

### QUESTION:

*The U.S. Food and Drug Administration receives many reports annually from consumers who experience adverse reactions following exposure to allergenic substances in foods. What procedures are followed to minimize the risk that food ingredients from the corn wet-milling industry will contain allergens that might pose a significant health risk in food products?*

### Summary

The U.S. Food and Drug Administration (FDA) has concluded that allergic reactions to corn-derived sweeteners do not represent a major health concern in the United States. Neither corn nor refined corn products are among the specific allergens that are required to be labeled under the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 3). The prevalence of corn allergy in the U.S. is exceedingly low — estimated to affect no more than 0.016% of the general population.<sup>1</sup>

Corn and corn wet-milling-based ingredients are not on the Codex Alimentarius Commission's recently-released list of foods that can cause hypersensitivity. Exposure and sensitization to corn allergens can occur externally (via direct skin contact) or internally (via consumption or inhalation). Though many clinical symptoms have been attributed to corn sensitivity, not all have been conclusively confirmed. Attributed symptoms include dermatitis, asthma, urticaria, migraine headache, ulcerative colitis, inflammatory/irritable bowel disease, celiac sprue and anaphylaxis.

Dermatitis and asthma are the most commonly cited symptoms of corn allergy. It must be noted that anaphylaxis is an extremely rare reaction to *any* allergen — no cases of anaphylaxis resulting from exposure to corn wet-milled products have been substantiated. It should also be noted that the *Merck Manual of Diagnosis and Therapy* defines celiac disease as a disorder caused by sensitivity to the gliadin fraction of gluten, a cereal protein found in wheat and rye and less in barley and oats.

### Wheat Gluten

Food ingredient products of the Corn Refiners Association (CRA) member companies should not contain allergens that pose a significant health risk either for the general population or for gluten- or sulfite-sensitive consumers. Corn protein, commonly referred to as corn gluten, should not be confused with wheat protein, referred to as wheat gluten, which is known to cause allergic reactions in some people. The overwhelming majority of cereal allergies can be traced to wheat gluten. Therefore, consumption of corn-based products should not be a problem for gluten intolerant consumers.

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Corn wet-millers commonly use sulfites such as sulfur dioxide to aid the milling process. While most is removed during subsequent washing and evaporation steps, trace sulfite may remain in certain products.

Member companies of the CRA strictly adhere to FDA labeling regulations for sulfites. FDA permits 20-40 ppm and 50 ppm sulfite in sweeteners and starches, respectively. Sulfite levels are monitored in all finished sweetener and starch products. Should the sulfite level exceed 10 ppm in these products, a written agreement between shipper and consignee concerning the presence and level of sulfites is sufficient to satisfy FDA's labeling requirement for 'foods for use in further processing.'<sup>2</sup> When this information is incorporated in finished product labeling, sulfite-sensitive consumers are able to recognize and avoid foods containing common sulfites.

### Regulatory Positions

Final regulations on nutrition labeling were published by FDA in January of 1993. FDA decided not to require identification of the source of starch used in sweetener production, because of the finding that "allergic reactions to sweeteners, particularly corn-derived sweeteners, do not represent a major health concern in the United States."<sup>3</sup>

The Food Allergen and Consumer Protection Act of 2004<sup>4</sup> requires disclosure of the presence of eight specific food groups which are designated as "major food allergens" on the label of packaged foods.<sup>5</sup> Congress did not designate corn or refined corn products as "major food allergens", and FDA guidance on compliance with the Act does not include reference to corn or refined corn products.<sup>6</sup>

The international Codex Alimentarius Commission also reviewed food allergens and published a list of those that are known to cause hypersensitivity. Included on the list are "cereals containing gluten: i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these."<sup>7</sup> It should be noted that corn is not among the cereal grains identified by the Codex Commission requiring special hypersensitivity labeling.

Thus, food ingredient products of CRA member companies should not contain allergens that pose a significant health risk either for the general population or for gluten- or sulfite-sensitive consumers.

### References

- 1 Loveless, M.H., Allergy for corn and its derivatives; experiments with a masked ingestion test for its diagnosis, *J Allergy*, 21:500, 1950.
- 2 Labeling of sulfites in standardized foods, *Federal Register*, 58(3):2855, 6 January 1993. 21CFR 130.9; see also 21CFR 101.100(a)(4).
- 3 Nomenclature for Sweeteners, *Federal Register*, 58(3):2865, 6 January, 1993.
- 4 Public Law 108-282 ("FALCPA").
- 5 "Major food allergens" specified in FALCPA are milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts and soybean.
- 6 FDA's guidance can be found at: <http://www.cfsan.fda.gov/~dms/alrguid.html>. See Guidance for Industry; Questions and Answers Regarding Food Allergens, including Food Allergen Labeling Consumer Protection Act of 2004 (Edition 3).
- 7 Codex Alimentarius Commission, Draft recommendations for the labeling of foods that can cause hypersensitivity (draft amendment to the general standard for the labeling of prepackaged foods), Alinorm 99/22, Appendix III, Section 4.2.1.4, 1999.