AMERICAN FROZEN FOOD INSTITUTE

Issue Brief: Acrylamide

In the early 2000s, researchers discovered that the chemical acrylamide forms in certain foods when they are subjected to high-temperature cooking methods, such as frying, grilling, roasting, baking, and toasting. Acrylamide is formed during the Maillard reaction, which is the primary chemical process determining flavor, color, and texture in many cooked foods. Specifically, the chemical results from the reaction of free asparagine and reducing sugars, both of which are commonly found in many foods. Studies have shown that acrylamide can be carcinogenic when consumed at high levels by laboratory animals. Recently the Food and Drug Administration (FDA) published a draft guidance on acrylamide in food. 1/ The draft guidance identifies a number of potential acrylamide mitigation strategies food manufacturers should consider. Acrylamide remains on California's list of Proposition 65 chemicals as a chemical known to the state of California to cause cancer or reproductive harm.

Legal Framework

FDA addresses acrylamide through its general food safety regulations; there are no acrylamide-specific FDA regulations. Under Section 402(a)(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA), a food is adulterated if it contains a poisonous or deleterious substance that may render it injurious to health. Substances that are not an "added substance" to the food, however, do not adulterate the food if the substance is present at levels that do not ordinarily render the food injurious to health. 2/ Acrylamide is not added to food, but rather is a result of the cooking process itself. FDA has not established a specific level at which the agency believes acrylamide would be injurious to health.

Section 418 of the FFDCA, added by the FDA Food Safety Modernization Act (FSMA), requires food facilities to conduct hazard analyses and implement risk-based preventive controls to address food safety hazards. 3/ FDA has issued a proposed rule that would establish the hazard analysis and preventive controls requirements. 4/ Although not identified by name under the proposed rule, acrylamide could be considered a chemical hazard that facilities would be expected to address in their food safety plans. The FSMA preventive controls rulemaking is ongoing, and the final details for the requirements remain uncertain.

1/ FDA, Draft Guidance for Industry: Acrylamide in Foods (Nov. 2013), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ChemicalContaminantsMetalsNaturalToxinsPesticides/ucm374524.htm.
2/ FFDCA § 402(a)(1); 21 U.S.C. § 342(a)(1).
3/ FFDCA § 418; 21 U.S.C. § 350g.
4/ 78 Fed. Reg. 3646 (Jan. 16, 2013).

Under California's Proposition 65, a company may not expose a consumer in California to a chemical known to the state of California to cause cancer or reproductive harm without first providing an adequate warning, unless the company can show the exposure poses no significant risk under conditions specified in the law. The law allows private litigants to file lawsuits against companies to enforce the warning requirement. California has identified acrylamide on its Proposition 65 list of chemicals known to the state as causing cancer or reproductive harm. California has established a maximum allowable dose level for acrylamide of 140 µg/day for male reproductive harm and a no significant risk level of 0.2 µg/day as a carcinogen. [Should we insert something to the effect that the Prop 65 warning does not apply if the substance is at or below the allowable level?] Food companies have also settled numerous lawsuits with the state and with private litigants setting target levels for acrylamide in specific foods and defining the warnings that must be provided by the parties to the settlements if the target levels are not reached.

Recent Developments

In November 2013, FDA released in draft form its *Guidance for Industry: Acrylamide in Foods*, which outlines specific strategies food manufacturers might use to reduce the level of acrylamide that forms in certain foods. The draft guidance "suggests a range of possible approaches" for reducing acrylamide and "is not intended to identify specific recommended approaches." Nor does the draft guidance suggest maximum levels for acrylamide in food. FDA does, however, "recommend that manufacturers be aware of acrylamide levels in their products" and "consider adopting approaches, if feasible, that reduce acrylamide in their products." The draft guidance contains recommendations for potato products (French fries, potato chips, and fabricated potato chips and snacks), cereal-based foods, and coffee. The recommendations range from source material selection and handling to processing techniques to labeling. The acrylamide reduction strategies described in the draft guidance vary in their level of scientific support, with FDA acknowledging that several possible reduction methods discussed in the draft guidance have not been fully validated or have seen ambiguous results.

