA ARCHIVE DOCUMENT

from 4.5 mg/kg/day (least toxic) to 0.00001 mg/kg/day (most toxic). EPA assessed the number of pesticides for which the exposure due to consuming wheat, apples, pears or asparagus that contain 5 ppb of pesticide was less than either 1%, 0.5% or 0.1% of the RfD for the pesticide. The results are shown in Table 1. The results suggest that virtually any pesticide will qualify for a TOR for use on a food item that is a "small" component of the diets of the general U.S. population or children aged 1 to 6 years, provided the residues are undetected and the LOQ of the analytical method is below 10 ppb.

The analyses presented in Table 1 examined the applicability of the revised TOR to pesticides that exhibit toxic effects for which a threshold dose, or "no observed adverse effect" dose can be established. A preliminary assessment of carcinogenic pesticides suggests that it may be possible to make TOR decisions for uses of carcinogenic pesticides on items that constitute minor components of adult diets. EPA believes that many pesticide uses could qualify for TOR approvals even when the Agency defines inconsequential risk to be 0.1% of the acceptable level of risk. Therefore, it is not necessary to modify the risk criteria, as suggested in the comments.

US EPA ARCHIVE DOCUMENT

Table 1. Pesticide uses that would qualify for TOR decisions at various risk criteria levels.

PESTICIDE USES THAT WOULD QUALIFY FOR TOR DECISIONS AT VARIOUS RISK CRITERIA LEVELS				
Chronic Exposures Assume residue in food of 5 ppb RfD values for chronic toxicity effects for 377 active ingredients Risk Criteria: 1%, 0.5%, or 0.1% of Chronic RfD				
CROP	EXPOSURE (mg/kg/day)	NUMBER of CHEMICALS where EXPOSURE is less than		
		1% RfD	0.5% RfD	0.1% RfD
Population Subgroup: U.S. population				
Wheat	0.000007	315	295	222
Apples	0.000005	329	313	253
Pears	0.000001	356	350	313
Asparagus	0.00000006	377	374	359
Population Subgroup: Children aged 1-6 years RfD for chronic toxicity effects not adjusted for FQPA safety factor				
Wheat	0.000017	292	266	159
Apples	0.000020	282	258	134
Pears	0.000001	352	343	301
Asparagus	0.000000008	377	377	377

3. What criteria would be used to define “essentially zero” risk for infants and children?

One commenter (18) asked what “acceptable risk” meant with respect to risks to infants and children or other subpopulations when EPA stated that risks from a TOR use would be less than 0.1% of acceptable risks.

Agency Response: The December 1998 proposed policy did not explain how EPA would handle risks to infants and children from a TOR use. EPA agrees with the commenter that the Agency’s position must be clarified.

In evaluating the incremental dietary risk posed by a pesticide, EPA will consider the

US EPA ARCHIVE DOCUMENT

nature of the hazard posed by the pesticide. For pesticides that exhibit toxic effects for which a threshold dose, or "no observed adverse effect" dose, can be established, EPA will evaluate the dietary risks that would result from a single exposure and from continuous exposures to the food that has been treated with a pesticide under a TOR decision. At issue is whether EPA will separately evaluate the incremental dietary risk posed by a proposed TOR use to each population subgroup, particularly infants and children, and consider other FQPA issues such as the additional safety factor for infants and children.

Because this is a policy to guide EPA's decision-making about what assumed residue levels pose so insignificant a risk as to not need tolerances under section 408, EPA believes it should be guided by section 408 in assessing the level of risk. To make a credible assertion that a TOR use poses inconsequential risks, the Agency's assessment will include a separate assessment of the risk from food to subpopulations, including infants and children as specified in section 408. In addition, if EPA has not established an FQPA safety factor, EPA will, as a matter of policy, decide the appropriate FQPA safety factor and will use it when evaluating the potential risk posed by the proposed TOR use to infants and children.

4. There should be special TOR criteria for seed treatment uses.

A developer of seed treatment products (14) wanted the opportunity to demonstrate that seed treatment uses result in "essentially zero" exposures. The commenter proposed alternative data requirements and criteria for demonstrating that seed treatments result in "essentially zero" exposures. A grower group (12) that produces seed crops from treated seed asked that the Agency's TOR process be modified to include "screenings" and straw derived from the seed crops. Seed crop producers may not feed to livestock the screenings and straw from their seed crops because there is a concern that there will be pesticide residues in the mature plant, including such tissues as screenings and straw. Seed crop producers must maintain records to show that screening and straw from the seed crop were not fed to animals. The TOR policy could eliminate this paperwork requirement.

