

Guidance for Industry

Channels of Trade Policy for Commodities with Vinclozolin Residues

DRAFT GUIDANCE

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Channels of Trade Policy for Commodities with Vinclozolin Residues

Draft Guidance

This draft guidance represents FDA's current thinking on the channels of trade provision and how this provision relates to FDA-regulated products with vinclozolin residues. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of applicable statutes and regulations. The draft guidance is being distributed for comment purposes in accordance with FDA's Good Guidance Practices (65 FR 56468; September 19, 2000).

Purpose

This guidance applies to firms in the food production and processing industries who handle food products that may contain residues of the pesticide chemical "vinclozolin." It is intended to present the Food and Drug Administration's (FDA's) policy on its planned enforcement approach for foods containing vinclozolin residues in accordance with the provision in section 408(l)(5) (hereinafter the "channels of trade provision") 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)). As such, this guidance will assist firms in understanding the types of showing under the channels of trade provision that FDA may find satisfactory, in accordance with its planned enforcement approach for such section.

The channels of trade provision¹ 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not unsafe solely because of the presence of a pesticide chemical residue whose tolerance (or exemption therefrom) has been revoked, suspended, or modified by the Environmental Protection Agency (EPA). When EPA takes an action, for example, that makes the use of a pesticide unlawful under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), or lowers or revokes the corresponding tolerance for that pesticide in food, such food that was lawfully treated with the pesticide and contains a pesticide chemical residue that does not exceed the previous tolerance, may not have cleared the channels of trade (e.g., may 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 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 policy for its planned approach to the enforcement of the channels of trade provision with respect to the pesticide chemical vinclozolin, and it is intended to assist firms in understanding the type of showing under

¹ The channels of trade provision 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 the 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.

the channels of trade provision that FDA may find satisfactory in accordance with its planned enforcement approach for such section. FDA has developed this guidance document because, as explained below, EPA has proposed to revoke the tolerances for this pesticide chemical on bell peppers, cucumbers, strawberries and stonefruit as quickly as possible after consideration of comments (see [REDACTED]). FDA anticipates that some of these foods bearing vinclozolin residues resulting from both lawful domestic application, and foreign application of this pesticide chemical will remain in the channels of trade after the tolerance revocations become effective. If FDA encounters such a food, it intends to invoke the channels of trade provision of FQPA consistent with its policy as set forth in this guidance document.

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 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. Without a tolerance or exemption from a tolerance, food containing pesticide residues 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 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 the FIFRA and the FFDCA, established a new safety standard for pesticide 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 tolerances and exemptions that were in effect when the law was signed. If EPA makes a determination that a pesticide's tolerance level does not meet the safety standard set forth by FQPA, the registration for the pesticide may be canceled for all or some uses. In addition, the tolerances for that pesticide may be lowered or revoked for the corresponding food commodities. Under section 408(l)(2) of the FFDCA, when the registration for a pesticide 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 such tolerance (or exemption in some cases) must be no later than 180 days after the date such cancellation becomes effective or 180 days after the date on which the use of the canceled pesticide becomes unlawful under the terms of the cancellation, whichever is later.

Tolerance Reassessment for Vinclozolin

As stated by EPA in its proposed rule to revoke certain vinclozolin pesticide tolerances ~~(insert FR cite from EPA proposal)~~, during a 1998 review of the vinclozolin toxicology data base, EPA determined that an additional tenfold margin of safety, as specified in the FQPA, was required to protect the safety of infants and children. Based on EPA's assessment of the acute dietary risk posed by vinclozolin, the use of the additional tenfold margin of safety rendered aggregate risk to vinclozolin under existing use patterns unacceptable. On July 30, 1998, EPA published a notice in the Federal Register (63 FR 40710-40712) announcing the cancellation of the FIFRA registered uses for the pesticide vinclozolin on strawberries and stonefruits. In the notice, EPA stated that BASF Corporation, the sole registrant for vinclozolin, had requested amendment of its registrations to terminate the use of vinclozolin on strawberries and stonefruits in June 1998, in response to potential action by EPA to revoke tolerances and cancel registrations due to unacceptable dietary risk. That notice informed the public of how it could

comment on the request for cancellation. One comment was received in response to the proposal, submitted on behalf of the California Strawberry Commission. This comment was fully addressed in a subsequent Federal Register Notice (63 FR 59557-59558) published by EPA on November 4, 1998 which announced the approval, with one minor change, of the proposed existing stocks provision for products containing vinclozolin. Under limitations on the use of existing stocks, the application of the pesticide vinclozolin on strawberries and stonefruit became unlawful after January 30, 2000.

