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Public Meeting
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Assessing Acrylamide in the U.S. Food Supply

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David R. Lineback, Director
Joint Institute for Food Safety and Applied Nutrition (JIFSAN)
University of Maryland,
College Park, MD 20742
Chair, Scientific Advisory Panel
American Association of Cereal Chemists (AACC)

Good afternoon. As Director of the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) at the University of Maryland, College Park and chair of the Scientific Advisory Panel, American Association of Cereal Chemists (AACC), I have had the opportunity to not only stay informed but also participate in many of the national and international scientific discussions that are ongoing with respect to the occurrence of acrylamide in foods.

The FDA draft action plan indicates JIFSAN will serve as the clearinghouse for continued international coordination and data sharing. We have been asked by the FAO/WHO to manage the international Acrylamide in Food Network that is being established as a result of one of the recommendations from the FAO/WHO Expert Consultation in June. The web-based network will invite all interested parties to share relevant data as well as ongoing investigations. We are actively engaged in this effort and strongly endorse the need for ongoing coordination and information exchange nationally and internationally. I think it is important to keep in mind that this is clearly a topic that has and will continue to be an international issue with efforts underway from governments, academia, and industry.

FDA is to be complimented for developing a thoughtful and very appropriate action plan for addressing the occurrence of acrylamide in food. I believe the Agency has identified a course of action that takes into account what is known, or more precisely what is not known, about acrylamide in foods and is consistent with the activities and directions being taken by national and international scientific bodies and government organizations.

Given that the issue of acrylamide in food only surfaced in late April of this year with the press announcement from Sweden, the progress and level of activity achieved by

scientists and government organizations in the United States and other countries is truly outstanding. With the excellent analytical work of the Swedish scientists and the recognition of the potential serious implications, the decision was made to release the findings via a press conference only a short time after the paper describing the investigation had been accepted for publication. This attitude of sharing is now characterizing the approach being used by scientists in many nations. For example, the Central Science Laboratory, who did the analyses in the UK and with whom JIFSAN has a cooperative relationship, shared details of the analytical methodology and some samples with us. This was then shared with FDA and other analytical groups within the U.S. Preliminary data are released and shared before the months required for publication in a scientific journals. This is moving the scientific investigations forward rapidly and emphasizing collaboration in approaching this complex issue.

With the rapidity with which this new and important information is being acquired and shared, I believe that care must be taken not to reach scientific, policy, and regulatory conclusions based on the most recent press statement, media release, or shared information. Plans for rapid, systematic approaches to obtaining essential information, such as FDA has developed, are being prepared in other countries and there is clear evidence that needed work is being initiated as quickly as possible. Decisions about what, if anything, must be done relative to acrylamide in foods should be made as quickly, but also responsibly, as can be done using sound, valid scientific information.

I want to share several observations, particularly with regard to what is occurring internationally. At the outset, I think it is the consensus among scientists, governments, and industry that the new and unexpected information provided in the announced finding of acrylamide in foods from Sweden and subsequently in other countries calls for the concerted effort that is underway to gather additional and new information needed to characterize the potential risks posed by acrylamide in food and determine what are appropriate and effective responses.

These informational needs can be grouped into four major areas:

- ?? Determination of the amount and extent of acrylamide in foods
- ?? Determination of the mechanism(s) involved in its formation in foods
- ?? Exposure and biomarkers
- ?? Toxicology and metabolic consequences.

This approach is being reflected in the meetings, discussions, and initiation of research internationally.

Data on Acrylamide in Foods

Data collected in Sweden and subsequently in a number of other countries, including the United States, UK, Norway, and Switzerland confirm the presence of acrylamide in selected types of food. This general finding has been sufficient to establish acrylamide in foods as a concern and to galvanize action at the international and national level.

However, the limited data available on acrylamide in foods has also demonstrated that much more information is needed as a fundamental first step. National and international bodies recognize that the full range of affected food types has not been determined. The extent to which acrylamide is found in home-prepared foods, in particular, remains a significant unknown. Similarly, within specific food types considerable variation has been found in the levels of acrylamide.

I am aware of no country or international body that has used the limited information available on levels of acrylamide in specific food types to take targeted regulatory action and, to my knowledge only one has issued a consumer advisory on specific product types. Norway's National Food Authority recommended "that people who eat a lot of potato chips in particular should consider to cut back for additional safety."

The limited data available and the consequent uncertainties about the levels of acrylamide within and across different foods contribute to the position taken in the June FAO/WHO consultation on acrylamide in food and the July opinion of the European Commission Scientific Committee on Food that existing general advice to the public on healthy eating remains valid and appropriate. Individual countries have also taken this approach when considering what, if any, advice is currently appropriate. The language used by the EU Scientific Committee on Food is: "The information available on acrylamide so far reinforces general advice on healthy eating. People should eat a balanced and varied diet, which includes plenty of fruit and vegetables, and should moderate their consumption of fried and fatty foods." I am not aware of any country, other than the two examples cited, or international body that believes enough information is available to give advice to consumers on individual products or categories of products.

