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Guidance for Industry

Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations

FINAL GUIDANCE

Comments and suggestions regarding this document may be submitted at any time. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the Docket Number 03D-0263.

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Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations

This guidance represents the Food and Drug Administration’s (FDA’s) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of applicable statutes and regulations. If you want to discuss an alternate approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

This guidance applies to firms in the food production and processing industries that handle food products that may contain residues of certain pesticide chemicals, for which tolerances have been revoked, suspended, or modified by the Environmental Protection Agency (EPA) under the provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996 (Pub. L. No. 104-170 (1996)). In particular, this guidance addresses food that may contain residues of pesticide chemicals for which the aforementioned EPA tolerance action occurred pursuant to the requirements of section 408(l)(2) of the FFDCA as amended by the FQPA.² It is intended to present the Food and Drug Administration’s (FDA) general

¹ This guidance has been prepared by the Division of Plant Product Safety in the Center for Food Safety and Applied Nutrition (CFSAN) at the U.S. Food and Drug Administration.

² §408(l)(2) of the FFDCA states the following:

REVOCATION OF TOLERANCE OR EXEMPTION FOLLOWING CANCELLATION OF ASSOCIATED REGISTRATIONS.--If the Administrator, acting under the Federal Insecticide, Fungicide, and Rodenticide Act, cancels the registration of each pesticide that contains a particular pesticide chemical and that is labeled for use on a particular food, or requires that the registration of each such pesticide be modified to prohibit its use in connection with the production, storage, or transportation of such food, due in whole or

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policy on its planned enforcement approach for foods containing such residues in accordance with the provision in section 408(l)(5) (hereinafter the “channels of trade provision”) of the FFDCA, as amended by the FQPA. This guidance will assist firms in understanding the types of showing under section 408(l)(5) of the FFDCA that FDA may find satisfactory, in accordance with its planned enforcement approach for the channels of trade provision.³

The channels of trade provision⁴ addresses the circumstances under which a food is not unsafe solely because of the presence of a pesticide chemical residue whose tolerance (or exemption therefrom) has been revoked, suspended, or modified by EPA. When EPA takes an action, for example, that makes the use of a pesticide chemical unlawful under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), or lowers or revokes the corresponding tolerance for that pesticide chemical in food, food that was lawfully treated with the pesticide chemical and contains a pesticide chemical residue that does not exceed the previous tolerance, may not have cleared the channels of trade (e.g., may

in part to dietary risks to humans posed by residues of that pesticide chemical on that food, the Administrator shall revoke any tolerance or exemption that allows the presence of the pesticide chemical, or any pesticide chemical residue that results from its use, in or on that food. Subsection (e) shall apply to actions taken under this paragraph. A revocation under this paragraph shall become effective not later than 180 days after--

- (A) the date by which each such cancellation of a registration has become effective; or
- (B) the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation, whichever is later.

³ This is a Level 1 guidance under FDA’s Good Guidance Practices regulation in 21 CFR 10.115. It is a generic guidance that FDA believes will be applicable to most pesticide chemicals that EPA will address. However, FDA may elect to publish a Level 1 guidance for a specific pesticide chemical in conjunction with future EPA tolerance actions if FDA determines that the generic approach in this guidance does not adequately address the pesticide chemical. Although the need for a separate Level 1 guidance for a particular pesticide chemical is expected to be rare, when necessary, FDA will issue such guidance in accordance with its Good Guidance Practices regulation in conjunction with the EPA action on the tolerance.

⁴ The channels of trade provision (§408(l)(5) of the FFDCA) states the following:

PESTICIDE RESIDUES RESULTING FROM LAWFUL APPLICATION OF A PESTICIDE.—

Notwithstanding any other provision of this Act, if a tolerance or exemption for a pesticide chemical residue in or on a food has been revoked, suspended, or modified under this section, an article of that food shall not be deemed unsafe solely because of the presence of such pesticide chemical residue in or on such food if it is shown to the satisfaction of the Secretary that—

- (A) the residue is present as the result of an application or use of a pesticide at a time and in a manner that was lawful under the Federal Insecticide, Fungicide, and Rodenticide Act; and
- (B) the residue does not exceed a level that was authorized at the time of that application or use to be present on the food under a tolerance, exemption, food additive regulation, or other sanction then in effect under this Act;

unless, in the case of any tolerance or exemption revoked, suspended, or modified under this subsection or subsection (d) or (e), the Administrator has issued a determination that consumption of the legally treated food during the period of its likely availability in commerce will pose an unreasonable dietary risk.

