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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1309]

Draft Guidance for Industry: Channels of Trade Policy for Commodities With Methyl Parathion Residues; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a proposed guidance document entitled "Guidance for Industry: Channels of Trade Policy for Commodities With Methyl Parathion Residues" (the proposed guidance). The proposed guidance presents FDA's policy for implementing the channels of trade provision for the pesticide chemical methyl parathion in of the Federal Food, Drug, and Cosmetic Act (FFDCA) as amended by the Food Quality Protection Act (FQPA) of 1996. The proposed guidance is intended to assist firms in understanding FDA's planned approach to the enforcement of this provision of the FQPA with regard to residues of methyl parathion in food.

DATES: Submit written comments concerning this guidance and the information collection by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments concerning the proposed guidance and the collection of information provisions to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the proposed guidance entitled "Guidance for Industry: Channels of Trade Policy for Commodities With Methyl Parathion Residues" to Donna L. Myers, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4681. Send one self-adhesive address label to assist that office in processing

your request. Comments and requests for copies should be identified with the docket number found in brackets in the heading of this document. A copy of the proposed guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4681, FAX 202-205-4422, e-mail: mkashtoc@bangate.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On August 3, 1996, the FQPA was signed into law. This law, which amends the Federal Insecticide, Fungicide, and Rodenticide Act (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, the Environmental Protection Agency (EPA), the agency responsible for regulating the use of pesticides (under FIFRA) and establishing tolerances for residues of pesticide chemicals in food commodities (under the FFDCA), is in the process of reassessing the pesticide tolerances and exemptions that were in effect when the law was signed. When the determination is made that a pesticide's tolerance level does not meet the safety standard set forth by the FQPA, the registration for the pesticide may be canceled for all or certain 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 FFDCA (21 U.S.C. 346a(1)(2)), 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.

When EPA takes such actions, food derived from a commodity that was lawfully treated with the pesticide may not have cleared the channels of trade by the time the revocation or new tolerance level takes effect. The food could be found by FDA, the agency that is responsible for monitoring pesticide residue levels and enforcing the pesticide tolerances in most foods (the U.S. Department of Agriculture (USDA) has responsibility for meat, poultry, and certain egg products), to contain a residue of that pesticide that does not comply with the revoked or lowered 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. However, the channels of trade provision of the FQPA address the circumstances under which a food is not unsafe solely due to the presence of a residue from a pesticide chemical for which the tolerance has been revoked, suspended, or modified by EPA. The channels of trade provision (section 408(l)(5) of the FFDCA) states the following:

PESTICIDE RESIDUES RESULTING FROM LAWFUL APPLICATION OF 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.

As part of the tolerance reassessment process mandated by the FQPA, in a cancellation order published in the **Federal Register** of October 27, 1999 (64 FR 57877), EPA cancelled, effective on the same date, several registered food uses for the pesticide methyl parathion (Ref. 1). These canceled food uses are as follows: Apples, artichokes, beets (greens alone), beets (with or without tops), broccoli, brussels sprouts, carrots, cauliflower, celery, cherries, collards, grapes, kale, lentils, kohlrabi, lettuce, mustard greens, 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.

Under the terms of the cancellation, the application of the pesticide on the crops specified became unlawful after December 31, 1999. This action was precipitated by EPA's determination that the dietary risks from exposure to methyl parathion exceeded the safety standard under the FFDCA. Consistent with section 408(l)(2) of the FFDCA, EPA is proposing in this issue of the **Federal Register** to revoke the pesticide tolerances for methyl parathion corresponding to the canceled food uses.

FDA anticipates that some foods bearing methyl parathion residues resulting from lawful application of this pesticide will remain in the channels of trade after the revocation of the applicable tolerance for methyl parathion (Refs. 2 through 4). If FDA encounters such a food bearing a residue of methyl parathion, it intends to address the situation in accordance with this proposed guidance. FDA has developed this proposed guidance to set forth its policy for how FDA plans to approach its enforcement of the channels of trade provision with respect to the pesticide chemical methyl parathion.

With this document, FDA is announcing the availability of the proposed guidance. The proposed guidance represents FDA's current thinking on its planned enforcement approach to the channels of trade provision and how such 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 purposes,

in accordance with FDA's policy for Level 1 Good Guidance Practices documents as set out in the **Federal Register** of February 27, 1997 (62 FR 8961).

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Suggested Documentation for Demonstrating Compliance With the Channels of Trade Provision

Description: Under the pesticide tolerance reassessment process that EPA was mandated to carry out under the FQPA, EPA has proposed to revoke the tolerances for the pesticide chemical methyl parathion on several food commodities. The FQPA includes a provision in section 408(1)(5) of the FFDCA, referred to as the "channels of trade provision," that addresses the circumstances

under which a food is not unsafe solely due to the presence of a residue from a pesticide chemical whose tolerance has been revoked, suspended, or modified by EPA.

