DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

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Dear Mr. Drozen:

This is in response to your e-mail communication of January 19, 2012, and additional issues you raised to me and other employees of the Food and Drug Administration (FDA) in a January 26, 2012, meeting at the Center for Food Safety and Applied Nutrition (CFSAN). Your e-mail and representation at the meeting were on behalf of the Brazilian Citrus Exporters Association (Citrus BR); however, in view of the other industry attendees at the meeting, including the Juice Products Association, we understand your position in this matter to also be that of the broader orange juice processing industry in the United States (U.S.).

As you know, FDA is currently testing samples of orange juice shipments from all countries and manufacturers that offer such shipments for import into the U.S. FDA has detained and refused shipments of imported orange juice concentrate, orange juice from concentrate, and not from concentrate (NFC) orange juice with quantifiable (greater than or equal to 10 ppb) residues of carbendazim (a fungicide recently applied to orange trees in Brazil because of a problem with black spot, a type of mold that grows on the trees).

You have asked FDA, when assessing orange juice shipments offered for import, now through June 2013, to determine whether the sampled product contains quantifiable residues of carbendazim on a single strength basis. Your request is based upon the fact that the orange juice concentrate will be diluted to single strength prior to consumption as well as the findings of the Environmental Protection Agency's (EPA's) risk assessment for the safety of orange juice containing residues of carbendazim. (http://www.epa.gov/pesticides/factsheets/chemicals/carbendazim_ra.pdf).

You chose the June 2013 date because, although the members of Citrus BR committed to cease use of carbendazim by the end of last month, orange juice shipments from Brazil may not be free of carbendazim residues for another 18 months. For the reasons set out below, we are declining your request in this matter.

Your e-mail communication provided several examples where FDA, by policy directive, assesses levels of certain contaminants in the single strength equivalent of juice concentrate samples as follows:

- Patulin in apple juice, apple juice concentrates and apple juice products - Compliance Policy Guide (CPG) Sec. 510.150
- Radionuclides in imported foods - CPG 560.750
- Lead in prune juice concentrate - Import Alert (IA) 30-02
- Heavy metals in fruit juices and fruit juice concentrates - IA 20-05

Unlike carbendazim, none of these contaminants is intentionally added to food – in most instances they enter food due to their presence in the environment, the exception being the case of IA 30-02, where the unintentional occurrence of excessive levels of lead (above those normally found in food due to lead's environmental occurrence) was associated with the operations of a specific processor. To the extent that these contaminants in food are due to the presence of the contaminant in the environment, the contamination is unavoidable to one degree or another. Put another way, it is infeasible in such cases to eliminate the contaminant from food which is plainly not the case with carbendazim, whose presence is the direct result of the intentional application of a fungicide resulting in pesticide chemical residues in food for which there is no EPA tolerance or tolerance exemption. In fact, as of February 8, FDA had collected 99 import orange juice samples under its current initiative, of which 63 have been non-violative for pesticide residues. Thirty-four (34) of those samples found with no pesticide residues were of orange juice concentrate. Fifteen (15) of the 99 samples were declared with a Country of Origin of Brazil, ten (10) declared as orange juice concentrate, four (4) as NFC orange juice, and the remaining shipment/sample declared as orange juice. One (an orange juice concentrate sample) of the fifteen samples with a declared Country of Origin of Brazil has been found to be non-violative.

We would also note that each of the contaminants referred to in your e-mail are added poisonous or deleterious substances subject to the adulteration and safety standard in the first clause of Section 402(a)(1) of the Federal Food, Drug and Cosmetic Act (the FFD&C Act), i.e., they adulterate a food when they are present in food in an amount that may render the food injurious to health. In assessing whether such a contaminant in a food may be injurious to health, it is appropriate to consider the level of the contaminant in the food as it would be consumed, i.e., the single strength equivalent in a juice concentrate sample.

