DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1309]

Final 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 final guidance for industry entitled ''Channels of Trade Policy for Commodities with Methyl Parathion Residues.'' This guidance presents FDA's policy for implementing the channels of trade provision for the pesticide chemical methyl parathion in section 408(l)(5) of the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Food Quality Protection Act (FQPA) of 1996. The final 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 at any time.

ADDRESSES: Submit written requests for single copies of the final guidance to the Office of Plant and Dairy Foods and Beverages (HFS–305), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the final guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS–305), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5321, FAX 202–205–4422, e-mail: mkashtoc@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of June 2, 2000 (65 FR 35376), FDA announced the availability of a draft version of this guidance for industry entitled ''Channels of Trade Policy for Commodities with Methyl Parathion Residues.'' The agency has finalized that draft guidance after considering the five comments that were received on the draft version.

In response to a suggestion in a comment, FDA is specifying in this final guidance, the method it intends to use to test for methyl parathion residues in foods. In response to comments asking for additional time and stating that firms need additional time to prepare to make showings, FDA is providing responsible parties with an additional 6 months, i.e., until July 1, 2001, to prepare, e.g., by compiling records, to make a showing to FDA to demonstrate that a processed food is within the scope of FDA's exercise of its enforcement discretion set forth in this guidance.

Several comments addressed the approach FDA stated it intended to follow if it were to find residues of methyl parathion in multiple ingredient foods for which all ingredients are subject to the current Environmental Protection Agency (EPA) methyl parathion tolerance revocation action, e.g., an apple-pear juice. The comments stated that the approach taken in the draft is not consistent with current FDA policy in a related situation regarding pesticide residues in multiple ingredient foods. Under existing FDA policy, if FDA finds a pesticide residue in a multiple ingredient food, e.g., mixed vegetables, in which there is a tolerance for the pesticide in some, but not all of the ingredients, FDA does not ask the responsible firm to demonstrate that the residue is not present in any of the ingredients for which there is no tolerance.

In response to these comments, FDA is revising its planned approach in this final guidance. If FDA finds a residue of methyl parathion in such a multiple ingredient food, e.g., apple-pear juice, to be within the scope of FDA's exercise of enforcement discretion, the responsible party should demonstrate that at least one of the food's ingredients could bear the methyl parathion residue as a result of a lawful application or use of this pesticide chemical. However, if the responsible party makes that showing, FDA does not intend to ask the responsible party to provide additional documentation showing that other ingredients in the food were not the source of the residue of methyl parathion.

FDA has also added additional examples in the final guidance on the approach it intends to follow if it finds methyl parathion residues in multiple ingredient foods in which some ingredients are subject to the current EPA methyl parathion tolerance revocation action and other ingredients are subject to tolerances that remain in effect or are not subject to a tolerance at all.

A comment asked if FDA considered whether methyl parathion could persist in the soil and transfer into crops grown after legal application of this pesticide was terminated by EPA. FDA has worked closely with EPA in developing this guidance, and EPA has given no indication to FDA that residues of methyl parathion persist in the environment such that a food could contain residues of methyl parathion resulting from the application of this pesticide to a previously grown crop. Thus, FDA intends to assume that any residue of methyl parathion found on a food results from application of the pesticide to the crop used to produce the analyzed food.

In response to a request in a comment, FDA, in the final guidance, has provided an example of a situation whereby FDA could come to possess 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 would constitute an unlawful use of methyl parathion.

Finally, in response to comments expressing concern that food retailers would reject food rather than accept the potential burden of making a showing as the ''responsible party,'' the agency advises that under its compliance program for pesticide residues in domestic foods (FDA monitors pesticide residues in both raw agricultural commodities and processed foods in interstate commerce under this program), samples for routine monitoring purposes are generally not collected at the retail level. The program directs that growers or packing sheds are the preferred sites for sampling fruits and vegetables. Thus, FDA does not expect that in the normal course of business, retailers will be in the role of the ''responsible party'' under this policy.

This final guidance is being issued as a level 1 guidance, consistent with FDA's policy for good guidance practices as set out in the **Federal Register** of September 19, 2000 (65 FR 56468). This guidance represents the agency'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. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the final guidance. 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 final 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.cfsan.fda.gov.

Dated: December 19, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–368 Filed 1–4–01; 8:45 am]

BILLING CODE 4160–01–F