Agency Response: The Agency will apply the criteria in the revised TOR Policy to seed treatment uses. As discussed above in unit I.C., a proponent of a TOR use would normally need 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.

With respect to screenings and straw, the TOR policy covers all potential food or feed forms produced from a crop. Thus, EPA would set a tolerance or tolerance exemption for residues in screenings or straw from a seed crop unless data showed that the TOR criteria were met for these food forms.

The comments argue that seed treatments are different from the potential food uses covered in the TOR Policy and that different criteria should be applied. EPA will reserve these issues for future discussion.

US EPA ARCHIVE DOCUMENT

E. How Will EPA Handle Risks from Other Exposures That Result from a TOR Use?

1. How would EPA account for drinking water exposures that may result from a TOR use?

One comment (17) indicated that EPA should clarify how it will handle drinking water exposures that may result from a TOR use. A TOR use could result in residues getting into drinking water supplies. Would EPA assess the incremental risk from drinking water when evaluating a proposed TOR use? Would EPA grant TOR status if the use is expected to result in exposures to the pesticide from drinking water? Would EPA apply the same risk criterion – 0.1% of acceptable risk – to risk from potential residues in drinking water?

Agency Response: After EPA has determined that a proposed new use meets the criteria for a TOR use and that no tolerance is required, the Agency will review the use to determine whether it meets the standard for registration in section 3(c)(5) or 3(c)(7) of FIFRA. Among other things, section 3(c)(5) specifies that the pesticide will perform its intended function without unreasonable adverse effects on the environment. Section 3(c)(7) similarly specifies that the pesticide will not increase the risk of unreasonable adverse effects on the environment. FIFRA defines "unreasonable adverse effects" at section 2(bb).

In 1996, the FQPA amended section 2(bb) of FIFRA to coordinate FIFRA with section 408 of the FFDCA. An unreasonable adverse effect is now defined as: (1) any unreasonable risk to man or the environment . . . ., or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug and Cosmetic Act . . . ." FIFRA section 2(bb)(2) applies to a registration decision when a tolerance is required for the use under consideration or the use otherwise results in residues in or on food. Accordingly, when deciding whether to register a use that meets the criteria for TOR status, EPA will apply FIFRA section 2(bb)(1) to decide whether pesticide residues in drinking water that are attributable to the proposed use pose an unreasonable risk.

2. How would potential exposures from a TOR use be handled in an aggregate risk assessment?

One commenter (11) asked how EPA would address potential exposures from a TOR use in an aggregate risk assessment of the pesticide. The commenter was concerned that a TOR use would be eliminated if a subsequent aggregate risk assessment showed that risks from a TOR use are unacceptable.

Agency Response: Generally, EPA would not consider potential food exposures from a TOR use in an aggregate risk assessment of the pesticide. The risk ceiling for a TOR use should be low enough that exposure (e.g., drinking water or other non-occupational exposure) from the TOR use would not have a measurable effect on aggregate exposure and risk. If aggregate risk for a pesticide is found to be unacceptable, EPA would consider the TOR use in determining what

US EPA ARCHIVE DOCUMENT

uses would have to be canceled, but EPA would be unlikely to focus its cancellation efforts on uses (such as TOR uses) that pose no significant risk.

F. Procedural Issues

1. Will EPA evaluate all existing and prospective uses for TOR eligibility?

Several commenters (8, 11, 14, 18, 19) addressed operational issues, asking whether EPA would evaluate: 1) all prospective uses for TOR eligibility or only those where the registrant requests TOR status; and 2) all existing uses for TOR eligibility.

Agency response: EPA believes that the TOR policy should be applied consistently and uniformly. Accordingly, the Agency intends to evaluate all existing and prospective uses for TOR eligibility. The Agency will evaluate the TOR eligibility of existing food uses during tolerance reassessment, reregistration or registration review. The Agency will also evaluate the TOR eligibility of all prospective uses during the risk assessment process and determine whether a tolerance is needed.

2. Will EPA charge tolerance fees for TOR eligibility evaluations?

Commenters on this issue (11, 18) asserted that a person should be able to request a TOR exception without petitioning for a tolerance and paying a fee. According to FFDCA section 408(m)(1), a fee can only be charged for actions under FFDCA section 408. Since a TOR review does not lead to an action under 408, a fee cannot be charged.

Agency Response: 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. However, the Agency does not intend to do so at this time.

