



GROCERY MANUFACTURERS OF AMERICA

MAKERS OF THE WORLD'S FAVORITE BRANDS OF
FOOD, BEVERAGES, AND CONSUMER PRODUCTS

1010 WISCONSIN AVE., NW
NINTH FLOOR
WASHINGTON, DC 20007
PHONE (202) 337-9400
FAX (202) 337-4508
www.gmabrands.com

October 30, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 02N-0393; Assessing Acrylamide in the U.S. Food Supply; Public Meeting; Draft Action Plan on Acrylamide; Availability; 67 Fed. Reg. 57827 (Sept. 12, 2002)

The Grocery Manufacturers of America, Inc. (GMA) appreciates this opportunity to offer comments concerning the Food and Drug Administration (FDA) draft action plan on acrylamide. These comments are provided with the intention of meeting the October 30 deadline established by FDA in its *Federal Register* notice of September 12, 2002. 1/ Because the upcoming workshop on acrylamide 2/ is almost certain to yield additional information of direct relevance to the agency's draft action plan, GMA intends to supplement these comments at the conclusion of that workshop.

GMA is the world's largest association of food, beverage, and consumer product companies. With U.S. sales of more than \$450 billion, GMA members employ more than 2.5 million workers in all 50 states. GMA speaks for food and consumer product manufacturers at the state, federal and international levels on legislative and regulatory issues.

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1/ 67 Fed. Reg. 57827 (Sept. 12, 2002).

2/ Joint Institute for Food Safety and Applied Nutrition (JIFSAN) and National Center for Food Safety and Technology (NCFST) Workshop, "Acrylamide in Food: What do we need to know? What are the responses?" (scheduled for October 28-2002).

I. GENERAL COMMENTS

FDA is to be commended for its rapid and thoughtful response to the acrylamide findings reported just a few months ago by the Swedish National Food Administration and Stockholm University. GMA shares the agency's concern regarding this substance and supports a full investigation into the potential implications of acrylamide exposure for public health. The agency is urged, in particular, to focus its initial efforts on the gathering of information necessary to a fundamental understanding of the critical issues of acrylamide formation, occurrence, and toxicology. With a sound understanding of these issues, the agency will be in a position to determine, what, if any, future regulatory action may be warranted.

The potential presence of acrylamide in food raises complex issues of science and policy. As the agency has recognized, there is uncertainty about the impact of acrylamide on public health. There is likewise substantial uncertainty about the formation of the substance in food. The possibly synergistic effects of time, temperature, and product composition are currently not known, and it is not possible to gain insight into these parameters based simply on end-product testing. Moreover, although high-carbohydrate foods such as bread and potatoes have been implicated, there is evidence to suggest that the issue may not be confined to such foods. Health Canada, for example, has described experiments finding that acrylamide is produced when asparagine, an amino acid, is heated with glucose, a sugar. Any research into acrylamide formation, therefore, must take into account multiple variables and potential confounding factors associated with this substance.

GMA is concerned that despite these uncertainties, the draft action plan appears to presume that some type of regulatory action will eventually be taken with respect to acrylamide. This presumption was also evident in some of the speeches presented by agency personnel at the September 30 public meeting. For instance, it was suggested that the agency must choose as a matter of prioritizing testing needs whether it should prioritize "exposure assessment leading to regulatory actions" or the examination of "occurrence variation leading to process improvements." 3/

For the past several years, CFSAN has effectively prioritized its workplan to ensure that resources are utilized in a manner that accomplishes the greatest public health benefit for consumers. With specific regard to acrylamide, of greatest concern is the issue of whether acrylamide at the levels

3/ Richard Canady, Ph.D, DABT, "Major Components of FDA's Action Plan for Acrylamide" (presented Sept. 30, 2002).

found in food is of toxicological significance, followed closely by the need to understand the circumstances that may lead to acrylamide formation. FDA is urged to commit available agency resources to first gaining a better understanding of these aspects of the acrylamide issue. Decisions regarding potential “regulatory actions” would not be prudent in the absence of a fundamental understanding as to whether acrylamide at the levels found in common foods is of toxicological significance. Similarly, decisions regarding recommended processing changes would not be appropriate until acrylamide formation is better understood. As JIFSAN Director Dr. David Lineback opined at the September 30, 2002 public meeting on acrylamide, “care must be taken not to reach scientific, policy, or regulatory conclusions based on the most recent press statement, media release, or shared information.” ^{4/}

In light of the multiple uncertainties, FDA is urged to refine its draft action plan to ensure that it does not suggest that eventual “regulatory action” is inevitable. It would be appropriate, of course, for FDA to include in the action plan its intention to assess available data and information in an effort to evaluate whether regulatory action may be justified. This aggressive, yet cautious, approach is sensible given the likelihood that acrylamide has been a component of the human food supply for perhaps thousands of years. It is also protective of public health because the risk, if any, posed by acrylamide may be addressed by adherence to existing dietary recommendations for a balanced diet rich in fresh fruits and vegetables. Finally, it permits full and careful consideration of the potential trade-offs that may be associated with certain types of proposed changes. For instance, any suggestion to modify time and temperature parameters must be weighed against the need to cook food in a manner that ensures both microbial safety and characteristic organoleptic qualities.

II. SECTION-BY-SECTION FEEDBACK

The following comments pertain to specific portions of the draft action plan.

A. Summary and Background

As discussed above, GMA is concerned that it is premature to suggest that “[i]dentifying mechanisms of formation will ultimately be an important step in identifying ways to reduce or prevent acrylamide formation during cooking.” Currently available information does not permit a conclusion

^{4/} David R. Lineback, Ph.D, “Assessing Acrylamide in the U.S. Food Supply” (presented Sept. 30, 2002).

that it will be necessary, feasible, or even desirable—considering the potential consequences on organoleptic properties and safety—to adopt processes to reduce or prevent acrylamide formation. It would be more appropriate to state that identifying methods of formation will ultimately be an important step in determining whether acrylamide formation may reasonably be prevented or reduced during cooking.

