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August 1, 2000

FDA Dockets Management Branch (HFA-305)
Food and Drug Administration
5600 Fishers Lane, Room 1061
Rockville, MD 20852

**RE: Channels of Trade for Commodities with Methyl
Parathion Residues, Draft Guidance, June 2, 2000**

Dear Sir or Madam:

The American Frozen Food Institute (AFFI) appreciates the opportunity to comment on the Food and Drug Administration (FDA) draft guidance concerning channels of trade for commodities with methyl parathion residues.

As you know, AFFI is the national trade association representing frozen food manufacturers, their marketers and suppliers. AFFI's 550 member companies are responsible for approximately 90 percent of the frozen food processed annually in the United States, valued at more than \$60 billion. AFFI members are located throughout the country and are engaged in the manufacture, processing, transportation, distribution and sale of products nationally and internationally. AFFI represents almost all processors of frozen fruit and vegetable products produced in the United States.

AFFI members generally support the recommendations within the draft guidance document. Specifically, AFFI understands that the channels of trade provision, Section 408(l)(5) of the Federal Food Drug and Cosmetic Act (FFDCA), provides that chemical residues in food which are the result of lawful application of the chemical prior to its revocation shall not be deemed unsafe solely because of the presence of the chemical. Section 408(l)(5) of the FFDCA also provides that the product is lawful as long as it was applied in accordance with appropriate provisions of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and that the residue does not exceed a level that was authorized at the time of application or use.

00D-1309

Frozen Foods in Commerce From the Date of the Tolerance Revocation through December 31, 2000

AFFI expects many frozen fruit and vegetable products which may contain trace residues of legally applied methyl parathion will be out of distribution by December 31, 2000. The agency's decision to presume that fruits and vegetables may contain legal residues of methyl parathion for a reasonable period after tolerance revocation is appropriate. Frozen fruits and vegetables which have legally applied residues of methyl parathion are not adulterated, and the agency is correct in not requiring such foods to prove legal application of methyl parathion through December 31, 2000.

Frozen Foods in Commerce after January 1, 2001

AFFI agrees the guidance is accurate in stating that "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." It is possible that some frozen commodities containing legally applied quantities of methyl parathion may remain in commerce after December 31, 2000. The guidelines would require that products tested and found to contain legal methyl parathion residues after January 1, 2001, document that the food was packed or processed prior to December 31, 2000.

While AFFI applauds FDA's decision to provide a reasonable time period after tolerance revocation during which its members will not be required to demonstrate lawful application of methyl parathion, the Institute believes the time period should be extended with respect to frozen fruits and vegetables. FDA has concluded that legal methyl parathion residues may remain on non-frozen fruits and vegetables in the channels of trade for approximately one year after tolerance revocation, but will not dissipate from frozen fruits and vegetables. The one-year extension was intended to provide adequate time to dissipate methyl parathion residues in non-frozen fruits and vegetables. Accordingly, December 31, 2000, is an appropriate date for non-frozen fruits and vegetables.

Frozen fruits and vegetables with legal methyl parathion residues, however, may remain in commerce for an additional three years. Frozen fruit and vegetable products should receive consideration at least similar to that afforded non-frozen products. AFFI recommends, therefore, that FDA not require documentation for frozen fruits and vegetables with legal methyl parathion residues until after December 31, 2001.

AFFI's request is reasonable given the difference in methyl parathion residue dissipation between frozen and non-frozen foods. Subsequent to December 31, 2001, AFFI believes its members will be able to provide documentation of lawful application for single ingredient frozen fruit and vegetable products, and should be able to meet the requirements for frozen fruit and vegetable blends.

General Documentation Issues

AFFI is concerned that the description contained in the guidance of documentation to be used after December 31, 2000, is somewhat confusing. On page 8 of the guidance, the agency indicates it is not mandating a particular type of documentation, but is leaving "to each firm's discretion" the decision regarding the documentation that is appropriate. The discussion contained on pages 8-9 of the guidance, however, is very specific in this regard. AFFI recommends the agency provide language in the final guideline that provides maximum flexibility.

AFFI notes that some documentation appears unnecessary. Specifically, processors who must comply with Category II, A., should not be required to identify how the product was treated and provide certification from the supplier. Certification alone should be sufficient, especially considering that the supplier or processor would be conducting an auditing program.

Documentation of Blended Products

FDA has stipulated that blend manufacturers will be required to document and maintain records of ingredients used in a blend. In the frozen juice example contained in the guidance, the manufacturer was required to document, if legal methyl parathion residues were found, that one ingredient was purchased prior to December 31, 2000, and others were certified not to have been treated with methyl parathion.

AFFI would expect the requirements stipulated in the frozen juice example would be applied to manufacturers of frozen vegetable blends, although production circumstances are somewhat different. In the frozen juice example, two methyl parathion free juices are blended with one juice that contains legal residues of methyl parathion. The resultant "blend" contains trace residues of methyl parathion. In this example, FDA indicated that as long as the manufacturer can document that the frozen pear juice was purchased prior to December 31, 2000, and sources of frozen apple juice were certified as methyl parathion free, the resultant juice blend meets channels of trade requirements.

Frozen vegetable blends may contain vegetables from numerous sources. For example, the broccoli used in a three-way blend may come from several different suppliers. Consequently, one package of blended frozen vegetables might be methyl parathion free, while the next could contain legal methyl parathion residues, or conceivably there could be a combination of the two in one package. Following FDA's rationale, the frozen vegetable blend manufacturer needs only to document that during a particular production run, source(s) of the ingredients used with legal methyl parathion residues were purchased prior to December 31, 2000, and other sources were certified to be methyl parathion free. AFFI would not expect, therefore, that the manufacturer would be required to document when ingredient supplies are changed during a production run.

Packaging or Processing Codes In Lieu of Purchase Dates

AFFI questions FDA's change in documentation requirements related to products in "Category II: other types of documentation." Elsewhere, FDA refers to documentation associated with **packing or processing codes** of tested products. In Category II, however, the agency refers to **purchases** for blended products sampled after January 1, 2001. AFFI suggests that since frozen fruits and vegetables may be pre-frozen and stored prior to packaging, the date of **packing or processing** is appropriate whereas the date of purchase is irrelevant. For consistency, AFFI suggests that all documents should demonstrate that the product was packed or processed prior to January 1, 2001. Such documentation should be sufficient to illustrate lawful application of methyl parathion.

Conclusion

AFFI appreciates the opportunity to provide comments on the FDA's draft guidance on channels of trade for commodities with methyl parathion residues. AFFI looks forward to the opportunity to work with FDA in the development of final guidelines.

Sincerely,



Leslie G. Sarasin, CAE
President and
Chief Executive Officer



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