3. How will EPA handle tolerances for existing uses that are found to be eligible for TOR status?

Commenters offered two points of view on how to handle tolerances for existing uses that are found to be eligible for TOR status. One commenter (16) suggested that EPA should request public comment on three options: a) tolerance exemption; b) reduce the tolerance to the LOQ of the new method; or c) keep the tolerance as is. Other commenters (8, 11,14, 18, 19) stated that once a TOR is established for a use, the tolerance is no longer needed and should be revoked. These commenters emphasized the public's need for consistent application of Agency policy to existing uses and new uses; if an existing tolerance is not needed, it should be revoked. Such revocations should not be given special priority.

Agency Response: The Agency believes that it should revoke tolerances after it has

US EPA ARCHIVE DOCUMENT

decided that a specific pesticide use qualifies as a TOR use. EPA finds that it would not be in the public's interest to adopt the suggestion that tolerances for uses that are eligible for TOR status be either retained or modified. It would be confusing if there were TOR decision rules for some uses and tolerances for other uses that are eligible for TOR status. Converting a tolerance to a tolerance exemption may be inappropriate because exemptions from tolerance do not establish limits on the residue levels, and the residue levels of a pesticide may need to be limited for safety reasons.

4. Who can apply for a TOR?

One commenter (12) asked that states or growers be able to request TOR decisions for pesticide uses.

Agency Response: EPA agrees with this comment and will clarify the TOR Policy to make it clear that anyone may ask EPA for a TOR decision.

5. Rescission of a TOR decision

Several commenters (8, 16) recommended that a TOR decision not be revoked if residue detections are due to occasional misuse. Rescission is appropriate if investigation shows that the TOR decision should not have been issued. Another commenter said that a TOR decision should not be revoked because of availability of a new method that can detect residues resulting from a TOR use.

Agency Response: The Agency agrees that enforcement would generally be a more appropriate regulatory response than revoking a TOR decision when residue detections are due to isolated incidents of misuse. The Agency agrees that rescission is appropriate when new information shows that the TOR should not have been issued. New information, however, may include availability of a new analytical method that can detect residues resulting from a TOR use. In this circumstance, EPA would consider a petition for a tolerance for residues resulting from the TOR use.

G. Should TOR Policy Be Issued as Guidance or as a Rule?

Several commenters (11, 16, 18, 19) urged EPA to issue the TOR policy as a rule. Some commenters recommended that EPA delay issuing the policy as a rule until the Agency has had some experience with the policy. Reasons given for issuing the policy as a rule include: 1) TOR will be applied to section 18 exemptions and the FFDCA requires EPA to issue regulations regarding establishment of tolerances and exemptions for section 18s; 2) a rule clarifies status of the policy and eliminates some procedural grounds for challenging it; 3) criteria for TOR status would appear in CFR with other regulations; and 4) the approach provides an opportunity for stakeholders to comment on the policy. One commenter (8) preferred that EPA issue the policy as guidance rather than as a rule.

US EPA ARCHIVE DOCUMENT

Agency Response: EPA has decided to issue the TOR policy as guidance and to defer issuing the policy as a rule until it has gained a body of experience in using this policy. Furthermore, EPA prefers to begin applying the policy now, rather than waiting until a procedural regulation becomes final. As discussed above in unit I.A.3.b. and c., EPA will issue individual TOR decisions as rules. EPA believes that these regulations will accomplish most of the objectives identified above. EPA acknowledges that it would be more convenient for the public if the criteria for making TOR decisions were located in the CFR with other regulations, but finds that its need for flexibility overrides its desire to codify its TOR decision criteria. To assure that the public has continued access to the latest version of the TOR policy, EPA will maintain a copy of each version of the TOR policy in the public docket for the TOR policy and post the current iteration of the TOR policy on its Internet website.

H. Effects of the Policy on Trade

1. Notification requirement

One comment (6) addressed the U.S. EPA's obligation under FQPA to discuss the impact of its tolerance actions on international trade. The commenter claimed that because a TOR decision is a decision to approve a use without setting a tolerance, it may be the kind of decision for which discussion specified in FFDCA section 408 (b)(4) is required. This provision stipulates that, if EPA's tolerance is established at a level different from a Maximum Residue Level established by the Codex Alimentarius Commission, EPA shall publish for public comment a notice explaining the reasons for departing from the Codex level.

The Canadian government commented that it could support the U.S. EPA's TOR policy provided that the EPA clearly explains its rationale, including the data supporting individual determinations, for not establishing a tolerance.

Agency Response: Because a TOR decision means a tolerance is not necessary under FFDCA section 408 for the residues that may result from the use, EPA believes that the FFDCA section 408 requirements, such as 408(b)(4), do not apply. Nonetheless, EPA plans to publish a rule for each TOR use under FFDCA sections 408(e) and 701. EPA expects that these rules would provide the analysis specified in FFDCA section 408(b)(4). The Agency believes that the notice and comment rule-making for TOR uses would satisfy the concerns of the Canadian government.