Issues to Watch

- FDA will consider comments received on its draft acrylamide guidance and is expected to work toward finalizing the draft guidance. Even before the guidance is finalized, FDA may expect food companies to consider how acrylamide mitigation strategies can be incorporated into their operations.
- FDA continues to gather information for a future risk assessment.5/
- FDA is expected to issue its final rule on hazard analyses and preventive controls within the next several years. It will be important to note how acrylamide is classified under the final rule and to identify what actions will be expected of food companies that identify acrylamide as a chemical hazard in their hazard analyses.

5/ FDA 2007 Regulatory Report: Acrylamide, Furan and the FDA (with updates) (http://www.fda.gov/Food/FoodborneIllnessContaminants/ChemicalContaminants/ucm194482.htm)

- Efforts have been and likely will continue to be made to amend the Proposition 65 program to remove or curtail the private attorneys general provision that allows private litigants to file lawsuits to enforce the law's warning provisions and to collect fees in the process. 6/

International Perspective

Acrylamide is considered a chemical food contaminant in the European Union (EU), but no regulatory maximum limits for acrylamide have been established for food. The European Food Safety Authority (EFSA) has conducted multiple evaluations of acrylamide, and EU Member States monitor acrylamide levels. 7/ EFSA's Scientific Panel on Contaminants in the Food Chain (CONTAM Panel) will be drafting a scientific opinion about consumer risks from acrylamide exposure. 8/ The preliminary full risk assessment is to be completed by mid-2014 before finalization first half of 2015.

The European Commission (EC) has developed "indicative values" for food groups considered to contribute the most to dietary acrylamide exposure. 9/ Indicative values are intended only as a guide to prompt investigation when higher levels occur so that enforcement authorities can gain more data. The EC can use this data to take measures to reduce acrylamide levels, but so far has not done so. The United Kingdom has no national maximum acrylamide limits for food but does participate in the data-gathering and evaluation program overseen by EFSA and the EC.

Food business operators in the EU have developed a voluntary scheme that is aimed at diminishing the levels of acrylamide in foods. The organization FoodDrinkEurope, which represents the European food and drink industry, developed an acrylamide toolbox that can be used by food producers to lower acrylamide levels in their products. Sector specific short brochures have also been developed.

Health Canada has initiated a call-for-data on the occurrence of acrylamide in foods in Canada. The goal is to determine the success of acrylamide reduction strategies implemented. 10/

AFFI Action Items

AFFI is maintaining its leadership role in addressing the issue of acrylamide in food:

6/ California enacted a law in the Fall of 2013 that made minor adjustments to the Proposition 65 program that do not affect how acrylamide is treated under the law.
7/ *See, e.g.*, European Food Safety Authority; Update on acrylamide levels in food from monitoring years 2007 to 2010. EFSA Journal 2012; 10(10):2938. [38 pp.] doi:10.2903/j.efsa.2012.2938.
8/ http://www.efsa.europa.eu/en/topics/topic/acrylamide.htm
9/ European Commission Recommendation of 8 November 2013 on investigations into the levels of acrylamide in food (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:301:0015:0017:EN:PDF)
10/ Technical Consultation - Health Canada Call for Data to Assess the Effectiveness of Acrylamide Reduction Strategies in Food (http://www.hc-sc.gc.ca/fn-an/consult/2013-acrylamide/index-eng.php)

- Engaged in the regulatory process to provide input on FDA's draft guidance for acrylamide strategies, including preparing comments with the assistance of Hogan Lovells US LLP;
- Working with affiliated organizations to prepare toolkits for acrylamide reduction strategies;
- Monitoring Proposition 65 enforcement actions, lawsuits, and settlements, and possible reform efforts in the state of California.

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