appears to have no conflict of interest that would preclude membership. Potential candidates are required to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts to permit evaluation of possible sources of conflict of interest.

Dated: August 21, 2009.

Wanda K. Jones,

Executive Secretary, Chronic Fatigue Syndrome Advisory Committee.

[FR Doc. E9–20568 Filed 8–25–09; 8:45 am]

BILLING CODE 4150–42–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0393]

Acrylamide in Food; Request for Comments and for Scientific Data and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments and scientific data and information.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments and scientific data and information on acrylamide in food. Acrylamide is a chemical that can form in some foods during certain types of high-temperature cooking. FDA is seeking information on practices that manufacturers have used to reduce acrylamide in food and the reductions they have been able to achieve in acrylamide levels. FDA is considering issuing guidance for industry on reduction of acrylamide levels in food products.

DATES: Submit comments and scientific data and information by November 24, 2009.

ADDRESSES: Submit written comments and scientific data and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments and scientific data and information to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Lauren Posnick Robin, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1639.

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

In 2002, scientists in Sweden announced the discovery of the chemical acrylamide in a variety of heated foods (Ref. 1). Further research subsequently determined that acrylamide can form in some foods during certain types of high-temperature cooking (Refs. 2 and 3). Acrylamide in food is a concern because it has been found to be carcinogenic in rodents and is therefore considered a potential carcinogen for humans (Refs. 4 and 5).

Since the identification of acrylamide in food, research around the world has centered on measuring acrylamide exposure in the diet, studying the toxicology and epidemiology of acrylamide exposure, and reducing (mitigating) acrylamide levels in food. Information on FDA's activities on acrylamide can be found on FDA's Web site (Ref. 6). FDA's research program has focused on toxicology but has also included research on mitigation for consumers (Ref. 7). Based on this research and other findings, FDA added information to its Web site in 2008 for consumers interested in reducing their acrylamide exposure from food. However, FDA's general advice for acrylamide and eating is for consumers to adopt a healthy eating plan consistent with the Dietary Guidelines for Americans (Refs. 6 and 8). The Dietary Guidelines for Americans suggests a diet that emphasizes fruits, vegetables, whole grains, and fat-free or low-fat milk and milk products; includes lean meats, poultry, fish, beans, eggs, and nuts; and is low in saturated fats, *trans* fats, cholesterol, salt (sodium), and added sugars.

FDA has not issued guidance for manufacturers on reducing acrylamide in food. However, it is anticipated that new information will soon be available about the toxicology of acrylamide, which may confirm acrylamide's carcinogenicity in laboratory animals. International efforts to develop approaches to acrylamide mitigation are also beginning to prove successful. Moreover, FDA is aware that at least some manufacturers in the United States are seeking ways to reduce acrylamide in their products. For these reasons, FDA is considering issuing guidance for industry on reduction of acrylamide levels in food products.

This document summarizes information available to FDA about acrylamide formation, exposure, toxicology, levels in food, and techniques to mitigate acrylamide. This notice also identifies areas in which additional data and information would be helpful to FDA in learning more about acrylamide mitigation techniques and levels of acrylamide in food. These areas are outlined in more detail in section II of this document.

B. Formation and Exposure

Acrylamide forms in foods primarily from a reaction between asparagine, an amino acid, and reducing sugars such as glucose and fructose. This reaction is part of the Maillard reaction, which leads to color, flavor, and aroma changes in cooked foods (Refs. 2, 3, and 9). Acrylamide formation usually occurs at elevated temperatures used when frying or baking (above 120 °C (248 °F)) and in low moisture conditions, although acrylamide has also been identified in some fruit and vegetable products heated at lower temperatures or higher moisture conditions (Refs. 10 through 13). Also, formation occurs primarily in plant-based foods, notably potato products such as French fries and potato chips; coffee; and cereal-grain-based foods such as cookies, crackers, breakfast cereals, and toasted bread.

Thousands of food samples have been analyzed for acrylamide since 2002. Based on its own database of acrylamide levels in U.S. foods (Refs. 12 and 13), FDA estimates acrylamide intake for the average U.S. consumer as 0.4 microgram/kilogram body weight/day (µg/kg-bw/d) (Ref. 14). International estimates for the average consumer range from 0.2 to 1.4 µg/kg-bw/d (Ref. 15). Based on estimates from different countries, the Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Expert Committee on Food Additives (JECFA) identified an average acrylamide intake of 1 µg/kg-bw/d for the general consumer and 4 µg/kg-bw/d for high consumers (Ref. 4).