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still be in interstate commerce) by the time the revocation or new lower tolerance level takes effect. Such food could be found by FDA to contain a residue of the revoked pesticide chemical or contain an amount of residue that exceeds the new lower tolerance. FDA would normally deem such food to be in violation of the law by virtue of it bearing an illegal pesticide residue. The food would be subject to FDA enforcement action as an “adulterated food” under section 402(a)(2)(B) of the FFDCA. However, the “channels of trade” provision provides an exception to such a finding by FDA provided that certain criteria are met.

This guidance document presents FDA’s general policy for its planned approach to the enforcement of the channels of trade provision with respect to affected pesticide chemicals for which tolerances have been either revoked, suspended or modified pursuant to section 408(1)(2), i.e., after EPA has cancelled the corresponding registration due in whole or part to dietary risk in humans. This guidance is intended to assist firms in understanding the type of showing under section 408(1)(5) of the FFDCA that FDA may find satisfactory in accordance with its planned enforcement approach. Firms should use this guidance document for this purpose except for situations in which the particular pesticide residue is one for which FDA has issued a Level 1 guidance document specifically for that pesticide chemical, e.g., methyl parathion and vinclozolin. FDA has developed this guidance document because, as explained below, it expects EPA to revoke, suspend, or modify the tolerances for several pesticide chemicals on various food commodities pursuant to the requirement of section 408(1)(2) of the FFDCA, as amended by the FQPA. FDA anticipates that some foods bearing such pesticide chemical residues resulting from both lawful domestic and foreign application or use will remain in the channels of trade or be introduced into U.S. commerce after the tolerance revocations, suspensions, or modifications become effective. If FDA encounters such a food, it intends to proceed consistent with the policy set forth in this guidance document.

This guidance document does not address enforcement of the channels of trade provision for residues of pesticide chemicals in food for which tolerances were revoked, suspended or modified by EPA, but for which the EPA tolerance action was not required pursuant to section 408(1)(2), i.e., tolerance actions not stemming from cancellation of a corresponding registration due to dietary risk considerations. For example, EPA may revoke the tolerances for a pesticide chemical in food because the registrant has requested that its registration be cancelled due to the cessation of its production. EPA’s policy is to allow time for food that may bear residues of such pesticide chemicals to clear the channels of trade prior to acting to revoke, suspend or modify the tolerance. As such, FDA believes that it is not likely to find such pesticide chemical residues in food following the EPA tolerance action. For these reasons FDA is not providing guidance for such situations. However, should FDA find a residue of such a pesticide chemical in a food for which the applicable tolerance has been revoked, suspended or modified apart from any consideration stemming from dietary risk to humans, the holders of the food are entitled under the channels of trade provision to make a showing that the residue is present as a result of a lawful application or use of the pesticide chemical. FDA intends to handle any such situations on a case-by-case basis.

This guidance document has been developed for situations involving the potential

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application of the channels of trade provision to human food and not animal feed. Any matter that might arise involving the potential application of the channels of trade provision to animal feed would be handled by FDA’s Center for Veterinary Medicine (CVM). To date, CVM has not developed guidance on this matter, and would currently handle any such situation on a case-by-case basis.

FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations unless specific regulatory or statutory requirements are cited. The use of the word “should” in Agency guidances means that something is suggested or recommended, but not required.

Background

Regulation of Pesticides

Pesticides are widely used to treat fruits, vegetables, grains, and other foods, and may be present in small amounts, as residues, after treatments. Before a pesticide may be sold in the United States, EPA evaluates the pesticide and determines whether or not to grant a registration that permits its sale and use.

Before allowing the use of a pesticide chemical on food crops, the EPA, under section 408 of the FFDCa, establishes a tolerance (maximum residue level), which is the amount of residue allowed to remain in or on each treated food commodity, or it establishes an exemption from the requirement of a tolerance for the pesticide chemical. Without a tolerance or exemption from a tolerance, food containing a pesticide chemical residue is considered adulterated under section 402(a)(2)(B) of the FFDCa and may not be introduced or delivered for introduction into interstate commerce (which includes importation into the U.S.). With the exception of meat, poultry, and certain egg products, for which the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) is responsible, FDA is charged with enforcing pesticide chemical tolerances in imported food and in domestically-produced food shipped in interstate commerce.

