
**U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
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**Guidance for Industry
Channels of Trade Policy for Commodities with Methyl
Parathion Residues**

Draft Guidance

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Comments and suggestions regarding this draft document should be submitted by August 1, 2000 to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. For questions regarding this draft document contact Michael Kashtock at (202) 205-4681.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition (CFSAN)
June 1, 2000**

DRAFT

**Guidance for Industry: Channels of Trade Policy for
Commodities with Methyl Parathion Residues¹**

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 "methyl parathion." It is intended to present the Food and Drug Administration's (FDA's) policy on its planned enforcement approach for foods containing methyl parathion 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 §408(l)(5) of the FFDCA that FDA may find satisfactory, in accordance with its planned enforcement approach for such section.

The channels of trade provision² addresses the circumstances under which a food is not unsafe solely because of the presence of a pesticide chemical residue that has been revoked, suspended, or modified by EPA.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 §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 methyl parathion, and it is intended to assist firms in understanding the type of showing under §408(l)(5) that FDA may find satisfactory in accordance with its planned enforcement approach for such section. FDA has developed this guidance document because, as discussed below, as part of the tolerance reassessment process mandated by FQPA, EPA has canceled several registered food uses of methyl parathion, and has proposed to revoke the corresponding tolerances for this pesticide chemical in food as quickly as possible after consideration of comments. FDA anticipates that some foods bearing methyl parathion residues resulting from lawful application of this pesticide chemical will remain in channels of trade after the revocation of the applicable tolerance for methyl parathion. If FDA encounters such a food bearing a residue of methyl parathion, it will 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 goods, 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 §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, FQPA was signed into law. This law, which amends both FIFRA and the FFDCFA, established a new safety standard for pesticide residues in food, with an emphasis on protecting the health of infants and children. In accordance with 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(1)(2) of the FFDCFA, 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 Methyl Parathion

In a cancellation order published in the FEDERAL REGISTER of October 27, 1999, EPA canceled, effective on the same date, several registered food uses for the pesticide methyl parathion (64 FR 57877). The cancellation was precipitated by EPA's determination that methyl parathion could not meet the FQPA safety standard as the pesticide is currently registered. Under limitations on the use of existing stocks, the application of the pesticide on the crops specified became unlawful after December 31, 1999, and in a final rule published in the Federal Register on January 5, 2001 EPA revoked the pesticide tolerances for methyl parathion corresponding to the canceled food uses (66 FR 1242). EPA had proposed to revoke the same pesticide tolerances in a notice published in the Federal Register on June 2, 2000 (65 FR 35307).

Methyl Parathion Residues in Foods Resulting from Legal Application

When applied to food crops in accordance with the canceled uses, methyl parathion residues dissipate by chemical degradation in the treated food at varying rates depending upon the storage conditions for the food. FDA has evaluated information provided by EPA which estimates how long residues of methyl parathion are expected to remain in various foods (Ref. 1). Each estimate is a worst case scenario in that EPA assumed the pesticide was applied to the crop on the last day application was legal under FIFRA, i.e., December 31, 1999, and at the maximum level permitted by law. These estimates indicate the following:

Foods stored at ambient (room) temperature

Methyl parathion residues in foods stored at ambient temperature are expected to dissipate to non-detectable levels within 9 months of the last pesticide application, i.e., by no later than September 2000. Examples of such foods included in EPA's estimates are apple cider, apple vinegar, dried cherries and plums, beans, and canned products such as fruits and vegetables.

Foods stored under refrigeration

Methyl parathion residues in foods stored under refrigeration are expected to dissipate to non-detectable levels within 1 year of the last pesticide application, i.e., by no later than December 2000. Examples of such commodities included in EPA's estimates are fresh apples, pears, tomatoes, carrots, celery, lettuce, grapes, cherries, spinach, and beans.

Frozen foods

Methyl parathion residues are not expected to further dissipate in storage after a food has been frozen. Thus methyl parathion residues may be expected to remain in frozen foods indefinitely. Examples of such foods included in EPA's estimates are frozen fruit juice and fruit juice concentrate, as well as frozen vegetables and beans.

