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Division of Document Management
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Food and Drug Administration
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**Comments**
RE: Docket No. FDA-2012-N-0711
Request for Comments and Information on Initiating a Risk Assessment for Establishing Food Allergen Thresholds
77 Federal Register74485, December 14, 2012

Dear Sir or Madam:

On behalf of the Grocery Manufacturers Association (GMA), and the food industry associations listed below, we are respectfully submitting comments to the Food and Drug Administration ("FDA" or "Agency") on initiating risk assessments for establishing food allergen thresholds.

Based in Washington, DC, GMA is the voice of more than 300 leading food, beverage and consumer product companies that sustain and enhance the quality of life for hundreds of millions of people in the United States and around the globe. Founded in 1908, GMA is an active, vocal advocate for its member companies, and a trusted source of information about the industry and the products consumers rely on and enjoy every day. The association and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices and effective public policy solutions developed through a genuine partnership with policymakers and other stakeholders. In keeping with its founding principles, GMA helps its members produce safe products through a strong and ongoing commitment to scientific research, testing and evaluation and to providing consumers with the products, tools and information they need to achieve a healthy diet and an active lifestyle. The food, beverage and consumer packaged goods industry in the United States generates sales of $2.1 trillion annually,

employs 14 million workers and contributes $1 trillion in added value to the economy every year.

The American Peanut Council (APC), founded in 1940, is the umbrella trade association for the entire U.S. peanut industry, including peanut farmers, shellers, brokers, manufacturers of peanut products and peanut butter, and the allied good and services providers. The Council, located in Alexandria, VA, promotes increased peanut consumption, research and the dissemination of knowledge of new technology, as well as improved processing, storage, handling and food safety practices. The Council also acts as a clearinghouse for information pertaining to actions by the federal government and is the industry forum for the exchange of ideas and information by the industry's leaders.

The Association for Dressings & Sauces (ADS) is the international trade association representing manufacturers of salad dressings, mayonnaise and condiment sauces and the suppliers to the industry.

Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, DC, is the leading trade association representing dietary supplement manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 100 companies that manufacture dietary ingredients and/or dietary supplements, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Learn more about us at www.crnusa.org.

The Institute of Shortening and Edible Oils (ISEO) is a trade association representing the refiners of edible fats and oils in the United States. Members of the Institute represent approximately 90% of the edible fats and oils produced domestically, which are used in baking and frying fats (shortening), cooking and salad oils, margarines, spreads, confections and toppings, and a wide variety of other food products.

The Juice Products Association (JPA) is a trade association whose international membership consists of major packers and distributors of a wide variety of fruit and vegetable juices, juice

beverages, drinks, jams, jellies, fruit spread and other fruit products. JPA represents a significant majority of the juice and juice beverage processors in the United States.

The National Confectioners Association (NCA) has represented candy, chocolate and gum makers since 1884. With over 600 manufacturer, supplier and broker members, NCA provides a voice to the confectionery industry through advocacy and education.

The National Milk Producers Federation (NMPF), based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's 30 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of more than 32,000 dairy producers on Capitol Hill and with government agencies.

Founded in 1904, the National Pasta Association (NPA) is an organization of pasta and pasta-related product manufacturers, millers and suppliers to the US pasta industry serving as a cohesive industry advocate, a promoter of pasta and a center of knowledge for its members, the government and the public. info@ilovepasta.org

In this letter, we will comment on the following elements:

- Industry supports implementation of science-based food allergen thresholds
- Industry suggests a collaborative effort to work with the Agency on development of guidance on use of food allergen thresholds
- GMA and the food associations who have joined this letter recommend that the Agency establish what constitutes "an allergic response that poses a risk to human health"
- GMA and the food associations who have joined this letter seek clarification regarding precautionary labeling in the context of food allergen thresholds
- GMA and the food associations who have joined this letter recognize the linkages between food allergen thresholds and the Food Safety and Modernization Act (FSMA) with respect to Good Manufacturing Practices (GMPs) and inspections within the Preventive Controls proposed rule. In addition, food allergen thresholds will have an impact on FSMA section 104, Performance Standards
- GMA and the food associations who have joined this letter suggest the Agency evaluate incident reports of exposure to undeclared major food allergens in packaged food and related reports of illness