Impact of the Food Quality Protection Act (FQPA)

On August 3, 1996, the FQPA was signed into law. This law, which amends both FIFRA and the FFDCa, established a new safety standard for pesticide chemical residues in food, with an emphasis on protecting the health of infants and children. In accordance with the FQPA, EPA is in the process of reassessing, under the new safety standard, the pesticide chemical tolerances and exemptions that were in effect when the law was signed. If EPA makes a determination that a pesticide chemical's tolerance level does not meet the safety standard set forth by the FQPA, the registration for the pesticide chemical may be canceled for all or some uses. In addition, the tolerances for that pesticide chemical may be lowered or revoked for the corresponding food commodities. As noted above, under section 408(l)(2) of the FFDCa, when the registration for a pesticide chemical is canceled or modified due in whole or in part to dietary risks to humans posed by residues of that pesticide chemical on food, the effective date for the revocation of the tolerance (or exemption in some cases) must be no later than 180 days after the date the

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cancellation becomes effective or 180 days after the date on which the use of the canceled pesticide chemical becomes unlawful under the terms of the cancellation, whichever is later.

Planned Enforcement Approach⁵

In order to avoid possible regulatory action against a food containing a residue of a pesticide chemical that is subject to the channels of trade provision, the party responsible for the food must, under section 408(l)(5) of the FFDCFA, demonstrate that the residue is present as a result of a lawful application or use of the pesticide chemical and that the residue does not exceed a level that was authorized at the time of that application or use.

Single Ingredient Foods

The following four examples illustrate FDA’s planned enforcement approach for single ingredient foods.

FDA may determine for a certain period of time following an EPA action, such as revoking, suspending, or modifying a pesticide chemical tolerance, that it is a reasonable exercise of FDA’s enforcement discretion to consider that a residue of that pesticide chemical found by FDA in a specific food, that is within the former tolerance, is the result of the lawful application or use of the pesticide chemical on the food. In such cases, FDA does not intend to ask the responsible party to make a showing to demonstrate that the residue is present as a result of a lawful application or use of the pesticide chemical, and does not intend to take regulatory action against the food on the basis of the presence of the pesticide chemical residue.⁶

1. For example, assume that EPA cancels the pesticide registration and use of pesticide XYZ on carrots effective January 1, 2005 and, in addition, revokes the tolerance for the pesticide chemical XYZ on carrots, effective on July 1, 2005. If FDA determines that, based upon the known degradation rate of pesticide chemical XYZ on fresh carrots, residues of pesticide chemical XYZ will degrade to non-detectable levels no later than 9 months after it is applied to carrots, i.e., no later than October 1, 2005, for any residue of pesticide chemical XYZ resulting from application on or before the last lawful use date of January 1, 2005, FDA believes that it is a reasonable exercise of its enforcement discretion to consider that fresh carrots found by FDA to contain residues of pesticide chemical XYZ within the former tolerance from July 1, 2005 through October 1, 2005, are not adulterated solely because of the presence of the XYZ pesticide chemical residue.⁷

⁵ FDA intends in its enforcement approach to use the methods for pesticide analysis cited in FDA’s compliance programs for pesticide residues in domestic and imported foods. The currently cited methods are those in the FDA Pesticide Analytical Manual (PAM) I, Sections 302, 303 and 304. The methods are available at www.cfsan.fda.gov under “Pesticides and Chemical Contaminants.”

⁶ As explained later in this guidance, FDA would determine in a Level 2 guidance document for any given pesticide tolerance revocation, suspension, or modification, what period of time FDA believes may be reasonable for the FDA to consider the presence of a pesticide chemical residue in a food to not be subject to a showing under § 408(l)(5) of the FFDCFA.

⁷ Although the examples in this guidance concern pesticide chemicals that are applied to food, e.g., by growers, the approaches in the examples would also be applicable to any pesticide chemical for which a

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If fresh carrots were found to contain a residue of pesticide chemical XYZ after October 1, 2005, in that instance it would appear, based upon the degradation rate of the pesticide chemical, that the application of the pesticide chemical to the carrots was made after the last lawful use date, i.e., after January 1, 2005, and the carrots would be subject to possible regulatory action. While the party responsible for the carrots would have the right under the law to make a showing that the residue is present as a result of a lawful application or use of the pesticide chemical, FDA does not expect that the responsible party would be able to make such a showing because no residues of lawfully applied pesticide chemical XYZ on fresh carrots would be expected to be detectable after October 1, 2005, based upon the degradation rate of the pesticide chemical.

