MCFA

Minor Crop Farmer Alliance

September 22, 2003

VIA E-MAIL AND U.S. MAIL

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 2003D-0263. Draft Guidance for Industry: Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency – 68 Fed. Reg. 43535-38. July 23, 2003.

To Whom It May Concern:

These comments are submitted by the Minor Crop Farmers Alliance ("MCFA") in response to the subject draft Guidance proposed by the Food and Drug Administration ("FDA" or "Agency"). MCFA is an alliance of more than one hundred national and regional organizations and individuals representing growers, shippers, packers, handlers and processors of various agricultural commodities, including food, fiber, nursery and horticultural products, and organizations involved with public health pesticides. MCFA has been substantially involved in various issues involving pesticides and implementation of the Food Quality Protection Act of 1996 ("FQPA").

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The MCFA is also a member of the Implementation Working Group ("IWG") which has submitted comments on the draft Guidance. Those comments are extremely comprehensive in identifying potential problems with the draft Guidance. Consequently, the MCFA endorses those comments and offers these additional, supplemental comments for the Agency's consideration.

As MCFA has previously advised both FDA and the U.S. Environmental Protection Agency ("EPA"), it is extremely important that both FDA and EPA operate in a manner to minimize the potential disruption to the food supply of the Nation. Except in those specific instances where EPA has advised that the consumption of a particular legally treated food over the duration of its "traditional" life in commerce would pose an unreasonable dietary risk (which the MCFA believes will be extremely rare occurrences), both FDA and EPA should operate so as to facilitate the distribution of lawfully treated food. If the FDA wants to preclude the subsequent distribution of a food that was lawfully treated pursuant to the EPA-authorized pesticide label, it is suggested that FDA consider buying the food in question. The person holding the food at the time of the FDA action should not be held liable for such regulatory decision when the pesticide was applied pursuant to a current EPA-granted registration that included EPA-approved directions for use. The easiest course for all concerned in almost every instance will be to allow the marketplace to function and allow for such a food containing a pesticide residue within the previously existing tolerance to be marketed.

MCFA is concerned with the rigor and extent of the database that may exist for each pesticide residue that may come into question. For example, it is known that certain pesticide residues may be found in various crops even though those specific crops have not been treated with the pesticide. This may likely be the result of uptake of the pesticide residue by the crop from the soil, such residues in the soil being present because of a prior application of the pesticide. It is not clear how such a situation would be handled by FDA. For example, assume that the pesticide residue would have been within the previously existing tolerance and the use has been cancelled as well as its associated tolerance under Section 408 of the Federal Food, Drug, and Cosmetic Act ("FFDCA"). In this circumstance, such a food is potentially at risk if the tolerance is prematurely revoked. It may take several years before such residues in the non-treated crop are below limits of quantitation. Both EPA and FDA should be aware of this possibility and extend the tolerance accordingly. EPA was authorized by the FQPA (codified at Section 408(l)(4) of the FFDCA) to issue tolerances to cover these kinds of residues, but EPA has not used this authority. It would make no sense to take adverse regulatory action prematurely in such circumstances.

It is also suggested that prior to taking any further action under this policy, FDA give notice to the interested public of the number of days a lawfully treated crop may contain detectible residues of the pesticide at issue. The interested public may then comment on whether the Agency's assumptions are correct.

MCFA appreciates the opportunity to provide these comments, and looks forward to the Agency's consideration of them. Please feel free to contact me if you have any questions, need additional information or want to discuss this further. I can be reached by telephone at 407-894-1351.

Respectfully submitted,

Daniel A. Botts

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Chairperson, Technical Committee

Minor Crop Farmer Alliance

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