- GMA and the food associations who have joined this letter believe the establishment of food allergen thresholds can advance the FALCPA ingredient exemption process
- GMA and the food associations who have joined this letter request the Agency review FALCPA Q&As regarding food allergen labeling

**Industry supports implementation of science-based thresholds:** GMA, its members and the food associations who have joined this letter, strongly support the concept of using risk assessments to establish thresholds for major food allergens. We note that food allergen dose/response reactivity is complex and is different for each major food allergen. Thresholds also vary widely from consumer to consumer within the allergic population. For at least some of the major food allergens, there is a small proportion of the allergic population who react to extremely low allergen levels. How to account for these individuals is an important element of implementing regulatory allergen thresholds. GMA and the food associations who have joined this letter specifically support the use of the quantitative risk assessment approach to thresholds.[1] As acknowledged in this notice, the "establishment of regulatory thresholds or action levels for major food allergens would help [FDA] determine whether, or what type of, enforcement action is appropriate when specific problems are identified." Industry agrees and fully supports this ultimate science-based conclusion. It is our belief that the establishment and use of food allergen thresholds could reduce the number of Class I recalls and reportable food registry (RFR) incidents without significantly increasing public health risk. In addition, we contend the establishment of thresholds will improve the quality of life of food allergic consumers by providing them with more meaningful food labels to make a clear decision about whether a food is appropriate for them to eat. GMA and the food associations who have joined this letter believe the industry would benefit from FDA guidance on how thresholds will be used by the Agency for enforcement and how the industry should apply any thresholds that may be established to enhance the protection of our consumers.

**Industry suggests a collaborative effort to work with the Agency on development of guidance on use of food allergen thresholds:** GMA and the food associations who have joined this letter encourage the Agency to work collaboratively with industry to define a food allergen threshold and how the thresholds will be used for enforcement action. We suggest that guidance needs to be developed on the evidence required to establish thresholds as well as the evidence

[1] Gendel S., Thresholds Working Group, *Approaches to Establish Thresholds for Major Food Allergens and For Gluten in Food*, 71 J. of Food Protection 1043-1088 (2008).

required to determine the level of allergenic protein needed to trigger allergic reactions with input from industry. We believe that industry is scientifically equipped to begin the development of such guidance and would like to engage in a collaborative effort working with the Agency. When the analytical and clinical data are assembled, defining thresholds will require agreement on the proportion of the food-allergic population that will set the threshold limit. Case-reports of individual food allergy reactions indicate that for some major food allergens there is a very small number of patients who react to extremely low allergen levels. How will these patients be considered in setting the thresholds? How will they be alerted to the possibility of trace levels of allergen that might be clinically significant to them? Once thresholds for major food allergens have been established and the limits of the thresholds are understood, GMA, its members and the food associations who have joined this letter urge the Agency to refrain from enforcement action and declaring packaged food products misbranded that may contain trace amounts of an undeclared allergen at or below the established threshold. Moreover, GMA and the food associations who have joined this letter believe that the Agency should not require any recalls for packaged food products that may contain trace amounts of an undeclared allergen at or below the established threshold as the risk to human health would be extremely low. Furthermore, manufacturers need to understand if the threshold and action level will be based on weight of the ingredient or form of the allergen in the food for an ingredient such as fish gelatin. We suggest that thresholds be established on a unit of measure such as milligrams of protein from the allergenic source (e.g. mg of total milk protein or mg of total peanut protein). The thresholds should be based on a defined and standardized unit of measure characterizing the source of the material. In addition, manufacturers will also need guidance on the basis of application of a threshold for translation to consumer exposure, for example, on a per serving or per eating occasion basis. Moreover, the Agency will need to define a clear risk communication program upon promulgation of threshold regulations, targeted especially to consumer education and the medical community.

**GMA and the food associations who have joined this letter recommend that the Agency establish what constitutes "an allergic response that poses a risk to human health" using objective criteria most relevant to public health:** Objective determinants are most informative to an assessment of risk. Objective criteria are scientifically based and can be readily measured, offering more definitive endpoints relevant to the consideration of risk to human health. To identify "an allergic response that poses a risk to human health," GMA and the food associations who have joined this letter recommend that FDA focus the analysis on objective criteria that are meaningful from a public health perspective, excluding minor, transient symptoms that can be measured objectively, as well as purely subjective considerations. Such an approach will allow

FDA to identify allergen thresholds that are protective of the allergic consumer while offering the clarity and other benefits FDA intends thresholds to achieve. The approach we suggest is consistent with existing regulatory standards that FDA has used to characterize and manage risk in similar contexts, including recall classifications, the "reasonable certainty of no harm" standard, and the *de minimis* doctrine. GMA and the food associations who have joined this letter recommend that the Agency factor in these existing approaches as potential thresholds are evaluated, and is willing to engage with FDA on this important topic.