2. It is possible that a situation could occur for another hypothetical pesticide, e.g., pesticide chemical ABC used on carrots, for which the dates of EPA action (cancellation of registration, last lawful use date and tolerance revocation) are the same as in the above example for pesticide chemical XYZ. However, the residues of pesticide chemical ABC in carrots do not degrade to undetectable levels as did residues of pesticide chemical XYZ, but rather remain at detectable levels on carrots during their entire storage and retail time period. In such a situation, FDA would determine when carrots treated on the last lawful use date, January 1, 2005, likely would be harvested, stored, and offered for sale. FDA would then determine the last date upon which the carrots would be offered for sale. For example, FDA might determine that the carrots treated on January 1, 2005, would be harvested by April 1, 2005, may be stored for 6 months (through October 1, 2005), and then may be offered for sale for 3 additional months, (through January 1, 2006). Under these circumstances FDA believes that it would be a reasonable exercise of its enforcement discretion to consider that fresh carrots found to contain residues of pesticide chemical ABC within the former tolerance from July 1, 2005 (the date of revocation of the tolerance) through January 1, 2006, are not adulterated solely because of the presence of the ABC pesticide chemical residue.⁸

If fresh carrots were found by FDA to contain a residue of pesticide chemical ABC after January 1, 2006, in that instance it would appear, based upon the last expected date of sale for fresh carrots lawfully treated with pesticide chemical ABC, that the application of the pesticide chemical to the carrots was made after the last lawful use date, i.e., after January 1, 2005, and the carrots would be subject to possible regulatory action. While the party responsible for the carrots would have the right under the law to make a showing that the residue is present as a result of a lawful application or use of the pesticide chemical, FDA does not expect that the responsible party would be able to make such a showing because no residues of lawfully applied pesticide chemical ABC on

tolerance was formerly in effect permitting residues in food resulting from uses in which the food was not directly treated, e.g., a revoked tolerance for residues of a pesticide chemical in food resulting from the application of the pesticide to cracks and crevices in food storage facilities.

⁸ The approaches in examples 1 and 2 are generally applicable to other foods that are stored for various periods of time, such as grains and processed foods. Depending upon the food, FDA would consider its maximum storage period and the degradation rate for the pesticide chemical in determining the time period during which the food generally would not be considered adulterated solely because of the presence of the pesticide chemical residue.

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fresh carrots would be expected to be found after January 1, 2006.

There are two general exceptions to the circumstances in examples 1 and 2 in this section under which FDA does not intend to typically consider that a pesticide residue found in a specific food, that is within the former tolerance, is the result of the lawful application or use of the pesticide chemical on the food. The first exception is the circumstance in which FDA has information indicating that there is a reasonable possibility that the residue resulted from an unlawful application or use of the pesticide chemical, e.g., an application of pesticide chemical XYZ to carrots after January 1, 2005, in example 1 above. Such information might be provided to FDA by another government agency with jurisdiction over pesticide usage that has concluded that an unlawful application or use of a pesticide chemical on a food crop took place. In such a circumstance, FDA does not intend to exercise its enforcement discretion as previously stated. Rather, FDA intends to ask the party responsible to show that the food complies with the channels of trade provision in order to avoid regulatory action against the food. In such cases, FDA plans to inform the responsible party that the food may be in violation of the FFDCA, and provide an opportunity for the party to respond and provide documentation demonstrating that the residue in the food resulted from a lawful application or use of the pesticide chemical on the food.

The second exception is the circumstance in which the food found to bear a residue of a given pesticide chemical is derived from a crop that was necessarily grown after the last lawful use date for that pesticide chemical on that food, as indicated by factors such as the growing season and shelf-life of the food in question. Based upon generally recognized agronomic principles (when crops are grown), and farm-to-market time requirements for agricultural commodities (shelf life), it is possible in certain instances to identify foods, such as certain items of fresh produce, that are grown after a certain date, (after the last lawful use date of a pesticide chemical). Food derived from any crop that is grown after the last lawful use date for a pesticide chemical on that food cannot meet the requirements of the channels of trade provision for residues of that pesticide chemical, because the application or use of the pesticide chemical on that food was unlawful. Thus, if FDA encounters a residue of such a pesticide chemical on any such food, FDA intends to subject that food to possible regulatory action.