Information provided to FDA by food industry associations indicates that certain processed foods (frozen, dried, and canned) may remain in channels of trade for up to 4 years after a product is harvested (Ref. 2 & 3). This fact, combined with EPA's residue dissipation estimates, indicates that methyl parathion residues resulting from lawful application of this pesticide may be expected to remain in foods stored under ambient, refrigerated, and frozen conditions for certain intervals beyond the date of revocation of the applicable tolerance. While the maximum time required for residues to dissipate in foods stored under ambient or refrigerated conditions is relatively short, i.e., no more than a year past the date the pesticide was last lawfully applied, methyl parathion residues are not expected to dissipate in frozen foods. Conceivably, frozen food products bearing methyl parathion residues resulting from lawful application could remain in the channels of trade for up to 4 years after the applicable tolerance revocation. FDA's policy for its enforcement of the channels of trade provision for any food found to bear residues of methyl parathion after the tolerance is revoked will be as follows:

Period from the date of tolerance revocation through December 31, 2000

Excluding frozen foods, FDA believes that methyl parathion residues in foods (i.e., foods stored at ambient temperature and under refrigeration) resulting from lawful application will dissipate to non-detectable levels within one year of the last potentially lawful pesticide application, i.e., no later than December 31, 2000. For foods that were subject to the former tolerance (including frozen foods) found from the date of tolerance revocation through December 31, 2000, to contain a methyl parathion residue that complies with the former tolerance, FDA intends to consider the presence of the residue (except in the circumstances noted in the following two paragraphs) to be a result of the lawful application of methyl parathion. Consequently, FDA, as a matter of its enforcement discretion, does not plan to deem such food to be adulterated under the channels of trade provision. Thus, FDA does not plan to ask the party responsible for such food to make a showing that such food in question meets the requirements of the channels of trade provision. Instead, the agency intends to consider the food to be in compliance with the channels of trade provision.

The first exception to the above is the circumstance in which FDA has information indicating that there is a reasonable possibility that a residue that is within the former tolerance found in food from the date of tolerance revocation through December 31, 2000, resulted from application of the pesticide to the crop after December 31, 1999, which constitutes an unlawful use of methyl parathion. In such a circumstance, FDA would not exercise its enforcement discretion as previously stated. Rather, FDA intends to ask the party responsible to show that the food complies with §408(l)(5) of the FFDCFA 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 FFDCFA, and provide an opportunity for the party to respond and provide documentation demonstrating that the methyl parathion residue in the food resulted from application of the pesticide to the crop prior to January 1, 2000.

The second exception is the circumstance in which the food found to bear a residue of methyl

parathion is derived from a crop that was necessarily grown in the year 2000, as indicated by its growing season and shelf-life. Based upon generally recognized agronomic practices (when crops are grown), and farm-to-market time requirements for agricultural commodities (shelf life), it is possible in certain instances to identify foods, e.g. certain items of fresh produce, that are the product of the current growing year. Food derived from any crop that is grown in the year 2000 cannot meet the requirements of the channels of trade provision, because application of methyl parathion to food crops became unlawful after December 31, 1999. Thus, if FDA encounters a residue of methyl parathion on any such food (e.g. fresh lettuce), that food would be subject to regulatory action.

FDA considered establishing separate periods for FDA's enforcement approach for foods stored under ambient conditions and foods stored under refrigeration. However, FDA is exercising its discretion and is establishing one period regardless of storage condition to avoid confusion among affected parties such as growers, importers and processors that could arise from multiple regulatory approaches being applied to such foods within a relatively short time period.

January 1, 2001 and Beyond

Based on estimates provided to FDA by industry groups, we expect that frozen foods with methyl parathion residues resulting from lawful application of the pesticide chemical may remain in the channels of trade for up to four years after the product was harvested. Consistent with FQPA, when FDA encounters such frozen food within 4 years of the tolerance revocation, bearing a methyl parathion residue within the former tolerance, FDA plans to ask for documentation from the party responsible to show that the food was packed or processed prior to or on December 31, 2000. In such cases, FDA intends to inform the responsible party that the food may be in violation of the FFDCFA, and provide an opportunity for the party to respond and provide such types of documentation.

In general, FDA anticipates that the party responsible will be able to provide appropriate documentation to the agency. Examples of documentation that may be appropriate for foods that are found to have methyl parathion residues within the former tolerance are provided in the next 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.