**GMA and the food associations who have joined this letter seek clarification regarding precautionary labeling in the context of food allergen thresholds:** Precautionary labeling is not required by the Food Allergen Labeling and Consumer Protection Act (FALCPA). Thus, there is currently an inconsistent approach to precautionary labeling, which has the potential to cause consumer confusion. Food allergic consumers and their caregivers should be able to trust food allergen labeling, including truthful, non-misleading precautionary labeling. GMA and the food associations who have joined this letter acknowledge that precautionary labeling is not a substitute for GMPs and should be used judiciously as referenced in comments submitted by GMA and the Food Allergy Issues Alliance.[2] GMA and the Food Allergy Issues Alliance suggested that precautionary labeling should only be used when all of the following criteria are met: the presence of the major food allergen due to cross contact is documented through visual examination, analytical testing, or other means in processing line, equipment, ingredient or product; the risk of the presence of a major food allergen is unavoidable even when current GMPs are followed; a major food allergen is present in some, but not all, of the product; and the presence of the major food allergen is potentially hazardous. GMA and the food associations who have joined this letter believe allergen thresholds can help establish guidelines for precautionary labeling and resolve issues associated with the theoretical presence of allergens that were not intended to be in the product. Furthermore, consistent definitions and use of precautionary labeling statements will help food allergic consumers make clear decisions about their food choices. GMA and the food associations who have joined this letter suggest that the guidance defining how and when to use precautionary labeling statements be similar to the science- and risk-based VITAL (Voluntary Incidental Trace Allergen Labeling) approach[3] to precautionary labeling developed by the Allergen Bureau in Australia and New Zealand. Further, GMA and the food associations who have joined this letter suggest that the Agency, in

[2] GMA and Food Allergy Issues Alliance comments submitted on May 31, 2001, Docket No. 00P-1322 [2000-P-0134], Food Labeling and Allergen Contamination Control (attached).

[3] Allergen Bureau: Australia and New Zealand, *VITAL an initiative of the Allergen Bureau. 13-14 September 2012*, Retrieved January 24, 2013, available at http://allergenbureau.net/downloads/resources/conferences-2012/ILSI-Europe-2012-The-VITAL-Experience.pdf

collaboration with industry, conduct consumer research to craft precautionary labeling statements that resonate with the consumer to enhance their understanding and ensure that consistent language for such statements is used industry wide.

**GMA and the food associations who have joined this letter recognize the linkages between food allergen thresholds and the Food Safety and Modernization Act (FSMA) with respect to Good Manufacturing Practices (GMPs) and inspections within the Preventive Controls proposed rule. In addition, food allergen thresholds will have an impact on FSMA section 104, Performance Standards:** The areas of GMPs and inspections relative to food allergens have very strong linkages to the proposed rules for FSMA, which addresses issues on the application of the regulatory thresholds or action levels for GMPs and inspections of food manufacturing facilities, and performance standards to evaluate risk-based food allergen preventive control measures and conduct allergen hazard analyses. Specifically, testing requirements have increased as a result of the proposed FSMA rule § 117.150(a)(2), which requires that food allergen controls are evaluated through scientific studies or by collection of technical information. In addition, our association members also report that a lack of reference materials and official testing methodologies makes allergen management challenging. GMA and the food associations who have joined this letter suggest that the detection requirement should be a science-based standard (i.e. established food allergen thresholds) as described in section 104(b) of FSMA instead of testing to assure zero allergens for all major food allergens. A science-based standard should enhance the Agency's ability to enforce the law more efficiently and the industry's ability to identify allergen levels that require action.

