

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0231]

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Certifier N. Hopkins

**Draft Report of the Threshold Working Group, Center for Food Safety and Applied Nutrition: Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food; Availability; Request for Comments and for Scientific Data and Information**

**AGENCY:** Food and Drug Administration, HHS.

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

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft report entitled "Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food." The draft report was prepared by an interdisciplinary group of scientists from FDA's Center for Food Safety and Applied Nutrition (CFSAN). This report was prepared to facilitate the further development of CFSAN's policy for food allergens, including the center's implementation of the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).

**DATES:** Submit comments and scientific data and information by [*insert 60 days after date of publication in the Federal Register*].

**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.fda.gov/dockets/ecomments>.

Submit written requests for single copies of the draft report to Sherri Dennis, Center for Food Safety and Applied Nutrition (see **FOR FURTHER INFORMATION CONTACT**). Send one self-adhesive label with your address to assist that office in processing your request. You also may request a copy of the draft report by faxing your name and mailing address with the name of the document you are requesting to the CFSAN Outreach and Information Center at 1-877-366-3322. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this document.

**FOR FURTHER INFORMATION CONTACT:** Sherri B. Dennis, Center for Food Safety and Applied Nutrition (HFS-06), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1903.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Food allergies are estimated to affect approximately six percent of infants and children and four percent of adults in the United States. A food allergy is an idiosyncratic response of the immune system to naturally occurring proteins in a food. The most severe and immediately life-threatening food allergic responses are associated with immunoglobulin E (IgE) mediated hypersensitivity. In this country, eight foods or food groups—peanuts, soybeans, cow's milk, eggs, fish, crustacean shellfish, tree nuts, and wheat—account for 90 percent of food allergies.

Food allergic reactions vary in severity, ranging from mild symptoms (such as skin or eye irritation) to severe, life-threatening responses (such as anaphylaxis or systemic shock.) The amount of protein needed to provoke an allergic response varies. Factors that affect the severity of an allergic response include the food from which the protein is derived, the nature of the

processing of the food, the food matrix containing the allergenic protein, and the sensitivity of the individual. There is a general consensus that, for most food allergic individuals, exposure to protein below a certain level is unlikely to elicit an allergic response. Although it has not been clearly defined, the term “threshold” has frequently been used to describe the lowest level of protein from an allergenic food that will elicit a response in a sensitive individual.

There is currently no known cure for food allergies. Accordingly, strict avoidance of the offending food or foods at levels that will elicit an adverse effect is the only means to prevent potentially serious reactions. Thus, food allergic consumers need accurate, complete, and informative labels on food to protect themselves.

In August 2004, Congress enacted the FALCPA (Public Law 108–282), which amends the Federal Food, Drug, and Cosmetic Act (the act), and requires that the label of a food product that is or contains an ingredient that bears or contains a “major food allergen” declare the presence of the allergen as specified by FALCPA. FALCPA defines “major food allergen” as one of eight foods or a food ingredient that contains protein derived from one of those foods. FALCPA provides two processes by which an ingredient may be exempted from the FALCPA labeling requirements—a petition process (section 403 of the act (21 U.S.C. 343(w)(6)) and a notification process (21 U.S.C. 343(w)(7)). Under the petition process, an ingredient may be exempt if the petitioner demonstrates that the ingredient “does not cause an allergic reaction that poses a risk to human health.” Under the notification process, an ingredient may be exempt if the notification contains scientific evidence that demonstrates that the ingredient “does not contain allergenic protein,” or if FDA previously has determined, under section 409 of the act (21 U.S.C. 348),

that the food ingredient does not cause an allergic response that poses a risk to human health. Understanding food allergen thresholds and developing a sound analytical framework for such thresholds are likely to be centrally important to FDA's analysis of, and response to, FALCPA petitions and notifications.

FALCPA also requires FDA to define and permit the use of the term "gluten free." Such labeling is important to patients suffering from celiac disease, an immune-mediated illness. Strict avoidance of gluten at levels that will elicit an adverse effect is the only means to prevent potentially serious reactions. Thus, consumers susceptible to celiac disease need accurate, complete, and informative labels on food to protect themselves. Understanding thresholds for gluten will help FDA develop a definition of "gluten free" and identify appropriate use of the term.

Section 204 of FALCPA directs FDA to prepare and submit a report to Congress. The report will focus principally on the issue of cross-contact of foods with food allergens, and will describe the types, current use of, and consumer preferences with respect to advisory labeling. Cross-contact may occur as part of the food production process where residues of an allergenic food are present in the manufacturing environment and are unintentionally incorporated into a food that is not intended to contain the food allergen, and thus, the allergen is not declared as an ingredient on the food's label. In some cases, the possible presence of the food allergen is declared by a voluntary advisory statement. Understanding food allergen thresholds and developing a sound analytical framework for such thresholds is also likely to be useful in addressing food allergen cross-contact and the use of advisory labeling.

Both as part of its ongoing risk management of food allergens and in response to FALCPA, CFSAN established an internal, interdisciplinary group (the Threshold Working Group). The Threshold Working Group was established to evaluate the current state of scientific knowledge regarding food allergies and celiac disease, to consider various approaches to establishing thresholds for food allergens and for gluten, and to identify the biological concepts and data needed to evaluate the scientific soundness of each approach. The draft report entitled "Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food" is the result of the working group's deliberations.