Based on measured levels of acrylamide in certain foods and on how frequently these foods are consumed in the United States, FDA identified the following 10 foods (in ranked order) that contribute the most acrylamide to the U.S. diet: French fries (restaurant prepared), French fries (oven baked), potato chips, breakfast cereals, cookies, brewed coffee, toast, pies and cakes, crackers, and soft (nontoasted) breads (Ref. 14). The JECFA evaluation concurred that the major foods contributing to total exposure for most countries were French fries, potato chips, coffee, pastry and sweet cookies, and breads and toasts (Ref. 4).

C. Toxicology

Several international toxicology evaluations of acrylamide have been completed since the identification of

acrylamide in food in 2002 (Refs. 4 and 5). An initial FAO/WHO consultation in 2002 called the presence of acrylamide in food ''a major concern'' based on acrylamide's ability to induce cancer and heritable mutations in laboratory animals. In 2005, an international evaluation of acrylamide by JECFA identified margins of exposure (MOEs) for acrylamide of 300 for general consumers and 75 for high consumers. JECFA considers the MOE of 300 calculated for acrylamide to be low for a compound that is genotoxic and carcinogenic and concluded that the levels of acrylamide in food were of concern.

Under the sponsorship of the National Toxicology Program, FDA's National Center for Toxicological Research (NCTR) embarked in 2002 on a series of new toxicology assays for acrylamide. These studies were designed to address deficiencies in earlier carcinogenicity studies and to provide more reliable data on potential carcinogenic risk of acrylamide and other potential effects of acrylamide exposure. The work at NCTR includes long-term carcinogenicity bioassays of acrylamide and its metabolite glycidamide in mice and rats, as well as toxicokinetic, bioavailability, mutagenicity, and neurodevelopmental studies (Refs. 16 through 34). NCTR's work also includes the development of a physiologically based pharmacokinetic model for acrylamide and glycidamide (Refs. 19 and 34).

D. Reduction of Acrylamide Levels in Food

Since the discovery of acrylamide in food in 2002, the international research community has explored numerous strategies for reducing acrylamide levels in food products. This work is summarized in the scientific literature (e.g., Refs. 35 through 48), as well as in guidance materials prepared by industry, other governments, and international organizations. Notable guidance materials include the Acrylamide ''Toolbox'' produced by the Confederation of Food and Drink Industries of the European Union (CIAA) (Ref. 49), CIAA ''Toolbox'' brochures on selected foods for small- and medium-sized businesses (Refs. 50 through 54), the ''Review of Acrylamide Mitigation in Biscuits, Crackers and Crispbread'' produced by the Association of the Chocolate, Biscuits, and Confectionary Industries of the European Union (CAOBISCO) (Ref. 55), and ''Guidelines to Authorities and Consumer Organisations on Home Cooking and Consumption'' and ''Manual on strategies to food industries, restaurants, etc., to minimize acrylamide formation'' produced by the Heat-Generated Food Toxicants: Identification, Characterization and Risk Minimisation (HEATOX) Project (Refs. 56 and 57). The Codex Committee on Contaminants in Foods (CCCF) has also prepared a Code of Practice for the Reduction of Acrylamide in Foods (Ref. 58), with the U.S. Delegation to CCCF participating in preparation of the code of practice as co-lead of the document working group.

Research on acrylamide mitigation has focused on reducing acrylamide in potato products, cereal-grain-based products (e.g., baked goods), and coffee through interventions directed at raw materials, additional ingredients, and processing (Ref. 58). As a result of this research, effective mitigation measures have been identified for reducing acrylamide levels in some potato and cereal products; however, no proven mitigation measures have been devised for coffee (Refs. 49 and 58).