In general, FDA anticipates that the party responsible for food found to contain methyl parathion residues (within the former tolerance) after the tolerance for the pesticide chemical has been revoked, will be able to demonstrate that such food was packed or processed on or prior to December 31, 2000, by providing appropriate documentation to the agency as discussed in the proposed guidance. FDA is not suggesting that firms maintain a certain set list of documents where anything less or different would likely be considered unacceptable. Rather, the agency is leaving it to each firm's discretion to maintain appropriate documentation to demonstrate that the food was so packed or processed.

Examples of documentation which FDA anticipates will serve this purpose may be divided into two categories: (1) Documentation associated with packing codes, batch records, and inventory records, and (2) other types of documentation. The first category includes the types of documents that many food processors routinely generate as part of their basic food-production operations. The second category may include documentation that processors generate for the express purpose of compiling information that may satisfy the showing required in the channels of trade provision, such as copies of product specification requirements (requesting that the supplier not provide commodities treated with methyl parathion to the processor), written acknowledgement from the supplier that it intends to comply with the above request, and records demonstrating that the processor carried out an auditing program (e.g., spot checks) to verify that incoming commodities did not contain residues of methyl parathion.

Description of Respondents: The likely respondents to this collection of information are firms in the produce and food-processing industries who handle food products that may contain residues of methyl parathion after the tolerances for this pesticide chemical have been revoked.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
67	1	67	3	201

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
333	1	333	20	6,660

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Estimates for the annual reporting burden were determined by using the maximum number of samples collected throughout a year that FDA believes may be found to contain methyl parathion residues. Because all residues are expected to have dissipated from nonfrozen foods by the time FDA intends to question firms about when a food product was packed or processed (i.e., after December 31, 2000), FDA included only frozen food in its estimate (i.e., processors of foods stored under refrigerated and ambient conditions were excluded) (Ref. 2). Although residues within the former tolerance resulting from legal application of methyl parathion are not expected to be found in nonfrozen foods after December 31, 2000, under the channels of trade provision, firms will have an opportunity to make a showing that any such food was packed or processed on or before this date.

Considering the variation in and effects of food handling, particularly with regard to the time between pesticide application and freezing, FDA estimated that potentially half of all frozen food products sampled may contain methyl parathion residues, and therefore, the responsible party, under the approach set forth in this guidance, would be subject to the reporting requirement since it would be the burden of the responsible party to demonstrate that food found to contain methyl parathion residues within the former tolerance was packed or processed on or before December 31, 2000.

When determining the annual recordkeeping burden, importers and domestic processors of frozen food commodities affected by the revocation of the pesticide chemical methyl parathion were considered. FDA estimated that most firms (at least 90 percent) maintain (or maintain access

to) Category I documentation (packing codes, batch records, inventory records, etc.) as part of their basic food production and/or import operations. It was presumed that the 10 percent of firms which do not maintain such documentation would likely begin maintaining (or maintaining access to) Category II documentation (other types of documentation, such as certification from the supplier that products do not contain methyl parathion) rather than instituting a system to begin maintaining Category I documentation. This being the case, a portion of the recordkeeping burden was calculated as the time required for the 10 percent of firms not currently maintaining Category I documentation, to develop and maintain (or maintain access to) Category II documentation.

As discussed in detail in the guidance, some firms (i.e., frozen juice manufacturers) may decide to maintain Category II documentation in addition to Category I documentation, as part of the showing under the channels of trade provision. FDA estimated that firms fitting this description represent approximately one third of the frozen fruit, vegetable, and juice-processing industry. Therefore, a portion of the annual recordkeeping burden estimate was calculated based upon the time required for these firms to develop and maintain Category II documentation.

Because all residues are expected to have dissipated from nonfrozen foods by the time FDA intends to ask for a showing under section 408(l)(5) of the FFDCA (i.e., after December 31, 2000), FDA used the number of frozen food processors when determining the annual recordkeeping burden. As with the annual reporting burden estimate, although nonfrozen food processors are entitled to make a showing under the channels of trade provision, they were excluded from this estimate because based upon residue dissipation estimates provided by EPA (Ref. 2), methyl parathion residues within the former tolerance resulting from legal application are not expected to be found in nonfrozen commodities after December 31, 2000.

