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RODRIGUEZ O'DONNELL ROSS FUERST UPDATE

FROM: Benjamin L. England, Esq.

RE: EPA Final Rule Reestablishing "Flow-Through" Provisions for Processed Foods Containing Pesticide Chemical Residues and its Impact on FDA Import Alert 99-08 Relating to Pesticide Chemical Residues in Processed Foods

DATE: June 9, 2005

Summary

In 1996, Congress passed the Food Quality Protection Act (FQPA) amending the Food Drug and Cosmetic Act (FDCA) to consolidate pesticide tolerance authority for foods in section 408 of the FDCA. The FQPA was intended to improve the quality and safety of foods and to ensure that risk assessments of pesticide residues in food, conducted by the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) properly consider the aggregate effect of pesticides on human and animal health. In the consolidation process, Congress moved a "flow-through" provision, which protected processed foods that are not intended for consumption "as is," to FDCA section 408 with minor changes. One of these minor changes was the dropping of the requirement in the "flow-through" provision that specified that residues in processed foods be judged against the raw food tolerance only when the processed food is at the "ready to eat" stage.

On June 8, 2005, EPA published a final rule updating generic pesticide chemical tolerance regulations. See *Updating Generic Pesticide Chemical Tolerance Regulations*, 70 F.R. 33354 (June 8, 2005). This regulation replaces the "flow-through" provision so that pesticide residues in processed foods are again judged against the raw food tolerance only when the processed food is at the "ready to eat" stage. EPA's regulation is effective on August 8, 2005.

As a result of EPA's action, companies that have been added to FDA's Import Alert 99-08 due to the apparent presence of pesticide chemical residues may have an immediate legal argument for petitioning FDA for removal from the import alert. Additionally, private laboratories that analyze processed foods for pesticide chemical residues may again report to FDA on a "ready-to-eat" basis as already provided for in FDA's PAM.

Background

In the preamble to its final rule EPA describes the "flow-through" provision that was lost in the passage of the FQPA as follows:

Traditionally, pesticide chemical tolerances on foods have been set primarily on raw agricultural commodities rather than processed foods. In the 1954 law establishing the modern system of pesticide tolerances, such tolerances were only authorized as to raw agricultural commodities. See 21 U.S.C. 346a(b) (1994). . . . Specifically, in seeking to coordinate action under the pesticides provision (section 408) and the food additives provision (section 409), Congress provided in section 402 that: ". . . where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the food shall, notwithstanding the provisions of section 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity" 21 U.S.C. 342(a)(2)(C) (1994). In sum, this provision applied the tolerance level for a pesticide residue in raw food to processed food derived from that raw food. The provision became known as the "flow-through" provision because it permitted, in most cases, legal residues in a raw food to flow-through to the processed commodity without adulterating that latter commodity. *See* 70 FR at 33356.

EPA also notes, "[t]here is no indication that Congress removed the requirement because it thought it was important that concentrated juices be analyzed 'as is' to determine whether or not they comply with tolerances applying to raw fruit and fruit juice in the form they are consumed. Obviously, examining whether concentrated apple juice meets a tolerance applicable to apple juice as consumed makes little sense from a risk perspective." *Id.* at 33357-58.

EPA's prior regulation on pesticide chemical residues in processed foods contained a "flow-through" provision, stating that such foods were not "unsafe" within the meaning of

section 406 of the FDCA as long as certain conditions were met. The result, however, was that such foods were still considered unsafe within the meaning of section 408 of the FDCA under all conditions. Generally speaking, foods that are unsafe within the meaning of FDCA section 408 are considered adulterated within the meaning of FDCA section 402(a)(2)(B). The prior EPA regulation, therefore, had no “flow-through” provision to protect processed foods from being deemed adulterated under the FDCA because the regulation did not apply to FDCA section 408. EPA’s final rule published on June 8, 2005 corrected this and *specifically reestablishes a “flow-through” provision for foods as to FDCA section 408.*