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

CATEGORY I: DOCUMENTATION ASSOCIATED WITH PACKING CODES, BATCH RECORDS, AND INVENTORY RECORDS

- A. If a product's label bears a packing code and the firm supplies documentation that relates that code to a packing date on or before December 31, 2000, we plan to regard such documentation as indicating that the food was packed prior to or on December 31, 2000, unless it falls within one of the two exceptions discussed earlier. FDA plans to exercise enforcement discretion for such food packaged during the stated period when methyl

parathion residues may be found on food that was lawfully treated under FIFRA.

- B. If a product's label bears a packing code and the firm supplies documentation that relates that code to a batch record indicating that the product was processed, e.g., formulated, on or before December 31, 2000, we plan to regard such documentation as indicating that the food was processed prior to such date, unless such food falls within one of the two exceptions discussed earlier. Batch records may also be combined with inventory records to demonstrate that the ingredients used to manufacture the food were purchased on or before December 31, 2000. FDA plans to exercise its enforcement discretion for such food processed during the stated period when methyl parathion residues may be found on food that was lawfully treated under FIFRA.

CATEGORY II: OTHER TYPES OF DOCUMENTATION

Documentation to be provided in addition to Category I

The types of documentation noted in the previous section may not be sufficient for the channels of trade provision for certain types of food products. For example, in some cases, firms may anticipate blending ingredients purchased prior to December 31, 2000 with ingredients derived from foods produced from crops grown afterward. In such cases, firms may need to provide additional documentation. For example, a juice manufacturer may blend frozen pear juice concentrate purchased prior to December 31, 2000 with apple juice produced from apples grown in 2001. If the blended juice product were found to contain a methyl parathion residue, which the processor believed to be due to the frozen pear juice concentrate, inventory records documenting that the frozen pear juice concentrate was purchased prior to December 31, 2000 could be shown to FDA; however, such documentation would not demonstrate anything about the apples used. The firm should provide additional documentation about the apples used to produce the product; such documentation should show that:

- A. The firm included in its product specifications for its apple juice supplier, the requirement that the apples used to make the juice had not been treated with methyl parathion, and the firm received certification from the supplier that the apples it used had not been treated with methyl parathion, and
- B. Either the supplier or processor carried out an auditing program, e.g., spot checks, to verify that incoming apples or apple juice did not contain residues of methyl parathion.

Alternatively, the firm could provide validated analytical documentation demonstrating that the firm, or the apple juice supplier, tested the lot of apple juice used to make the production lot of the blended juice in question, and found no detectable residue of methyl parathion.

Documentation which may be provided as an alternative to Category I

In some cases, when a product is found to contain a methyl parathion residue within the former tolerance, regardless of whether it is a blended product (e.g., apple-pear juice) or a single-crop product (e.g., grape juice), the responsible firm may wish to provide documentation for the channels of trade provision under Category II in lieu of providing documentation associated with packing codes, batch records, or inventory records (Category I). An example of such a firm would be one that does not routinely maintain Category I documentation as part of its food production operations that may wish to develop a certification and auditing program rather than

develop and maintain a system of documentation involving packing codes, batch records, or inventory records.

If a product is found to contain a methyl parathion residue within the former tolerance, FDA intends to, using its enforcement discretion, consider Category II documentation sufficient to demonstrate that the product ingredients covered by such documentation are not the cause of the residue. However, if a firm wishes to use Category II documentation in this manner, it should also demonstrate that the residue may be attributed to at least one product ingredient in which a methyl parathion residue could be present as the result of lawful application of the pesticide chemical under FIFRA (i.e., the ingredient is derived from a crop to which the application of methyl parathion was permitted) and the ingredient used was derived from product inventoried on or before December 31, 2000 (i.e., purchased on or before this date).

In this instance, when:

1. Category II documentation is supplied by the firm responsible for the product demonstrating that it received certification from its suppliers that the ingredients purchased after December 31, 2000 were derived from crops not treated with methyl parathion, and the supplier or processor carried out an auditing program to verify that the same ingredients did not contain residues of methyl parathion, and
2. the responsible firm can demonstrate that at least one product ingredient was purchased prior to or on December 31, 2000 and may contain a methyl parathion residue resulting from a legal application of the pesticide chemical under FIFRA,

FDA plans to exercise its enforcement discretion for such food containing ingredients purchased during the stated period when methyl parathion residues resulting from lawful treatment under FIFRA may be found on the food.