GMA and the food associations who have joined this letter recognize that the Agency has defined "cross-contact" in the proposed rule §117.3 as "Cross-contact means the unintentional incorporation of a food allergen into food." However, we suggest that the overall goal of protecting food allergic consumers would be enhanced if the term were changed to "allergen cross-contact" or a similar term. The change in terminology would further clarify what appears to be the Agency's intention to address allergen related cross-contact and not confuse the term with "cross contamination." In addition, GMA and the food associations who have joined this letter suggest that the Agency define "cross contamination" to ensure that contamination is not associated with allergen management. These proposals would serve to clearly demarcate the two terminologies, "cross-contact" and "cross contamination," which often are used erroneously and interchangeably in the food industry. However, GMA, its members and the food associations who have joined this letter would confirm its understanding that the addition of the term "cross-contact" should not result in a change in industry practices or regulatory inspection/enforcement. Prior to the language change there has been an obligation on industry's part to avoid the

mislabeling of food and therefore the language addition of "cross-contact" is not a new concept or manufacturing process for either the industry or the FDA.

**GMA and the food associations who have joined this letter suggest the Agency evaluate incident reports of exposure to undeclared major food allergens in packaged food and related reports of illness:** GMA, its members and the food associations who have joined this letter note that there have been cases of Class I recalls where consumers have been potentially exposed to undeclared major food allergens without known consequential incidents or illness. In these cases, there was more of a likelihood of a hazard than an actual hazard posing risk to human health. For example, a manufacturer recalled several hundred thousand cases of product due to potential cross-contact with soy protein from processing equipment.[4] As reported in the recall notice, there were no known reports of illness related to this incident.[5] Even though such information is from industry-driven data, the reporting of an observation of no known illnesses is legally binding and serves as solid evidence worth evaluation. According to the third annual report on the reportable food registry,[6] 37.9% of the reports were due to undeclared allergens, yet similar numbers of consumers suffering allergic reactions does not exist. GMA and the food associations who have joined this letter suggest that the Agency cross reference these reportable food incidents similar to the potential soy cross-contact recall previously referenced with data on reported illnesses to better understand linkages between Class I recalls and known incidents of illness. Furthermore, we suggest that the Agency integrate its records systems (i.e. Reportable Food Registry, inspection reports, 483s, enforcement reports, CARES database, etc.) to take advantage and utilize the information already collected to incorporate into the Agency's risk management approach and risk assessment process to assess an incident. The establishment of major food allergen thresholds and action levels could reduce the number of Class I recalls each year without increasing risk to public health and thereby reduce the strain on resources for the Agency, retailers and manufactures as a result of these recalls.

**GMA and the food associations who have joined this letter believe the establishment of food allergen thresholds can advance the FALCPA ingredient exemption process:** GMA and the food associations who have joined this letter believe the establishment and application of

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[4]Food and Drug Administration, *Enforcement Report for February 15, 2012*, available at http://www.fda.gov/Safety/Recalls/EnforcementReports/ucm292057.htm

[5]Food and Drug Administration, *Recall Firm Press Release*, January 27, 2012, available at http://www.fda.gov/Safety/Recalls/ucm289496.htm

[6] FDA Foods and Veterinary Medicine Program, *the Reportable Food Registry: Targeting Inspection Resources and Identifying Patterns of Adulteration, Third Annual Report: September 8, 2011 – September 7, 2012*, available at http://www.fda.gov/downloads/Food/ComplianceEnforcement/RFR/UCM349856.pdf

regulatory allergen thresholds/action levels will aid the FALCPA notification exemption process by shaping the definition of "does not contain allergenic protein." The current notification process requires that a manufacturer provide scientific evidence that demonstrates that the food ingredient does not contain allergenic protein. The establishment of food allergen thresholds will help the agency develop criteria to evaluate FALCPA petitions. To date, there have been very few food ingredient exemptions through the FALCPA notification or petition processes. The use of thresholds/action levels in the exemption process could aid food allergic consumers as well as industry by focusing attention on foods that contain levels of allergenic protein that cause allergic reactions (i.e. milk powder versus a dairy flavor).

