



## Apple Processors Association

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August 1, 2000

**To:** Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re:** The FDA Proposed guidance document entitled, "Guidance for Industry: Channels of Trade Policy for Commodities with Methyl Parathion Residues."  
Docket Control Number 00D-1309

The Apple Processors Association (APA) is respectfully submitting comments in response to a request from the Food and Drug Administration (FDA) for comments on the Agency's proposed guidance document, "*Guidance for Industry: Channels of Trade Policy for Commodities with Methyl Parathion Residues.*" APA acknowledges that the proposed guidance document represents FDA's policy for implementing the channels of trade provision for methyl parathion in accord with the Environmental Protection Agency's cancellation of specific food applications, including on apples. APA represents the makers of quality apple products from the whole apple, such as apple juice, sauce, and slices. Our member companies grow a significant proportion of the apples processed in their plants, and are committed to providing safe, high-quality, and affordable products to consumers.

We fully support the effort to ensure the safety of produce as well as other foods -- especially those commonly consumed by children. Furthermore, APA does not contest the EPA's cancellation of use for methyl parathion given the determination that methyl parathion poses an unacceptable aggregate risk. We also agree with EPA's statement, upon the August 2, 1999 announcement of the methyl parathion risk management decision, that the current food supply is safe, and that the Agency's focus should be on restricting applications in growing seasons beginning in the year 2000.

Although APA is in general support of the guidance document, the Association believes that FDA should provide clear evidence of the timeframe for dissipation of methyl parathion residues in processed apple products and should allow the food industry sufficient time for products to clear the channels of trade. We are not convinced that the current guidance document reflects a fair assessment of the time it will take for residues to dissipate or for a processed product to clear the channels of trade. The APA is also concerned about burdensome documentation requirements and the apparent presumption of guilt after January 1, 2001.

APA is pleased that FDA has chosen to consider varying rates of dissipation that depend on the storage conditions for foods. However, it is not clear that the proposed timeframe of one year for dissipation in the current guidance document for shelf-stable and refrigerated foods are accurate. APA would like to know what methodology and factors that EPA used to calculate the dissipation rates. We are also concerned that EPA dissipation estimates, to our knowledge, did not include applesauce, juice, or canned apples for pie filling. APA believes that FDA should

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provide an extended timeframe or clear evidence that such dissipation figures apply to all processed apple products.

We are also pleased that FDA aims to allow sufficient time for products to clear the channels of trade. It is not realistic to suggest however that products using legally treated apples would have cleared the channels of trade within a one-year timeframe. Apples intended for processing may sometimes be held in cold storage for more than a year before processing, and distribution and sale may add years to that time. The NFPA letter that is cited in the guidance document recommended a period of three years for clearing of the channels of trade for 95% of a product. While APA does believe that four years is a reasonable timeframe for frozen foods, such as frozen apple juice from concentrate, to leave the marketplace, we ask that FDA extend the time before requiring documentation to two years.

APA is also concerned about the substantial, and in some cases inappropriate, burden that documentation requirements will impose. Requiring validated analytical documentation of residue monitoring of all ingredients in a blended product or certification in addition to spot-checking is overly burdensome and unnecessary, especially where legal application to the probable source has been determined. If a residue is found in a blended product and the company is able to show legal application of methyl parathion to the probable source of the residue, without further evidence implicating a company, FDA should presume 408(1)(5) conditions are met with Category I documentation. The stipulation that analytical results are necessary to show methyl parathion was not illegally applied is inconsistent with the other standards of proof FDA has put forward.

Furthermore, the guidance should provide some indication of the amount of time a company would have to produce obligatory documentation to the Agency. Though it is generally available, compiling information on packing codes, inventory records and certification requirements (especially for blended products), is time consuming. Our member companies take precautions to determine what pesticides are on their products, including time, frequency and amount of pesticide sprayed, but they would need appropriate notice and adequate time to produce such documentation. Due to the amount of documentation required and the fact that a close grower/processor relationship does not always exist, FDA should allow companies a six-month grace period to provide adequate documentation verifying legal application of methyl parathion. APA would also suggest that the guidance should specifically disallow FDA from removing products from shelves or entering a processing plant without specific evidence that indicates illegal use of pesticides.

In conclusion, APA hopes that the final guidance document will reflect a fair assessment of the time it will take for methyl parathion residues to dissipate in processed products and will also provide for appropriate time for products to clear the channels of trade. APA also hopes that FDA will limit currently proposed documentation requirements while products are clearing the channels of trade. If you have questions regarding our comments, please feel free to contact us at (202) 659-1858. Thank you for the opportunity to comment.

NC/pw

Sincerely,



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Vice President, Food and Nutrition Policy



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