Regarding available studies of occupational exposure to acrylamide, which did not show an increased cancer risk, FDA notes that “these studies do not rule out the possibility that acrylamide in food can cause cancer, both because of the limited number of people in the studies and because the route of exposure for the workers was not through food.” It is true that these studies do not eliminate acrylamide as a potential carcinogen. It might also be fairly stated, however, that if acrylamide is not carcinogenic at the high doses involved in these studies, it is unlikely to be carcinogenic at the low levels present in food.

B. Major Goals

GMA fully supports FDA efforts to assess dietary exposure to acrylamide, develop and refine appropriate analytical methods, assess the potential risks to public health, keep stakeholders informed of progress made on the issue, and to develop and foster related public/private partnerships. GMA further supports appropriate research to identify the mechanisms responsible for the formation of acrylamide in food, so long as such research is well-designed and accounts for the multiple variables and confounding factors that may be involved.

It is premature, however, for the agency to state as a “major goal” efforts to “identify means to reduce acrylamide exposure.” In light of the multiple uncertainties surrounding the acrylamide issue, the most appropriate goal along these lines is to evaluate whether, based on evolving information, it is advisable or feasible to identify means to reduce acrylamide exposure.

It likewise seems appropriate to characterize the goal regarding public/private partnerships as intended to gather scientific and technological information and data for assessing the *potential* human risk, not “the human risk,” of acrylamide in food.

C. Actions

GMA supports FDA efforts to analyze foods for acrylamide content. Of concern, however, is FDA’s statement that these samples will be used “to estimate variation within and across key food types as part of processing evaluations and to determine the incidence of formation across the food supply.” End product testing will not, in and of itself, provide insight into the

impact of varying processing techniques, nor will it yield information concerning the incidence of formation across the food supply. Even within the same product category, there will be multiple variations in terms of time, temperature, and related processing parameters that cannot be discerned from end product testing.

Moreover, for any consumer products that are prepared per package directions and then analyzed, it cannot be assumed that package instructions are consistently followed by consumers and thus will yield definitive results of likely acrylamide formation. For example, some consumers of frozen french fries may prefer their fries slightly undercooked, while others may routinely cook the product until crispy. Any evaluation of analytical results for such products would need to take into account the inevitable consumer variations.

Finally, in light of the unique, wholly unforeseen circumstances created by the acrylamide issue, FDA is urged to maintain as confidential information the brand names of any products that are tested for acrylamide.

D. Toxicology

GMA urges that any studies conducted for purposes of evaluating acrylamide toxicity be conducted at doses reasonably related to the levels of acrylamide that are likely to be consumed through food. Although it is certainly appropriate to allow for a margin of safety, extremely high doses having little or no basis in reality raise issues regarding the relevance of the testing to real-life circumstances and thus should be avoided.

It is not clear what is meant by the statement that “FDA will therefore participate in all experimental protocol designs to assure regulatory needs are met.” For the reasons stated above, GMA is concerned that it is premature based on currently available data and information to assume that regulatory action on acrylamide will be necessary or feasible.

E. Research and Outreach on Formation

The action plan states that FDA will “encourage industry to adopt processes that are successful at reducing acrylamide.” It would be more appropriate for the agency to encourage industry to examine product composition and processing measures to determine the factors that influence acrylamide formation and to assess whether changes may be feasible for purposes of reducing acrylamide formation. For the reasons stated above, it is premature to assume that processes that may reduce acrylamide formation are available and can be used to produce currently marketed products.

Similarly, prior to encouraging research on “the effects of process changes on acrylamide levels,” FDA must be convinced that different processes are reasonably expected to yield different results with respect to acrylamide formation. Stated differently, a more realistic goal would be to encourage research into the mechanisms of acrylamide formation and to identify process-related considerations that may play a role.

F. Methodologies

FDA is urged to prepare and distribute check samples to confirm there is no unacceptable variation in acrylamide findings among laboratories and testing methods.

G. Consumer Messages

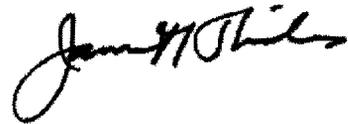
Until the key issues of acrylamide formation, exposure, and toxicity are better understood, FDA should encourage consumers to follow established recommendations concerning diet and health. By choosing a balanced diet that adheres to current dietary recommendations, consumers may minimize any risk that may be posed by acrylamide. FDA is urged to proceed with extreme caution prior to recommending any changes in consumer cooking practices, as such a message may cause confusion in relation to longstanding advice to cook foods thoroughly for microbial food safety considerations.

H. Regulatory Options

GMA is concerned by FDA’s stated plan to “develop and revise regulatory options as additional knowledge is gained on acrylamide in food.” The agency further states that “many of the items in the draft action plan are geared toward achieving that end.” These statements appear to suggest that FDA is planning some type of regulatory action regardless of the results of its activities intended to assess the potential human risk. Again, this conclusion is premature. It would be without precedent for FDA to take action and commit to a particular regulatory approach regarding a substance in food in the absence of the most basic information regarding the substance’s formation, incidence in the diet, and toxicity. The agency is urged to focus its resources on understanding these key aspects of the acrylamide issue prior to committing to a regulatory approach that may ultimately be without basis in sound science.

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GMA is committed to enhancing the safety and quality of America's food supply through cooperative and science-based regulation. GMA looks forward to working with the agency on the acrylamide issue and would be pleased to discuss with CFSAN any of the points made in these comments.



James H. Skiles
Vice President and
General Counsel