



JAN 09 2012

Carol Freysinger
Executive Director
Juice Products Association
750 National Press Building
529 14th St., NW
Washington, DC 20045

Dear Ms. Freysinger,

The Food and Drug Administration (FDA or the Agency) is issuing this letter to alert the orange juice processing industry to the Agency's position with respect to recent reports of the finding of the fungicide carbendazim in orange juice.

Fungicides are chemical compounds or biological organisms used to kill or inhibit fungi or fungal spores that can cause serious damage in agriculture. Carbendazim is approved for use in a variety of crops, including citrus, in many countries. In the United States, however, the Environmental Protection Agency (EPA) has not approved carbendazim for use as a fungicide on oranges, nor has it established a tolerance or an exemption from the need for a tolerance for carbendazim in orange juice in the United States. Thus, carbendazim in orange juice is an unlawful pesticide chemical residue under the Federal Food, Drug, and Cosmetic Act.

On December 28, 2011, FDA learned from a juice company that it had detected low levels of carbendazim (in the low parts per billion range) in its and competitors' currently marketed finished products, and in certain orange juice concentrate that is not on the market. Industry reports indicate that carbendazim is present in orange juice products from the 2011 crop from Brazil, where the fungicide is used legally under Brazilian law to combat black spot, a type of mold that grows on orange trees.

The Environmental Protection Agency has conducted a preliminary risk assessment based on the recent reports of carbendazim in orange juice. Based on that risk assessment, EPA has concluded that consumption of orange juice with carbendazim at the low levels that have been reported does not raise safety concerns. FDA does not intend to take action to remove from domestic commerce orange juice containing the reported low levels of carbendazim. FDA is, however, conducting its own testing of orange juice for carbendazim, and, if the agency identifies orange juice with carbendazim at levels that present a public health risk, it will alert the public and take the necessary action to ensure that the product is removed from the market.

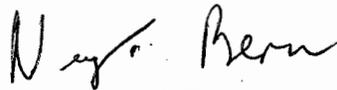
FDA is also sampling import shipments of orange juice and will deny entry to shipments that test positive for carbendazim.

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The FDA appreciates the industry informing the FDA of the issue. We request that you inform us of the juice industry's plans for ensuring that suppliers in Brazil (or elsewhere) refrain from using this pesticide in a manner that results in illegal residues in orange juice products intended for the United States.

If you or your members should have any questions or concerns regarding this matter, please feel free to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "Nega Beru". The signature is written in a cursive style with a large initial "N" and a long, sweeping underline.

Nega Beru, Ph.D.
Director
Office of Food Safety
Center for Food Safety
and Applied Nutrition