Mechanisms of Acrylamide Formation

A great deal of attention is being given nationally and internationally to determine the mechanisms for acrylamide formation in foods. Temperature and time are two factors that are consistently identified. Given these important factors, however, various ways of preparing food, with the exception of boiling, have not been eliminated as contributing to acrylamide formation. In fact recent evidence tends to indicate that it is the actual temperature and time, rather than the method, which contributes to acrylamide formation in food. Knowing the mechanisms of acrylamide formation, including possible reactants and precursors, is critical information for identifying possible ways of reducing or minimizing formation. There is recognition that home and commercial food preparation methods need to be considered. For example, during the information seminar held by the German Federal Institute for Health Protection of Consumers and Veterinary Medicine, it was noted, "A special problem is posed by the preparation of deep-fried, baked, and fried foods in the home, mass catering facilities, and restaurants. Experiments show that this critical substance is also formed there."

Ongoing research dealing with the mechanisms of acrylamide formation reinforces the need for FDA and others engaged in dealing with this issue to stay current with rapidly developing information and not to commit to a course of action that may prove

inappropriate. On September 11, Health Canada issued a letter that describes model experiments that found when asparagine (the most predominant free amino acid found in potatoes) is heated with glucose, a “reducing” sugar (also present in potatoes), acrylamide is produced. French fries made from some potatoes had only one-fifth the acrylamide levels of others, because the potatoes were initially lower in asparagine. Last week, at an Association of Analytical Chemists meeting, work done by Procter & Gamble was reported showing that the amino acid, asparagine, coupled with a carbonyl source like glucose (dextrose), is a major precursor of acrylamide in food products. The carbons and nitrogen in acrylamide were found to come from asparagine, with the source of nitrogen in acrylamide being the asparagine amide nitrogen. These studies, yet to be published, may be significant in finding ways to affect acrylamide formation and in identifying what foods may be of interest. However, being able to reduce the amount of acrylamide formed does not indicate what the effect will be on food safety or the nature of the food product. These reports demonstrate that mechanistic research is underway and that new information will likely be surfacing at a rapid pace.

Determining Possible Risk to the Public

While national and international organizations are taking the presence of acrylamide in foods very seriously given what is known about the compound, there remains major scientific uncertainties and the need for research to determine if and what the health risk is from acrylamide in foods. Since acrylamide is apparently formed during food preparation at relatively high temperatures, we must remember that we have most probably been exposed to acrylamide in foods since we started using heating in food preparation. Statements from national and international organizations repeatedly emphasize that there is insufficient information to determine what the risk is. Similarly, there is not agreement on whether or if a quantitative risk determination for acrylamide in food is possible.

For example, the need for research to address the question of whether acrylamide and, specifically acrylamide in food, causes human cancer has been described. The FAO/WHO consultation acknowledged that quantitative human cancer risks using experimental animal carcinogenicity data have been attempted using different models. However, the consultation did not reach consensus on how quantitative risk assessment based on animal data should be used to estimate human cancer risk from acrylamide in food. Clearly, determining and, if possible, quantifying human risk is of interest internationally, but without additional research and resolution of scientific uncertainties, there does not appear to be a consensus on this issue within the scientific community or among government organizations.

Relevance of FDA’s Plan of Action to International Efforts

Acrylamide in foods is definitely an issue receiving national and international attention. In my opinion, FDA has developed an appropriate and aggressive plan of action that is consistent and in keeping with other national and international efforts. The EC Science Committee on Food recommended initiatives for research related to the following:

- ?? The mechanisms of formation of acrylamide in food
- ?? Levels in food and extended dietary exposure assessments, covering also national variations
- ?? Bioavailability of acrylamide in food
- ?? Elucidation of the mode of action as a carcinogen
- ?? Investigation of the relationship between dietary intake of acrylamide and formation of glycidamide-DNA adducts
- ?? Analysis of dietary acrylamide intake, exposure biomarkers, and disease endpoints in existing European and worldwide epidemiological cohorts
- ?? Epidemiological studies on cancer in populations of known high exposure, such as occupationally exposed workers

These priorities recognize that much more scientific information is needed to meet the recommendation of the Committee that levels of acrylamide in food should be as low as reasonably achievable. I believe the FDA proposed plan of action is definitely consistent with the steps being taken by the EC Science Committee on Food and other national and international bodies and will make a significant contribution to this global effort.

Thank you for the opportunity to share these remarks with you. I will attempt to answer any questions you may have.