In some cases, FDA may be unable to exercise enforcement discretion concerning the presence of a pesticide chemical residue without asking the responsible party to make a showing to demonstrate that the residue is present as a result of a lawful application or use of the pesticide chemical. The following two examples are illustrative.

3. Expanding upon the example for pesticide chemical XYZ and carrots, assume that FDA determines that degradation of residues of this pesticide chemical does not continue once carrots have been frozen. If FDA were to find a residue of pesticide chemical XYZ in frozen carrots in December of 2005, FDA would need additional information before it could conclude that the residue was present as the result of a lawful application or use of the pesticide chemical, and that the food is within the scope of FDA’s exercise of its enforcement discretion set forth in this guidance. FDA intends to give the party

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responsible for the carrots an opportunity to provide that information, which could be done by showing FDA documentation that the carrots were either purchased from the grower, processed, e.g., peeled or frozen, or packed on or before a date referred to hereafter as the “showing date,” which in this example is October 1, 2005 (see discussion below on how FDA intends to determine showing dates). This information would allow FDA to conclude that the residue was present as a result of a lawful application or use of the pesticide chemical because it would demonstrate that fresh carrots bearing the residue were handled by the processor on or before the showing date, i.e., during the time period when residues resulting from the lawful application of pesticide chemical XYZ would be expected to be present on the carrots. In the absence of a showing by the processor such as the one described in this example, FDA intends to subject the carrots to possible regulatory action.

4. If FDA found a residue of pesticide chemical ABC on frozen carrots in March 2006, FDA would need additional information before it could conclude that the residue was present as the result of a lawful application or use of the pesticide chemical, and that the food is within the scope of FDA’s exercise of its enforcement discretion set forth in this guidance. FDA intends to give the party responsible for the carrots an opportunity to provide that information, which could be done by showing FDA documentation that the carrots were either purchased from the grower, processed, e.g., peeled or frozen, or packed on or before the showing date, which in this example is January 1, 2006 (see discussion below on how FDA intends to determine showing dates). This information would allow FDA to conclude that the residue was present as a result of a lawful application or use of the pesticide chemical because it would demonstrate that fresh carrots bearing the residue were handled by the processor on or before the showing date, i.e., during the time period when residues resulting from the lawful application of pesticide chemical ABC would be expected to be present on the carrots. In the absence of a showing by the processor, such as the one described in this example, FDA intends to subject the carrots to possible regulatory action.

Multiple Ingredient Foods

The following five examples illustrate FDA’s planned enforcement approach for multiple ingredient foods.

1. If FDA finds a residue of a pesticide chemical in a multiple ingredient food, for which all ingredients were subject to an EPA tolerance revocation, suspension or modification, and that residue amount does not exceed the amount that would have been permitted under any of the former tolerances (based upon the amount of each ingredient in the food), the responsible party would need to demonstrate that at least one of the ingredients in the food could bear the pesticide residue as a result of a lawful application or use of the pesticide chemical. Such a demonstration could be accomplished by providing records showing that the finished product was packed on or before the showing date for such ingredient, or if packing occurred after that date, a firm could provide records showing that at least one of the ingredients was handled by the processor on or before the showing date for the ingredient. For example, assume that EPA revokes the tolerance of pesticide chemical XYZ in peaches, grapes, and melons, and FDA establishes a showing date of

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March 1, 2005, for residues of this pesticide chemical in these three foods when frozen. If FDA finds a residue of pesticide chemical XYZ in a frozen fruit salad that contains only peaches, grapes, and melons, and that residue does not exceed the amount that would have been permitted under any of the former tolerances (based upon the amount of each ingredient in the food), the responsible party could make a showing that the fruit salad was packed on or before March 1, 2005. Alternatively, the party could make a showing that one of these three ingredients was placed into frozen inventory on or before that date. This information would allow FDA to conclude that the residue was present as a result of a lawful application or use of the pesticide chemical because it would demonstrate that an ingredient that could lawfully bear the residue was handled by the processor on or before its showing date, i.e., during the time period when residues resulting from the lawful application of pesticide chemical XYZ would be expected to be present on the ingredient. In the absence of a showing by the processor, such as the one described in this example, FDA intends to subject the food to possible regulatory action.