FDA’s Import Alert 99-08

After enactment of the FQPA, FDA began analyzing imported processed foods for pesticide chemical residues and judging the laboratory results on a concentrated, dehydrated, or dried basis rather than a reconstituted or “ready-to-eat” basis. As FDA found pesticides at concentrations above EPA tolerances, the agency added the foreign processors and the processed foods to its Import Alert # 99-08 because their processed foods appeared to be adulterated within the meaning of FDCA sections 402(a)(2)(B) and 408. *See DETENTION WITHOUT PHYSICAL EXAMINATION OF PROCESSED PRODUCTS FOR PESTICIDES*, Import Alert 9908, at http://www.fda.gov/ora/fiars/ora_import_ia9908.html (issued July 6, 1994, last revised June 6, 2005) (last viewed June 9, 2005). Consequently, processed food products from foreign processors were increasingly being “automatically detained” by FDA automatically due to the criteria in the Import Alert.

Importers of these automatically detained processed food products hired private laboratories to analyze for pesticide residues as specified in the alert. The private laboratories reported pesticide analytical results to FDA on a “ready-to-eat” basis. This form of reporting was fully consistent with FDA’s Pesticide Analytical Manual (PAM) because FDA never revised the PAM to remove the “flow-through” reporting of pesticides residues on processed foods. *See* USFDA, CFSAN, Office of Plant and Dairy Foods and Beverages, PESTICIDE ANALYTICAL MANUAL (PAM), Table 104-a (1994, Updated Oct. 1999) at <http://www.cfsan.fda.gov/~frf/pami1.html> (last viewed June 9, 2005). FDA, however, began rejecting private laboratory packages that reported pesticide results on processed foods on a “ready-to-eat” basis.

Based upon several entries that FDA detained or refused, we intervened with FDA arguing that the Agency’s implementation of the FQPA in this manner contravened the Agency’s own guidance, EPA’s regulations as they then existed, and Congress’ intent in passing the FQPA. Moreover, the Import Alert was probably in violation of the Administrative Procedures Act because it was being implemented as a rule without the required notice and comment. *See* 5 U.S.C. § 704.

The EPA final rule has returned the effect of the original “flow-through” for processed foods that contain pesticide residues above tolerance levels but which are not consumed “as is”

and requires FDA to judge such products on a “ready-to-eat” basis. It should be noted that the regulation only directly addresses pesticide residues for which a tolerance exist for the raw agricultural commodity. It is silent as to those pesticide residues for which no tolerance exists for the raw agricultural commodity. However, FDA has traditionally exercised enforcement discretion for “trace” amounts of pesticide residues for which no EPA tolerance exists even on raw agricultural commodities. Therefore, it is both reasonable and likely that FDA will extend this enforcement discretion to processed foods when the pesticide residue results are reported out on a “ready-to-eat” basis.

Text of the EPA Final Rule

EPA’s final rule makes several revisions to existing EPA regulations found at 40 CFR Part 180. The most significant regulatory revisions for the purpose of this update are:

- The addition of a definition for the FDCA (new 40 CFR 180.1(c));
- Revised language that states that a “processed food will not be considered unsafe within the meaning of FDCA sections 402 and 408(a), despite the lack of a tolerance or exemption for the pesticide chemical residue in the processed food” (new 40 CFR § 180.1(e) (emphasis added));
- New language expressly providing that pesticide chemical residues in processed foods, for which there is an existing EPA tolerance, will be judged on a “ready-to-eat” basis and explicitly references, by way of examples, “fruit juice concentrates, dehydrated vegetables, and powdered potatoes” (new 40 CFR 180.1(i)(10))¹

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If you have any questions regarding the information contained in this update, or if you require assistance in obtaining release of imported processed foods or removal from FDA’s Import Alert 99-08, please do not hesitate to contact Benjamin L. England, at 202-293-3300 ext 112 or via email at bengland@rorfgw.com.

¹ . The final rule incorrectly cites the revised subsections of 40 CFR § 180.1. It properly recites the use of previously reserved paragraph (c), the deletion of paragraph (d), the renumbering of paragraphs (e) through (p) as paragraphs (d) through (o) respectively, and the addition or modification of new paragraphs (e), (j), and (n). However, it actually revises new paragraphs (h) and (i) and it seems to add them to new paragraph (e). This, we suspect will be corrected in a following Federal Register Notice. In the attempt to reduce the impact of EPA having confused the various paragraphs in section 180.1, we have cited the revisions using the *correct* nomenclature.