

QUESTION:

Hard or sharp foreign objects in food may cause consumer injury. What procedures are followed to minimize the risk that food ingredients from the corn wet-milling industry will contain foreign matter that might pose a significant health risk in food products?

Summary

- The U.S. Food and Drug Administration (FDA) has established regulatory action guidance for foreign matter in food ingredients and products. Hard or sharp objects 7mm or longer represent a potential physical hazard in food.
- The products of Corn Refiners Association, Inc. (CRA) member companies pass through numerous screening and filtration unit processes during their manufacture. These unit processes are designed to remove foreign matter from finished products that infringe FDA's particle size guidelines. Thus, products of the CRA member companies may be among the safest and highest quality ingredients available to food manufacturers and consumers.

1. U.S. Regulatory Action Guidance^{1,2,3}

The U.S. FDA recently concluded a study that evaluated a) 190 reports of foreign objects in food received by FDA's Health Hazard Evaluation Board over a period of 25 years; and b) a review of the scientific literature concerning physical hazards in food products. It is significant that none of the reports involved products of the corn wet-milling industry.

A product should be considered adulterated if it contains:

- a hard or sharp foreign object that measures 7 to 25 mm in length *and* the product is ready-to-eat *or* requires only minimal preparation steps that would not eliminate, invalidate or neutralize the hazard prior to consumption.

A product may be considered adulterated, after review of the hazard by FDA, if it contains:

- a hard or sharp foreign object that measures 7 to 25 mm in length and the product requires additional preparation or processing that may have an effect on the presence of the foreign object in the finished food;

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- a hard or sharp foreign object less than 7 mm in length and a special risk group, such as infants, surgery patients or the elderly is among the intended consumers of the product;
- a hard or sharp foreign object over 25 mm in length.

In conducting its review of the possible health hazard, FDA will consider various factors, including the intended use of the product, subsequent processing steps, official guidance and requirements concerning unavoidable natural defects and other mitigating factors.⁴

Though it contains no foreign objects meeting the criteria above, a product could be considered adulterated if a review by the Center for Food Safety and Applied Nutrition (CFSAN) finds the product unfit for food consumption. CFSAN product reviews typically evaluate subsequent processing steps, extent of contamination, intended use, official guidance and requirements concerning unavoidable natural defects, and other mitigating factors that could eliminate, invalidate or neutralize the hazard prior to consumption of the food product.

2. Corn Wet-Milling Industry^{5, 6}

CRA member companies have upgraded raw materials handling, facilities, manufacturing processes and equipment, and shipping practices to remain abreast of technological advances. Dry and liquid products emerging from corn wet-milling unit processes should be free of particles judged by FDA to represent a potential physical hazard in food. Thus, products of CRA member companies may be among the safest and highest quality ingredients available to food manufacturers and consumers.

Facilities

Corn wet-milling is essentially a closed process: processing equipment, reactors and tanks are enclosed wherever possible to prevent foreign matter from entering. Ducts, pipes and fixtures are located to avoid food contamination from drips, condensate and falling dust and debris. Most wet-milling plants enforce a no glass policy; bulbs, fixtures and skylights located above food processes are protected to prevent contamination in case of breakage. Buildings, structures, processing equipment and utensils should be maintained in good operating condition, and should be cleaned and sanitized in accordance with Good Manufacturing Practices (GMP).

Corn Handling

Corn used for wet-milling is purchased according to U.S. Grading Standards established by USDA. These standards specify permissible amounts of damaged kernels, broken corn and foreign material. Stones and metal are removed from incoming corn by screening through devices such as coarse wire mesh (commonly 1/4th to 3/8th inch) and passage through ferrous magnets.

Manufacturing Processes

Cleaned corn is ground in the mill house in an aqueous process that liberates the fiber, starch, protein and germ (oil) fractions. After the germ fraction is floated off, the remaining slurry passes through wash screens that retain the fiber but allow the starch and protein fractions to pass through. Wash screens are typically 325 mesh (@ 50 micron = 0.050 mm), retaining all but the smallest, microscopic particles.

Wet mill starch is the raw material for production of native and modified starches, dextrins, maltodextrin, corn syrups, dextrose, high fructose corn syrup (HFCS), crystalline fructose and a variety of fermentation products (ethanol, citric acid, lactic acid, etc.). Starches, dextrins and maltodextrins typically pass through a series of washing, filtering, slurring, dewatering, screening and drying unit processes.

Corn syrups, HFCS, fructose and fermentation products receive additional refining, including enzyme and carbon treatment and ion exchange. These unit processes are arranged as packed beds, thereby functioning as supplementary filtration steps.

Most liquid products conclude with a final filtration step. Dried products commonly pass through a rare earth magnet during packaging as a final precaution against foreign matter contamination.

Shipping Practices

Bulk shipments are made by rail in special hopper, tank and box cars, by motor transport in similarly designed trucks or in other food-grade approved shipping containers. Containers should be carefully cleaned and inspected prior to loading. Bulk containers should be sealed with tamper-evident seals designed to ensure that product is not adulterated in route to the customer. See *CRA Food Safety Information Papers: Transportation*⁷ for further information.

References

- ¹ Olsen, A.R., Regulatory action criteria for filth and other extraneous materials, *Regulatory Toxicology & Pharmacology*, 28:181, 1998.
- ² FDA/ORA, Compliance Guideline: Adulteration involving hard or sharp foreign objects, Section 555.425, 3/23/99.
- ³ U.S. Code Title 21: Food & Drugs, Section 342: Adulterated Food, Paragraph (a): Poisonous, insanitary (sic), etc., ingredients.
- ⁴ Compliance Policy Guide, Section 555.425 – Foods – Adulteration Involving Hard or Sharp Foreign Objects.
- ⁵ Smith, Robert, Quality control in corn refining, *Corn Annual*, Corn Refiners Association, Inc, Washington, DC, 1981.
- ⁶ Purdue, J.C., A.E. Staley Manufacturing Company, personal communication, March 2000.
- ⁷ Corn Refiners Association, Inc., *CRA Food Safety Information Papers: Transportation*, Washington DC, 2000.