2. If the amount of the pesticide chemical residue found in the multiple ingredient food in the last example exceeded the level permitted under one of the former tolerances (based upon the amount of that ingredient in the food), but did not exceed the total amount that would have been permitted under all of the former tolerances, the responsible party could not make a showing with respect to only one ingredient as provided in the previous paragraph, if that ingredient was the one for which the amount of the residue in the food exceeded that which would have been permitted under the former tolerance. In such a case, to be within the scope of FDA’s exercise of enforcement discretion under this guidance, FDA anticipates that the responsible party would need to make a showing that would account for the residue in at least one additional ingredient of the food. In addition, the total residue amount in the food would have to have been permitted under the former tolerances for the ingredients for which the showing is made (based upon the amounts of those ingredients in the food). Such a demonstration could be accomplished by providing records showing that the finished product was packed on or before the earliest showing date for all affected ingredients, or if packing occurred after that date, a firm could provide records showing that two or more of the individual ingredients were placed in frozen inventory by the processor on or before their respective showing dates. This information would allow FDA to conclude that the residue was present as a result of a lawful application or use of the pesticide chemical because it would demonstrate that ingredients bearing the residue at permitted levels were handled by the processor on or before their showing dates, i.e., during the time period when residues resulting from the lawful application of the pesticide chemical would be expected to be present on the ingredients. In the absence of a showing by the processor such as the one described in this example, FDA intends to subject the food to possible regulatory action.

3. If FDA finds a residue of a pesticide chemical in a multiple ingredient food for which one or more of the ingredients are subject to an EPA tolerance revocation, suspension, or modification concerning that pesticide chemical, and other ingredients are subject to current tolerances for that pesticide chemical, FDA does not intend to regard such a situation as falling under the channels of trade provision if the amount of the residue in the food complies with the current tolerance or tolerances (based upon the amount of

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each ingredient in the food). For example, if EPA revoked the tolerance for pesticide chemical ABC in strawberries, but a tolerance remained in effect for pesticide chemical ABC in melons, and FDA found a residue of pesticide chemical ABC in a fruit salad containing strawberries and melons, which was within the tolerance for melons (based upon the amount of melons in the food), FDA does not intend to regard such a situation as falling under the channels of trade provision and does not intend to ask the responsible party to make a showing that the food is within the scope of FDA’s exercise of its enforcement discretion set forth in this guidance.⁹

4. If the amount of the residue of pesticide chemical ABC in the last example exceeded the current tolerance for pesticide chemical ABC in melons (based upon the percentage of melons in the fruit salad), but did not exceed the total amount that would have been lawful under the current and former tolerances, e.g., for strawberries and melons, the responsible party should be prepared to make a showing with respect to the strawberry ingredient to enable FDA to conclude that the food is within the scope of FDA’s exercise of its enforcement discretion set forth in this guidance.

5. If FDA finds a residue of a pesticide chemical in a multiple ingredient food for which one or more of the ingredients are subject to an EPA tolerance revocation, suspension, or modification concerning that pesticide chemical, and the remaining ingredients are not subject to current or former tolerances for that pesticide chemical, the responsible party should be prepared to make a showing with respect to one or more of the ingredients that are subject to the EPA tolerance action (as in examples 1 and 2 in this section) to enable FDA to conclude that the food is within the scope of FDA’s exercise of its enforcement discretion set forth in this guidance. FDA does not intend to ask the responsible party to provide additional documentation showing that the ingredients not subject to current or former tolerances did not contain residues of the affected pesticide chemical.

Imported Foods

In the interest of fairness, FDA intends to subject the importation of any food bearing a residue (within the former tolerance) of a pesticide chemical for which a tolerance has been revoked, suspended, or modified to the same enforcement approach as that set forth in this guidance document for a domestic food.

The following three examples illustrate how FDA intends to exercise its enforcement discretion for the imported commodities as illustrated in the following three examples:

1. Further expanding on the example for pesticide chemical XYZ on fresh carrots in example #1 under "Single Ingredient Foods", if carrots are offered for import in August 2005 and are found by FDA to contain a residue of pesticide chemical XYZ within the former tolerance, FDA intends to consider, as a matter of its enforcement discretion, the importation of such a food to be a result of the lawful application or use of pesticide chemical XYZ. Consequently, FDA does not plan to deem such food to be adulterated.

⁹ However, if FDA had other evidence indicating that the residue of pesticide ABC in the fruit salad was due to the ingredient for which the tolerance had been revoked, e.g., strawberries, the responsible party should be prepared to make a showing with respect to the strawberry ingredient to enable FDA to conclude that the food is within the scope of FDA’s exercise of its discretion set forth in this guidance.