Potato products. For potato products, mitigation practices directed at raw materials focus on controlling reducing sugar levels, for example: (1) Selecting potato cultivars that are low in reducing sugars, (2) checking sugar levels of incoming potato lots using chemical analysis or fry testing, (3) storing potatoes above 6 °C (43 °F) to avoid low-temperature sweetening, (4) using reconditioning to lower sugar levels in stored potatoes, and (5) avoiding use of immature potatoes, which have higher sugar levels. Other mitigation practices for potato products address additional ingredients, including using the enzyme asparaginase to reduce levels of the acrylamide precursor asparagine, partially substituting potato ingredients with nonpotato ingredients, and formulating recipes to include ingredients such as sodium pyrophosphate and calcium salts (Refs. 49 and 58). Finally, acrylamide mitigation practices for potato products also address processing steps. For French fries, such practices include: (1) Washing or blanching (with or without added ingredients such as sodium pyrophosphate and cation salts), (2) cutting thicker potato pieces, (3) removing fines (fine pieces of potato), (4) setting fryer temperature no higher than 175 °C (347 °F), and (5) cooking fries to a golden yellow color rather than a golden brown color. For potato chips, such practices include: (1) Optimizing time and temperature cooking conditions, (2) cooking to a golden yellow color, (3) utilizing vacuum frying or flash frying with rapid cooling, and (4) using optical sorting to remove darker chips (Refs. 49 and 58).

Cereal grain products. In cereal-grain-based foods, strain selection and agronomic practices targeted at reducing asparagine levels in raw materials (such as ensuring adequate sulfur fertilization) show potential to reduce acrylamide (Refs. 49 and 58). Mitigation measures directed at additional ingredients include use of asparaginase to deplete asparagine and partial substitution of higher-asparagine flours (e.g., wheat, rye) with lower-asparagine flours (e.g., rice). Substitution of whole-grain flours with highly processed flours can also reduce acrylamide, but use of highly processed flours does not provide the nutritional benefits associated with whole-grain flours. Other ingredient-directed measures that may reduce acrylamide in baked goods include substitution of ammonium-based raising agents with potassium- and sodium-based raising agents, avoidance of reducing sugars during baking, addition of calcium salts, and modification of the use of minor ingredients (e.g., spices) and rework (Refs. 49 and 58). Processing changes shown to decrease acrylamide in cereal-based foods include adjusting the time-temperature profile of baking processes, extending dough fermentation times, controlling final moisture content, and not over-baking or over-toasting foods (Refs. 49 and 58).

E. Levels of Acrylamide in Food

Measured acrylamide levels in food are summarized in multiple databases, publications, and evaluations (e.g., Refs. 4, 12, 13, and 59). Levels of acrylamide in food vary widely, from undetectable amounts in some cereal grain- and potato-based products (e.g., untoasted bread and mashed potatoes) to more than 5000 µg/kg in a cereal grain product (e.g., grain-based coffee substitute) (Refs. 12 and 13). Acrylamide levels also can vary widely within individual food types (e.g., Ref. 12). For example, in data collected by FDA, levels of acrylamide in potato chips varied from nearly 120 µg/kg to over 1200 µg/kg (Ref. 12). There may also be considerable variation within different lots of the same product due to variation in raw materials and processing conditions. Despite the wide range of acrylamide levels for a given food, the availability of proven mitigation practices (Refs. 49 through 58) suggests that it may be feasible to recommend, for some foods, levels for acrylamide that all manufacturers should be capable of achieving.

II. Request for Comments and for Scientific Data and Information

FDA is seeking additional scientific data and information on (1) methods for

reducing acrylamide levels in food and (2) reductions that manufacturers have been able to achieve in acrylamide levels. Accordingly, FDA invites all interested parties to submit comments and scientific data and information on the topics identified. FDA is also seeking specific data and other information on the following questions:

A. Methods for Reducing Acrylamide Levels in Food

1. Are you (manufacturers) currently taking any steps to reduce acrylamide levels in your food products? If yes, what methods are you using? Please list mitigation methods by food type (e.g., potato chip) and, where possible, by product line (e.g., potato chip line one). It is not necessary to identify product line by brand name. Please provide as many details as possible, including being specific about changes to methods, e.g., identify new and previous frying temperatures rather than simply indicating that the frying temperature was lowered.

2. Which methods, if any, have not proved successful or cost-effective for reducing acrylamide in your products? Please identify food types and/or product lines for which particular methods have not proved successful or cost-effective. Where possible, identify the reasons these methods have not proved successful or cost-effective.