By contrast, a food that bears or contains an unsafe pesticide chemical residue is adulterated under Section 402(a)(2)(B) (21 U.S.C. 342(a)(2)(B)). A pesticide chemical residue is deemed to be unsafe under Section 408(a) of the FFD&C Act (21 U.S.C. 346a(a)) if no tolerance or exemption from the requirement of a tolerance is in effect for the residue. Because there are no tolerances (or exemptions) in effect for residues of carbendazim or its parent compounds benomyl and thiophanate-methyl in or on oranges or orange juice, a residue of carbendazim in orange juice concentrate or NFC orange juice is, by operation of law, an unsafe pesticide chemical residue and such food is

adulterated within the meaning of Section 402(a)(2)(B). In addressing pesticide chemical residues in or on food for which no tolerance or exemption from the requirement for a tolerance is in effect, the statute does not provide for consideration of the form of the food bearing or containing the residue as compared to the form in which it will be consumed.

By deeming unauthorized pesticide chemical residues in food to be adulterants and thus unlawful, the FFD&C Act ensures that agricultural pesticide residues in food have been demonstrated to be safe prior to application of a pesticide to specific crops. This feature of the law also reinforces the pesticide registration requirement in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), which EPA administers. Under FIFRA, EPA registers a pesticide for use on a crop and, under the FFD&C Act, establishes a tolerance or tolerance exemption for the pesticide chemical residues in food from such use. This ensures that pesticide chemical residues present in food are safe to consume. Carbendazim and its parent compounds are not registered in the U.S. for use on oranges and thus U.S. orange growers are legally precluded from using them.

Therefore, FDA intends to continue to test orange juice concentrate, orange juice from concentrate, and NFC orange juice shipments offered for import. To the extent FDA finds quantifiable residues of carbendazim, such shipments are subject to FDA detention and refusal. FDA's handling of orange juice shipments has been no different from FDA's handling of any food products found to contain unlawful pesticide chemical residues. The detentions, refusals and additions to Import Alert 99-08 currently taking place are all routine actions and have been part of FDA's process for decades.

You also stated that there is a cognizable WTO claim if FDA does not base its compliance determination for shipments offered for import on levels of carbendazim in the juice on a single strength basis, as it is doing for juice already produced or imported and present on the U.S. market. We disagree. The fact that the agency decides to prevent food products, such as orange juice, that contain residues of unauthorized pesticides from entering U.S. commerce is not inconsistent with U.S. WTO obligations. The assertion made by Citrus BR during the January 26 meeting that there is some misunderstanding on the part of Brazilian citrus growers concerning the application of U.S. pesticide tolerance requirements does not and should not bear upon FDA's enforcement of the FFD&C Act requirements. We consider the assertion that FDA's testing of product as offered for import, whether concentrate or single strength, poses an international trade issue to be without merit.

In your e-mail communication, you also stated that the relevant section of FDA's Pesticide Analytical Manual (PAM) indicates that juice concentrate should be tested on a single strength basis for pesticide residues. The guidance in the PAM as applied to the testing of juice concentrate was never explicitly established as FDA's policy for assessing residues of pesticides in foods for which no tolerance or exemption from the requirement for a tolerance is in effect. Application of this guidance to assessing residues in foods for which a tolerance is in effect ensures that FDA's determination of the residue's compliance with the tolerance requirements in 40 CFR Part 180 is consistent with the

methodology used by EPA in assessing the pesticide chemical under the safety standard in Section 408 and EPA's provision in 40 CFR 180.1(i)(10) regarding food sample preparation (added by EPA in 2005; see 70 FR 33354).

We reviewed Dr. Prusa's economic analysis (including his responses to our questions) of the effect of not having Brazilian imports available to the U.S. market because of carbendazim contamination. In general, we recognize that the use in Brazil of a pesticide not authorized in the U.S. and FDA's detention of shipments bearing illegal residues has affected the orange juice market and has economic impacts. In our view, however, these impacts do not warrant a change in FDA's enforcement of the statutory scheme in the FFD&C Act for imported orange juice concentrate to prevent the introduction into the U.S. of food that contains illegal residues, in this instance of carbendazim. Without enforcement, we could not ensure that the food supply is protected against unlawful pesticide chemical residues in food offered for import, and if our enforcement is not consistent, it would provide an unfair advantage to those who have not taken the steps and incurred the expenses necessary to ensure that food they offer for sale in the U.S. complies with the requirements of the law.

Sincerely yours,

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