Additional dietary and aggregate risk concerns were identified by EPA in 2000 when vinclozolin was reevaluated for the purposes of reregistration. Subsequent to this reevaluation, EPA decided to propose to revoke the pesticide tolerances for vinclozolin on bell peppers and cucumbers,² in addition to the pesticide tolerances for vinclozolin on strawberries and stonefruit, as quickly as possible after consideration of comments.

Vinclozolin Residues in Foods Resulting from Legal Application to Strawberries and Stonefruit

FDA believes that strawberries or stonefruit to which vinclozolin was applied on or before the last date domestic application was lawful under FIFRA, i.e., on or before January 30, 2000, have been sold to the ultimate consumer as fresh produce, or have undergone commercial processing, and possibly even final packing by July 1, 2000. This allows for a period of time between application of the pesticide and harvest of these crops, taking the length of their growing seasons into account. It also allows for a period of time after harvest of the crop, for its distribution and sale to consumers or food processors, taking into account the perishable nature of these commodities. Thus, by the date of publication of this guidance document, strawberries and stonefruit with lawful residues, available for sampling and analysis under FDA's pesticide residue monitoring program, should have been incorporated into processed food products. Based upon information provided to FDA by EPA (Ref. 1), vinclozolin residues present on

² Vinclozolin is not registered for use on bell peppers and cucumbers in the U.S. The tolerances for vinclozolin on bell peppers and cucumbers provided for the importation of these commodities with vinclozolin residues.

strawberries or stonefruit at the time of processing may persist in the processed/packed food for an indeterminate time and may be detectable upon analysis of that food while that food remains in the channels of trade.³

Vinclozolin residues on cucumbers and bell peppers

Since vinclozolin is not registered for use on bell peppers and cucumbers in the U.S., only imported cucumbers and bell peppers will be affected by EPA's proposal to revoke the tolerances for vinclozolin on such products. FDA believes that bell peppers and cucumbers that bear residues of vinclozolin and that will be imported into the U.S. before the proposed tolerance revocations become effective will either be consumed as fresh produce or will be further processed within three months of the effective date of the tolerance revocations. This allows for a period of time after importation of these commodities, for their distribution and sale to consumers or food processors, taking into account the perishable nature of these commodities. Based upon information provided to FDA by EPA (Ref. 1), vinclozolin residues present on bell peppers or cucumbers at the time of processing may persist in the processed/packed food for an indeterminate time and may be detectable upon analysis of that food while that food remains in the channels of trade.

Planned Enforcement Approach: Strawberries and Stonefruit⁴

1. Fresh strawberries and stonefruit

If FDA finds a residue of vinclozolin on fresh strawberries or fresh stonefruit in domestic commerce on or after the effective date of the revocation of the pesticide tolerances for vinclozolin in such produce, FDA intends to subject the food to regulatory action. FDA

³ 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.

⁴ In following this enforcement approach, FDA intends to use the methods for vinclozolin 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."

plans to consider that the residue is present as a result of an application of vinclozolin that was not lawful under FIFRA, i.e., applied after January 30, 2000. Similarly, if FDA finds a residue of vinclozolin on fresh strawberries or fresh stonefruit offered for import on or after the effective date of the revocation of the pesticide tolerances for vinclozolin in such produce, FDA does not intend to allow importation of the food.

2. Processed strawberries and processed stonefruit

If FDA finds a residue of vinclozolin on processed strawberries or processed stonefruit in domestic commerce on or after the effective date of EPA's revocation of the tolerances for vinclozolin, and such residue is within the former tolerance, FDA intends to ask the party responsible to show that the food is within the scope of FDA's exercise of its enforcement discretion set forth in this guidance in order to avoid regulatory action against the food. In such cases, FDA intends to inform the responsible party that the food may be in violation of the FFDCA, and provide an opportunity for the party to provide documentation demonstrating that the food was packed or processed on or before July 1, 2000. FDA intends to afford firms the opportunity to make such a showing until July 1, 2004. FDA does not believe that processed strawberries and stonefruit with lawfully applied residues of vinclozolin will be in the channels of trade after that date (see footnote #3). Similarly, during the same time period, if FDA finds a residue of vinclozolin that is within the former tolerance, on processed strawberries or processed stonefruit offered for import, 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 this policy for domestic processed food, i.e., documentation that the product was packed or processed on or before July 1, 2000.