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FDA does not plan to ask the party responsible for such food to make a showing that the food in question is within the scope of FDA’s exercise of its enforcement discretion set forth in this guidance. Instead, the agency intends to consider the food to be in compliance with the channels of trade provision.

2. However if the carrots are offered for import in December 2005 and are found to contain a residue of pesticide chemical XYZ that is within the former tolerance, FDA intends to detain the food. In such cases, FDA intends to inform the responsible party that the food appears to be in violation of the FFDCA. While the party responsible for the carrots could attempt to make a showing that the residue is present as a result of an application or use of the pesticide chemical on or before January 1, 2005, for the same reasons discussed above in example #1 under "Single Ingredient Foods," regarding domestic carrots under similar circumstances, FDA does not expect that the responsible party would be able to make such a showing.

3. Continuing with the example of pesticide chemical XYZ and carrots, if frozen carrots are offered for import in December 2005, and are found at that time by FDA to contain a residue of pesticide chemical XYZ within the former tolerance, FDA intends to detain the entry. FDA intends to, as a matter of its enforcement discretion, consider releasing the entry only if the responsible party provides the same type of documentation that FDA would consider under its policy for the comparable domestic food, i.e., documentation that the carrots were either purchased from the grower, processed, e.g., peeled or frozen, or packed on or before October 1, 2005.

General Considerations

FDA intends to afford firms the opportunity to make a showing through the last date that FDA anticipates that food made from lawfully treated commodities will remain in the channels of trade. For certain processed foods, i.e., frozen, dried, and canned foods, this date will generally be 4 years from the time the treated crop is harvested.¹⁰

FDA also advises firms that they may include in showings, data on a pesticide chemical’s degradation, its last application date, or the time period that a food remains in commerce, etc., that are different from the data that FDA used in establishing its enforcement policy concerning a specific pesticide chemical residue in food. FDA will evaluate the data presented by the firm on its own merit, and will not deem the food to be adulterated if the showing of the firm meets the requirements of the channels of trade provision, even if such showing does not on its face satisfy the parameters of FDA’s enforcement policy for that pesticide chemical/food combination.

It should be noted that the opportunity to make a showing under the channels of trade provision is not provided under the FFDCA for food bearing pesticide chemical residues

¹⁰ Based upon information referenced in the guidance document entitled “Channels of Trade Policy for Commodities with Methyl Parathion Residues,” the availability of which was announced in the Federal Register on January 5, 2001 (66 FR 1247), certain processed foods (frozen, dried and canned) may remain in the channels of trade for up to 4 years after the crop is harvested.

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that are not potentially subject to the channels of trade provision, such as when the residue of a revoked pesticide chemical in a food exceeds the prior tolerance for the food or when a residue of a pesticide chemical is found in a food for which no tolerance ever existed.

How FDA will Determine Showing Dates

FDA intends to consider the following factors in determining the showing dates:

1. If the degradation rate of the pesticide chemical on a fresh food is known, it is possible to determine when residues resulting from application or use on the last lawful use date will diminish to non-detectable levels in a fresh food from which a processed food is prepared. In such a situation, FDA is likely to designate the showing date for the processed food as the last date on which a residue resulting from a lawful application or use of the pesticide chemical would be detectable in the fresh food. In example #3 under Single Ingredient Foods above, the hypothetical showing date for frozen carrots with a residue of pesticide chemical XYZ, i.e., October 1, 2005, is illustrative of this approach inasmuch as it is the last date upon which residues of lawfully applied pesticide chemical XYZ would be expected to be detectable on fresh carrots as described in example #1 under Single Ingredient Foods above.
2. If residues of a pesticide chemical do not degrade to non-detectable levels on a food, but remain at detectable levels during the entire time that the food remains in the channels of trade in fresh and processed form, FDA is likely to designate the showing date for the processed food as a date derived by allowing a reasonable time for the lawfully treated fresh produce to clear the market. In example #4 under Single Ingredient Foods above, the hypothetical showing date for frozen carrots with a residue of pesticide chemical ABC, i.e., January 1, 2006, is illustrative of this approach inasmuch as it is the last projected date of sale for fresh carrots lawfully treated with pesticide chemical ABC, as described in example #2 under Single Ingredient Foods above.
3. In some instances, the showing date may be a date before the date of revocation of the tolerance. This could occur in the case of a highly perishable food, e.g., strawberries, bearing a pesticide chemical residue that does not degrade to non-detectable levels, e.g., pesticide chemical ABC. In such a case, FDA intends to use the approach in the previous paragraph, i.e., the showing date would be a date derived by allowing a reasonable time for the lawfully treated produce to clear the market. For example, if EPA establishes January 1, 2005, as the last lawful use date for pesticide chemical ABC on strawberries, and revokes the tolerance for pesticide chemical ABC on strawberries on July 1, 2005, FDA may determine that strawberries treated on the last lawful use date will be harvested and sold to processors or consumers no later than May 1, 2005. The showing date for processed strawberries, e.g., frozen strawberries bearing a residue of pesticide chemical ABC would be May 1, 2005, but FDA would not request a showing under the channels of trade provision for frozen strawberries found to contain residues of pesticide chemical ABC until the effective date of the tolerance revocation, i.e., after July 1, 2005.