3. What changes in ingredients (e.g., addition of cation salts, amino acids, or spices; blanching with sodium pyrophosphate; substitution of grains or sugars; replacement of ammonium bicarbonate) have proved effective and feasible in lowering acrylamide levels in your products? Please provide specific details about product types and manufacturing process changes.

4. Do you use asparaginase to lower acrylamide levels in any of your products? If so, in which of your products has asparaginase proved effective and feasible in lowering acrylamide levels? Please provide specific details about product types and manufacturing process changes.

5. What changes in precooking parameters (e.g., blanching, fermentation) and cooking parameters (e.g., time and temperature of cooking, final moisture content) have proved effective and feasible in lowering acrylamide levels in your products? Please provide specific details about product types and manufacturing process changes. Are techniques such as flash frying and vacuum frying feasible methods of acrylamide reduction?

6. What mitigation methods might be more or less appropriate for small manufacturers? Please provide a rationale for your response.

7. Do you monitor acrylamide formation and reduction? If yes, what endpoint (e.g., browning, measurement of acrylamide levels) do you use?

8. What are standard practices in the United States for delivery, storage, temperature control, reconditioning, and screening (e.g., by fry testing) of potatoes? What potato cultivars in the United States are appropriate for production of French fries, potato chips, and other potato-based snacks? What cultivars are not acceptable for producing these products and/or roasting or frying potatoes at home? Is it appropriate to specify an acceptable level of reducing sugars in incoming lots of potatoes and, if so, what level is appropriate?

9. What changes have you made, if any, to the instructions on food packaging to reduce acrylamide formation during final preparation of food products by consumers?

10. Aside from changes to the instructions on food packaging, are there other steps that manufacturers can take to help consumers reduce acrylamide in food, such as labeling in-store potatoes for appropriate use?

11. Are there other important sources of information on reducing acrylamide levels in food that FDA has not identified in this document? If yes, please identify such sources.

12. Are there any other sources of information about proposed acrylamide mitigation techniques (particularly as applied to U.S. products) that might be more useful or accurate than the information described in this document?

B. Levels of Acrylamide in Food

Among the information that would be helpful to FDA in potentially recommending levels for acrylamide in food is data on reductions achieved by manufacturers using mitigation techniques. Some information on acrylamide levels can be found in existing databases and publications (Refs. 4, 12, 13, and 59), but these databases may reflect, at least in part, acrylamide levels before mitigation measures were applied. Data from more targeted or ongoing sampling plans (e.g., Refs. 60 through 64) and from legal settlements (Ref. 65) may also be useful sources of information on acrylamide levels in food, although some of this information may be limited in scope or applicable primarily to European products.

1. What acrylamide levels have you observed before and after applying mitigation practices? Please break down your data by food type (e.g., potato chip) and, where possible, by product line (e.g., potato chip line one). It is not necessary to identify a product line by brand name. Please include, if possible, measurements of acrylamide levels in individual samples, as well as statistical endpoints (e.g., means, medians, standard deviations). Finally, please identify the acrylamide mitigation measures you used to achieve these reductions.

2. Do you anticipate being able to achieve further reductions by applying different or additional approaches? If yes, please identify the approaches. If no, please explain what limits your ability to further reduce the levels of acrylamide in particular products.

3. What factors, if any, have affected your ability to consistently achieve certain levels of acrylamide or certain percentage reductions?

4. For what food types, if any, would it be appropriate to recommend levels for acrylamide? Please provide an explanation of your response.

5. What reduced acrylamide levels should manufacturers be able to achieve for the following foods: French fries, potato chips, breakfast cereals, coffee, and cookies and other baked goods? What reduced acrylamide levels should manufacturers be able to achieve for other potato- or corn-based snacks?

6. What additional factors, if any, should FDA consider if it recommends levels for acrylamide in foods?

7. Are there important sources of information that FDA has not identified in this document on levels of acrylamide in food and reductions in acrylamide levels achieved by manufacturers? If yes, please identify such sources.

8. Are there any other sources of information about attainable levels of acrylamide in food that might be more useful or accurate than the information described in this notice?

C. Comments

Interested parties may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 or send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c)