3. Multiple ingredient processed foods containing strawberries or stonefruit

If FDA finds a residue of vinclozolin in a multiple ingredient food containing only strawberries and stonefruit, to be within the scope of FDA's exercise of enforcement discretion under this guidance, the responsible party would need to demonstrate that at least one of the ingredients in the food could bear the vinclozolin residue at the level found as a result of a lawful application or use of this pesticide chemical. In the case of a food such as a fruit salad, in which the amount of the vinclozolin residue found was below the former tolerance for strawberries and stonefruit, such a demonstration could be

accomplished by providing records showing that the finished product was packed prior to July 1, 2000, 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 prior to July 1, 2000. In such a case for a frozen strawberry-peach fruit salad, if the responsible party can make this showing with respect to the peach ingredient, FDA does not intend to ask the responsible party to provide additional documentation showing that the strawberries used in the salad did not contain vinclozolin, even if the strawberries were not handled by the processor prior to July 1, 2000.

If the amount of vinclozolin found in a frozen strawberry-peach fruit salad exceeded the level of the former tolerance for vinclozolin in one of the source commodities e.g., peaches (based upon the percentage of peaches in the salad), but did not exceed the cumulative amount that would have been lawful under both of the former tolerances e.g., strawberries and peaches, the responsible party could not make the showing only with respect to the peaches as provided in the previous paragraph. In such a case the responsible party should be prepared to make a showing with respect to both the peaches and strawberries to enable FDA to conclude that the food is within the scope of FDA's exercise of its discretion set forth in this guidance.

If FDA finds a residue of vinclozolin in a multiple ingredient food containing strawberries or stonefruit, plus another ingredient that is subject to a current tolerance for vinclozolin, e.g., a frozen raspberry-peach fruit salad, FDA would not regard such a situation to fall under the channels of trade provision if the amount of vinclozolin in the food complies with the current tolerance, i.e., the tolerance for raspberries (based upon the percentage of raspberries in the salad), and thus, FDA 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 discretion set forth in this guidance.⁵

If the amount of vinclozolin found in a frozen raspberry-peach salad exceeded the level of the current tolerance for vinclozolin in raspberries (based upon the percentage of raspberries in the food), but did not exceed the cumulative amount that would have been lawful under the current and former tolerances e.g., for raspberries and peaches, the

⁵ However, if FDA had other evidence indicating that the vinclozolin residue in such a food was due to the ingredient for which the tolerance had been revoked, e.g., the peach ingredient in this example, the responsible party should be prepared to make a showing with respect to the peach 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.

responsible party should be prepared to make a showing with respect to the peach 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.

If FDA finds a residue of vinclozolin in a multiple ingredient food containing strawberries or stonefruit, plus another ingredient for which there is no current tolerance for vinclozolin, e.g., a frozen strawberry-melon fruit salad, 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. FDA does not intend to ask the responsible party to provide additional documentation showing that an ingredient not subject to a current or revoked tolerance, e.g., melon, did not contain vinclozolin.

In general, for processed foods containing strawberries or stonefruit subject to EPA's tolerance revocations, 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 vinclozolin 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 vinclozolin residues within the former tolerance are provided below under "Examples of Documentation that May be Useful to Show Applicability of the Channels of Trade Provision."

Planned Enforcement Approach: Bell Peppers and Cucumbers^{6,7}

1. Fresh cucumbers and bell peppers

Upon the effective date of the EPA tolerance revocations for these commodities, FDA does not intend to allow the importation of fresh bell peppers or cucumbers bearing a

⁶ See footnote No.3.

⁷ FDA intends to afford firms the opportunity to make a showing under this policy until 4 years from the date of the tolerance revocations. FDA does not believe that processed bell peppers and cucumbers produced from legally imported commodities with residues of vinclozolin will be in the channels of trade after that date. See footnote No. 3.

residue of vinclozolin into the U.S.