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How FDA will Publish Information about Specific Pesticides

For each pesticide chemical that is to be the subject of an EPA tolerance revocation, suspension, or modification pursuant to section 408(l)(2) of the FFDCA, FDA intends to publish on our website, as a Level 2 guidance, the showing dates we intend to use for affected food commodities with a residue of that pesticide chemical. At the same time, we intend to also publish on our website, as part of the Level 2 guidance, any other determinations we have made about residues of the pesticide chemical, such as time periods during which we intend to consider that a pesticide chemical residue found in a food is the result of lawful application or use and thus needs no showing. In addition, when appropriate, we intend to publish as part of the Level 2 guidance, the last date that we anticipate that lawfully treated commodities, fresh and processed, would remain in the channels of trade. We intend to post the Level 2 guidance on the FDA pesticides website (<http://www.cfsan.fda.gov/~lrd/pestadd.html>) in conjunction with EPA's proposed action concerning the pesticide chemical. EPA's proposal will generally refer readers to this website to view the applicable Level 2 guidance. Under our Good Guidance Practices regulation in 21 CFR 10.115, persons may comment on the guidance document at any time and, as appropriate, FDA will revise the document in response to the comments. Should EPA's final action differ from its proposal in a way that impacts the guidance, FDA intends to revise the guidance document as appropriate.

Examples of Documentation that May be Useful to Show Applicability of the Channels of Trade Provision

In general, for foods containing residues of pesticide chemicals for which tolerances have been revoked, suspended, or modified under the FFDCA, either in domestic commerce or offered for import, FDA anticipates that the party responsible will be able to provide appropriate documentation to the agency in the event that such food bears a residue of the pesticide chemical that is within the former tolerance for that food, consistent with the principles set forth in this guidance. Examples of documentation that may be appropriate for foods that are found to have residues of such pesticide chemicals within the former tolerance are provided in this section. We are not suggesting that firms maintain a certain set list of documents where anything less or different would likely be considered unacceptable. We are leaving it to each firm's discretion to maintain appropriate documentation to demonstrate that the food is subject to the channels of trade provision. Listed below are some examples of types of documentation that FDA may find acceptable for demonstrating that a food meets the requirements of the channels of trade provision:

1. Dated invoices, bills of sale, airway bills, customs entry forms, etc., may all be helpful in establishing channels of trade applicability. For example, a bill of sale could be provided to indicate that a processor purchased carrots from a grower on or before the showing date for pesticide chemical XYZ on carrots to demonstrate that the processor handled the carrots during the period of time that FDA believes is reasonable to consider the exercise of its enforcement discretion.
2. If a product's label bears a packing code and the firm supplies documentation that relates that code to a packing date, we intend to regard such documentation as indicating

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that the food was packed on the indicated date. This packing date documentation could be provided to indicate that a processor packed carrots on or before the showing date for pesticide chemical XYZ on carrots to demonstrate that the processor handled the carrots during the period of time that FDA believes is reasonable to consider the exercise of its enforcement discretion.

3. If a product’s label bears a packing code and the firm supplies documentation that relates that code to a batch record indicating a date on which the product was processed, e.g., peeled, blanched, frozen, we plan to regard such documentation as indicating that the food was processed on the indicated date. Batch records may also be combined with inventory records to demonstrate that the ingredients used to manufacture the food were purchased by a specified date. The batch records and inventory records could be provided to indicate that a processor processed or purchased carrots on or before the showing date for pesticide chemical XYZ on carrots to demonstrate that the processor handled the carrots during the period of time that FDA believes is reasonable to consider the exercise of its enforcement discretion.