Imported Foods

Upon the effective date of the revocation of the pesticide tolerance for methyl parathion, FDA intends to subject the importation of any food bearing a residue of methyl parathion that is within the former tolerance to the same enforcement approach as that set forth in this guidance document for domestic food. In the interest of fairness, FDA intends to exercise its enforcement discretion for the imported commodities for which the tolerance for methyl parathion will be revoked by EPA as follows:

1. During the period from the date of tolerance revocation through December 31, 2000, FDA intends to consider, as a matter of its enforcement discretion, the importation of a food bearing a methyl parathion residue that is within the former tolerance, and not subject to either of the two exceptions discussed earlier for domestic food, to be a result of the lawful application of methyl parathion. Consequently, FDA does not plan to deem such food to be adulterated under the channels of trade provision. Thus, FDA does not plan to ask the party responsible for such food to make a showing that such food in question meets the requirements of the channels of trade provision. Instead, the agency intends to consider the food to be in compliance with the channels of trade provision.
2. During the period from the date of tolerance revocation through December 31, 2000,

FDA intends to detain any food offered for import, bearing a residue of methyl parathion, if the food is subject to either of the two exceptions discussed earlier. For example, if the agency has information indicating that there is a reasonable possibility that a residue that is within the former tolerance resulted from application of the pesticide to the crop after December 31, 1999, which EPA would consider to be an unlawful application or use within the meaning of section 408(l)(5) of the FFDCA, FDA intends to ask the party responsible to show that the food complies with section 408(l)(5) of the FFDCA 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 methyl parathion residue in the food resulted from application of the pesticide to the crop prior to or on December 31, 1999.

Further, FDA intends to detain any food offered for import, bearing a residue of methyl parathion, if the food was derived from a crop that was necessarily grown in the year 2000, as indicated by its growing season and shelf-life. Based upon generally recognized agronomic practices (when crops are grown), and farm to market time requirements for agricultural commodities (shelf life), it is possible in certain instances to identify foods, e.g., certain items of fresh produce such as fresh lettuce, that are the product of the current growing year in the country of origin.

3. After December 31, 2000, if FDA finds a methyl parathion residue, that is within the former tolerance, in any food other than a frozen food offered for import, FDA does not intend to allow importation of that food, unless the party responsible can provide documentation to show that the food was packed or processed on or prior to December 31, 2000. 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 respond and provide such types of documentation.

If FDA finds a methyl parathion residue that is within the former tolerance in a frozen food offered for import, the entry will be detained. FDA will, 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 frozen domestic food, e.g., documentation that the product was packed or processed on or before December 31, 2000.

References

1. EPA, 1999. Residue Dissipation Chart containing draft estimates of methyl parathion dissipation rates in commodities under various storage conditions.
 2. American Frozen Food Institute, October 26, 1999. Letter to FDA estimating the amount of time frozen fruits and vegetables are likely to remain in commerce prior to being purchased by the consumer (i.e., how long they are to remain in the channels of trade).
 3. National Food Processors Association, August 23, 1999. Letter to FDA estimating the amount of time processed foods are likely to remain in the channels of trade.
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Footnotes

¹ The proposed guidance represents FDA's current thinking on the channels of trade provision and how this provision relates to FDA-regulated products with methyl parathion residues. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. The proposed guidance is being distributed for comment in accordance with the FDA's policy for Level 1 Good Guidance Practices documents, as set forth in the Federal Register of February 27, 1997 (62 FR 8961).

² 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 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.

³ Treatment of the following with methyl parathion will be prohibited after December 31, 1999: apples, artichokes, beets (greens alone), beets (with or without tops), broccoli, Brussels sprouts, carrots, cauliflower, celery, cherries, collards, grapes, kale, lentils, kohlrabi, lettuce, mustard green, nectarines, peaches, pears, plums (fresh prunes), rutabagas (with or without tops), rutabaga tops, spinach, succulent beans and peas, tomatoes, turnips (with or without tops), turnips greens, vegetables leafy Brassica (cole), and vetch.

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