For three months after the effective date of the tolerance revocations, e.g., through (*date to be inserted in final guidance based upon date of EPA final revocation action*), if FDA finds a residue of vinclozolin on imported fresh bell peppers or fresh cucumbers in domestic commerce, and the residue complies with the former tolerance, FDA intends to exercise its discretion and not take enforcement action against the food to allow foods that were legally imported prior to the effective date of the tolerance revocations to reach the ultimate consumer or be sold for further processing.

Beyond three months after the effective date of the tolerance revocations, e.g., beginning on (*date to be inserted in final guidance based upon date of EPA final revocation action*), if FDA finds a residue of vinclozolin on fresh bell peppers or fresh cucumbers in domestic commerce, it intends to subject the food to enforcement action.

2. Processed bell peppers and processed cucumbers

FDA recognizes that imported fresh or processed bell peppers and cucumbers with residues of vinclozolin may legally enter the U.S. prior to the effective date of the tolerance revocations; and that some fresh produce may subsequently undergo processing. As stated above, FDA believes that fresh imported bell peppers and cucumbers will be processed further within three months of the effective date of the tolerance revocations. For three months following the effective date of the tolerance revocations, if FDA finds a residue of vinclozolin on imported fresh or processed bell peppers or imported fresh or processed cucumbers in domestic commerce, and such residue is within the former tolerance, FDA intends to exercise its enforcement discretion and not take enforcement action against the food.

Beyond three months after the effective date of the tolerance revocations, if FDA finds a residue of vinclozolin on processed bell peppers or processed cucumbers in domestic

commerce, and such residue is within the former tolerance, FDA intends to ask the party responsible to show that the food is within the scope of FDA's exercise of its enforcement discretion set forth in this guidance in order to avoid regulatory action against the food. In such cases, FDA intends to inform the responsible party that the food may be in violation of the FFDCA, and provide an opportunity for the party to provide documentation demonstrating that the imported food was packed or processed no later than 3 months after the effective date of the tolerance revocation. FDA intends to afford firms the opportunity to make a showing for a period of 4 years, after which time, it does not believe that processed foods containing imported bell peppers or cucumbers that bore lawful residues of vinclozolin at the time of importation, will remain in the channels of trade.

Upon the effective date of the tolerance revocations for these commodities, if FDA finds a residue of vinclozolin that is within the former tolerance, on processed bell peppers or processed cucumbers offered for import, 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 this policy for domestic processed food, i.e., documentation that the product was packed or processed no later than 3 months after the effective date of the tolerance revocation. FDA intends to afford firms the opportunity to make a showing for a period of 4 years.

3. Multiple ingredient processed foods containing bell peppers or cucumbers

Beyond three months after the effective date of these tolerance revocations, if FDA finds a residue of vinclozolin in a multiple ingredient processed food containing bell peppers or cucumbers in domestic commerce, FDA intends to use a similar approach to the one that it described for multiple ingredient foods with residues of methyl parathion 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). If FDA determines that the responsible party must make a showing with respect to the bell pepper or cucumber ingredient of the multiple

ingredient food, the responsible party would need to demonstrate that the product was processed or packed no later than 3 months after the effective date of the tolerance revocation.

In general, for imported bell peppers or cucumbers found to contain vinclozolin pesticide residues that are within the former tolerance, FDA anticipates that the party responsible will be able to provide appropriate documentation to the agency. Examples of documentation that may be appropriate for such foods that are found to have vinclozolin residues within the former tolerance are provided in the following section.

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

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.

DOCUMENTATION ASSOCIATED WITH PACKING CODES

If a product's label bears a packing code and the firm supplies documentation that relates that code to a packing date, we plan to regard such documentation as indicating that the food was packed on the indicated date. FDA plans to exercise enforcement discretion for foods subject to EPA's tolerance revocation, bearing a residue of vinclozolin that is within the former tolerance and that have been packaged during the periods stated above for each food category.

DOCUMENTATION ASSOCIATED WITH BATCH RECORDS, AND INVENTORY RECORDS

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.,

formulated, 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 on a specified date. FDA plans to exercise enforcement discretion for foods subject to EPA's tolerance revocation, bearing a residue of vinclozolin that is within the former tolerance and that have been packaged during the periods stated above for each food category.

References

1. EPA memorandum of June 15, 2000 entitled "Safe Harbor Assessment for Vinclozolin on Stone fruits and Strawberries. Request for Additional Information."