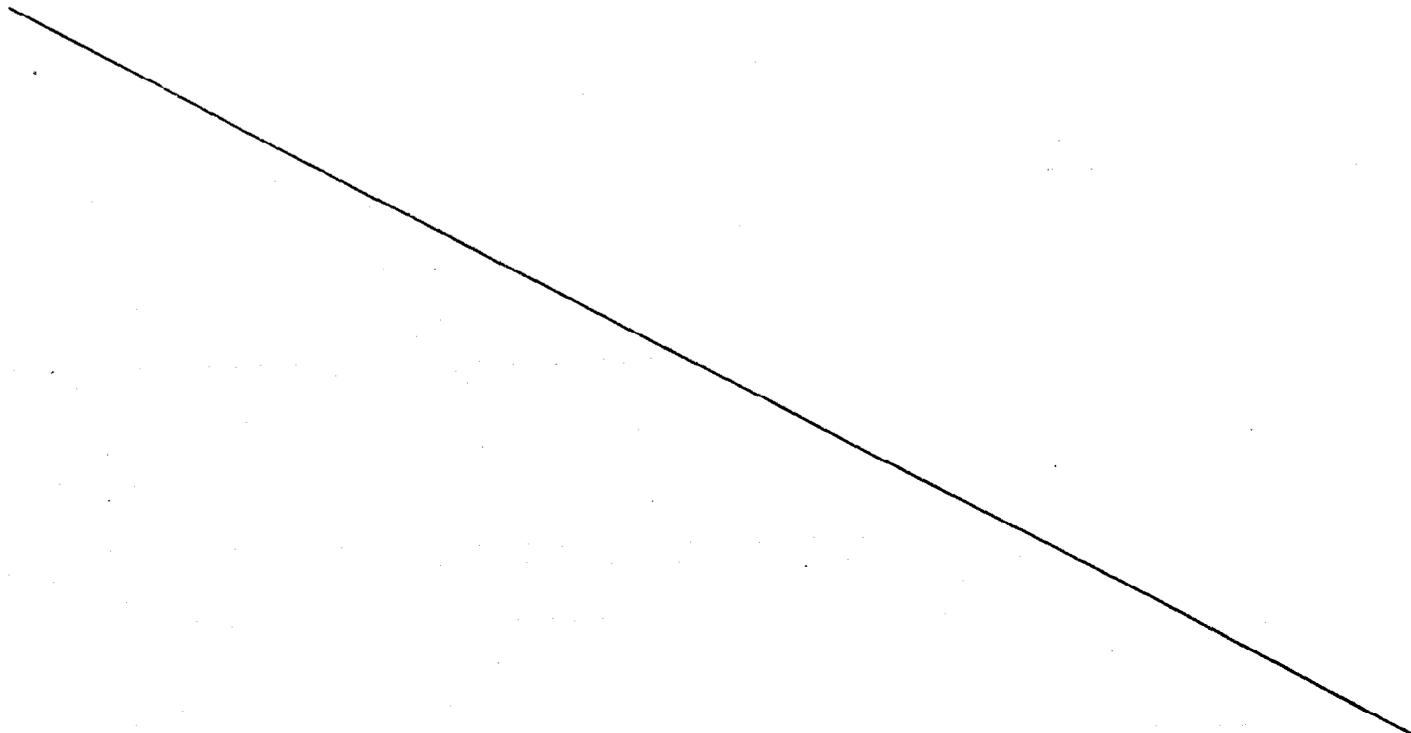
III. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the proposed guidance by [*insert date 60 days after date of publication in the Federal Register*]. Two copies of any comments are to be submitted, except that individuals may submit

one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The proposed guidance may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. An electronic version of this draft guidance is available on the Internet at <http://www.fda.gov/>.

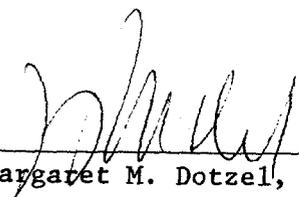
IV. References

The following references have been placed on display at the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Cancellation Order from the Environmental Protection Agency Canceling the Registration for Methyl Parathion Effective October 27, 1999 (www.epa.gov/fedrgstr/EPA-PEST/1999/October/Day-27/p27800.htm), **Federal Register** (64 FR 57877), October 27, 1999.
 2. Environmental Protection Agency, Residue Dissipation Chart, Draft Estimates of Methyl Parathion Dissipation Rates in Commodities Under Various Storage Conditions, 1999.
 3. American Frozen Food Institute, 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 Likely to Remain in the Channels of Trade), October 26, 1999.
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4. National Food Processors Association, Letter to FDA Estimating the Amount of Time Processed Foods Are Likely to Remain in the Channels of Trade, August 23, 1999.

Dated: 5/26/00
May 26, 2000.


Margaret M. Dotzel, Associate Commissioner for Policy.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F