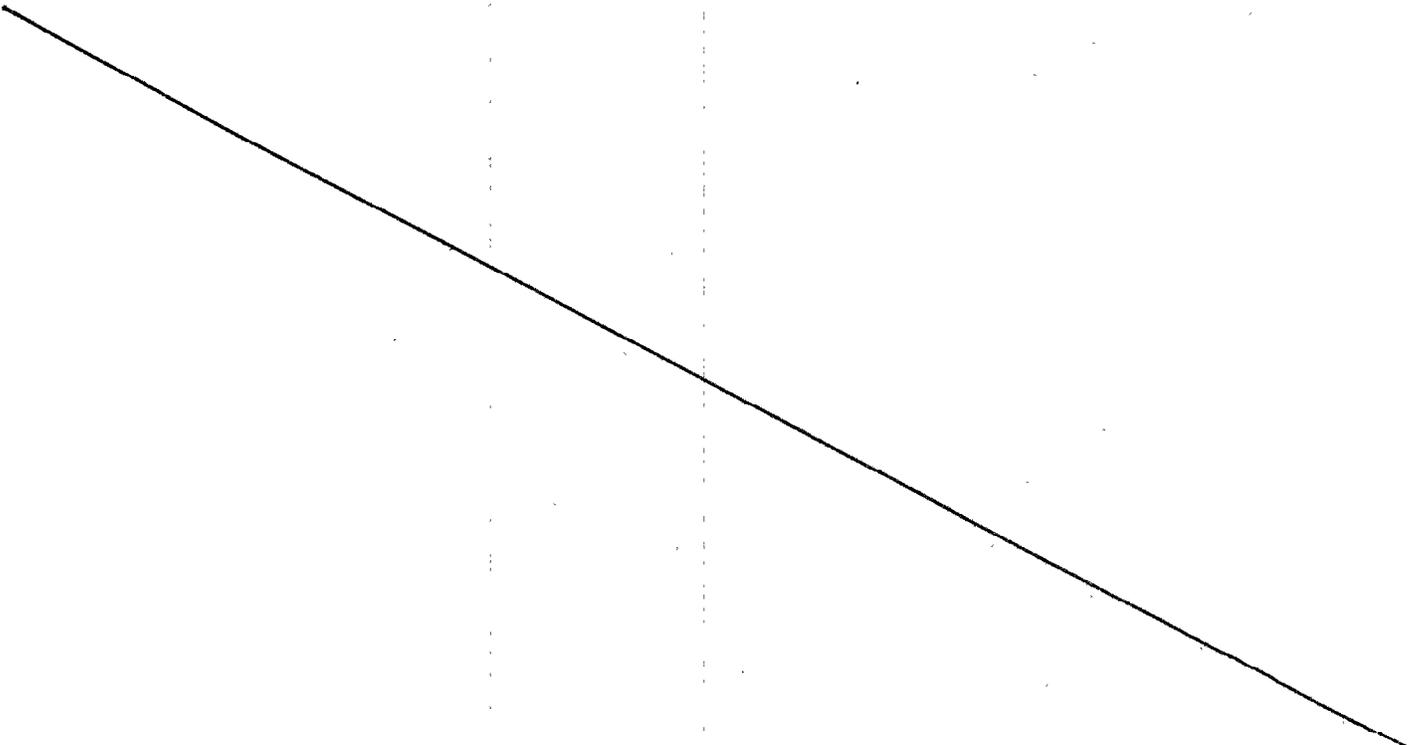
In the **Federal Register** of May 23, 2005 (70 FR 29528), FDA announced a meeting of the agency's Food Advisory Committee (FAC) on July 13, 14, and 15, 2005. At this meeting, the FAC will be asked to evaluate the draft report entitled "Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food." In particular, the FAC will advise FDA whether, in the committee's view, the draft report is scientifically sound in its analyses and approaches and adequately considers available relevant data on food allergens and on gluten. In seeking the committee's advice, FDA plans to pose a series of scientific questions. These questions will be posted on CFSAN's Web site at <http://www.cfsan.fda.gov/~lrd/vidtel.html> on July 12, 2005. Members of the public who may wish to participate in the FAC meeting, by written submission or an oral presentation, should consult the meeting notice for information regarding such participation.

In addition to the FAC proceedings, the agency believes it would be useful to receive public comments on the Threshold Working Group's draft report. The draft report describes a number of areas in which the working group

concluded that the body of scientific data relating to food allergen thresholds is incomplete. Accordingly, FDA requests that members of the public submit comments and any relevant scientific data and information, particularly data and information that can fill the data gaps identified in the draft report.

## **II. Request for Comments and for Scientific Data and Information**

Interested persons should submit comments and scientific data and information to the Division of Dockets Management (see **ADDRESSES**). Three copies of all comments and scientific data and information are to be submitted. Individuals submitting written information or anyone submitting electronic comments may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by supporting information. Received submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Information submitted after the closing date will not be considered except by petition under 21 CFR 10.30.



**III. Electronic Access**

The draft report is available electronically at <http://www.cfsan.fda.gov/~dms/wh-alrgy.html>.

Dated: 6/14/05  
June 14, 2005.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

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