2. Potential trade irritant

Several commenters (6, 11, 16) alleged that the TOR policy could produce trade irritants. For example, if a foreign grower uses a pesticide with a TOR clearance, detected residues might occur in the commodity because of some circumstance that was not considered in the U.S. EPA's review of the pesticide. The commodity would be denied entry into the U.S. In another example, if a U.S. grower uses a pesticide with a TOR clearance, commodities with undetected residues

US EPA ARCHIVE DOCUMENT

may be sent to a country where use of the pesticide has not been approved. This could be a trade irritant because it could give U.S. producers an advantage over local producers of the same commodity. One commenter (11) suggested that the proposed TOR policy would not promote harmonization with trading partners because countries who rely on EPA actions when setting their own standards may misunderstand TOR policy. One commenter (6) suggested it would be appropriate for North American Free Trade Agreement (NAFTA) members to develop a position on this issue jointly.

Agency Response: In the first example, foreign food producers or others could apply for a tolerance for the residues on imported commodities. In the second example, the receiving government would have the opportunity to express its concerns in comments to a published notice about EPA's intent to find that a particular pesticide use qualifies for TOR status. EPA will communicate the TOR policy carefully in order to minimize misunderstandings. By publishing individual TOR decisions, EPA would delineate what is covered, and what is not covered, under the U.S. policy.

With respect to the suggestion that the EPA bring the TOR issue to NAFTA, the Agency believes that such consultation is not necessary at this time. EPA's TOR policy does not appear to raise any issues that negatively affect trade among NAFTA partners. Should issues arise, EPA would consider how best to address them.

3. TOR could enhance trade

A State regulatory agency (8) stated that adoption of the TOR policy would enhance trade, especially for treated seed. The State reported that it has registered some seed treatments under section 24(c) of FIFRA for use only on seeds intended for export because there is no U.S. tolerance for the residue on seeds. If EPA finds that such uses are eligible for a TOR determination, the seed-treatment use could be registered under FIFRA section 3 for use throughout the U.S. or under FIFRA section 24(c) for use within the State granting the FIFRA 24(c) registration.

Agency Response: EPA agrees that application of the TOR policy would clarify the need for a tolerance for food grown from treated seeds and may lessen potential barriers to interstate commerce of treated seed. However, the TOR Policy does not seem to have much impact on international trade.

US EPA ARCHIVE DOCUMENT

II. List of Commenters

Number	Name and Affiliation
1-3	EPA-generated documents.
4	(time extension request)
5	Arthur Craigmill et al., *Extension Toxicology Network.*
6	Chris Warfield, *AgrEvo*, Gloucester, Ontario, Canada.
7	Daniel Byrd, *Consultants in Toxicology, Risk Assessment and Product Safety,* Washington, DC.
8	George Robinson, *Idaho State Department of Agriculture*, Boise, ID.
9	(misfiled item from another docket.)
10	Elaine Vargas, *Novigen Sciences*.
11	Priscilla Friedman, *DuPont Agricultural Products,* Wilmington, DE.
12	Blair Wilson, et al., *Food Producers of Idaho, Inc.,* Meridian, ID.
13	Michael Ginevan, *M.E. Ginevan and Associates,* Silver Spring, MD.
14	*Gustafson LLC*.
15	Christian Herr, *Pennsylvania Department of Agriculture,* Harrisburg, PA
16	Dave Whitacre, *Novartis*.
17	John Sullivan, *American Water Works Association,* Washington, DC.
18	Mark Maslyn, *FQPA Implementation Working Group,* Washington, DC.
19	C. A. Franklin, *Health Canada, Pest Management Regulatory Agency,* Ottawa, Ontario, Canada.
20	Stacey Zawel, *Grocery Manufacturers of America,* Washington, DC.
21	(Duplicate of item 4.)

US EPA ARCHIVE DOCUMENT

L1	John Rossner, *Oregon Farm Bureau,* Salem, OR.
L2	John Lincoln, *New York Farm Bureau,* Glenmont, NY.
L3	Jack Laurie, *Michigan Farm Bureau,* Lansing, MI.
L4	Sam Moore, *Kentucky Farm Bureau,* Louisville, KY.
L5	Sharon Hayes, *Dole Food Company, Inc.*, Westlake Village, CA.
L6	Andrew Jovanovich, *Keller and Heckman, LLP*, Washington, DC.
L7	Jean-Mari Peltier, *California EPA/Department of Pesticide Regulation,* Sacramento, CA.

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