**GMA and the food associations who have joined this letter request the Agency review FALCPA Q&As regarding food allergen labeling:** GMA and the food associations who have joined this letter respectfully requests that FDA review and revise the list of the 19 tree nuts found in the final guidance document published by the Agency in October 2006. [7] In the FALCPA, the term "major food allergens" is defined to include tree nuts. GMA suggested that a "major food allergen" is an allergen that triggers allergic reactions that are both serious and prevalent in the food allergic population in comments previously submitted to the agency on industry guidance pertaining to food allergens.[8] Included in these comments was a scientific literature review entitled "Tree Nut Allergy Review" (noted below and appended) conducted by GMA on tree nuts, which concluded there is no scientific basis supporting the inclusion of 10 out of the 19 "nuts" on the Agency list.[9] For seven out of the ten "nuts" (beech nuts, butternuts, chinquapin, ginkgo nuts, hickory nuts, pili nuts, and sheanuts), there are no reports in scientific literature that these nuts trigger allergic reactions. Further, these "nuts" lack the prevalence and severity of allergic reactions that warrant the classification as a "major food allergen" as discussed in our "Tree Nut Allergy Review." Additionally, GMA and the food associations who have joined this letter believe that FDA deviated from the commonly understood meaning of "tree nuts," at least as the term is understood by the scientific community, regulatory bodies in other countries, at least one consumer group and the food industry. Therefore, we are requesting that the Agency remove "beech nuts, butternut, chestnut, chinquapin, coconut, ginkgo, hickory

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[7] Food and Drug Administration, *Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen and Consumer Protection Act* 2004 *(Edition 4); Final Guidance*, available at http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm059116.htm

[8] GMA Comment on Docket No. 2005D-0490 [2005-D-0227], Guidance for Industry: "Questions and Answers Regarding Food Allergens, including the Food Allergen and Consumer Protection Act 2004" Edition 4 submitted May 14, 2007(attached).

[9] *Id., Attachment I, "Tree Nut Allergy Review" (attached).*

nuts, lichee, pili nuts and sheanuts" from the list of tree nuts because these ten nuts cannot be reasonably classified as "tree nuts" for the purpose of food allergen labeling.

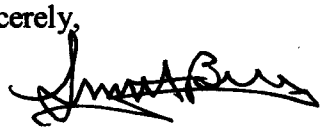
In addition, GMA and the food associations who have joined this letter recognize that FALCPA labeling requirements do not apply to major food allergens that are unintentionally added to a food as a result of cross-contact. Specifically, the potential of cross-contact of unintentional allergens with raw agricultural commodities as a result of adventitious mixing is exempt from FALCPA labeling. As acknowledged by the Agency, cross-contact may result from customary growing and harvesting of crops. For example, low levels of soybeans may be found in wheat or vice versa due to shared harvesting and transport equipment. If food allergen thresholds are established and rulemaking is promulgated, the Agency may need to review and/or revise its final guidance on food allergen labeling as it pertains to cross-contact with unintentional major food allergens. GMA, its members and the food associations who have joined this letter support the current exemption and urge the Agency to preserve the exemption if food allergen threshold regulations are established.

Summary:

GMA and the food associations who have joined this letter fully support the use of risk assessment-based approach to establish food allergen thresholds/action levels. The establishment of such thresholds would provide industry with clear guidelines to determine if enforcement action is appropriate when specific problems are identified. Specifically, food allergen thresholds would assure responsible and protective application of GMPs, and would enable efficient enforcement of the law. The establishment of food allergen thresholds will also help define when and how precautionary labeling should be used and outline a consistent approach for industry to use for labeling. Further, food allergen thresholds will help define when a product "does not contain allergenic protein" for the purposes of granting food ingredient exemptions under FALCPA. Moreover, GMA and the food associations who have joined this letter believe the industry will need a better understanding of how food allergen thresholds will be used by the Agency for enforcement action and how industry should apply those thresholds. It is also our belief that the establishment of food allergen thresholds will improve the quality of life for food allergic consumers and enhance public health by providing more meaningful food labels that allow consumers and their caregivers to make clear decisions about what food is appropriate for them to eat.

Thank you for considering our comments on this extremely important issue.

Sincerely,



Leon Bruner, DVM, PhD
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for Scientific and Regulatory Affairs
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Grocery Manufacturers Association

And on behalf of:

The American Peanut Council (APC)

Association for Dressings & Sauces (ADS)

National Pasta Association (NPA)

Council for Responsible Nutrition (CRN)

The Institute of Shortening and Edible Oils (ISEO)

The Juice Products Association (JPA)

National Confectioners Association (NCA)

National Milk Producers Federation (NMPF)

National Pasta Association (NPA)

cc: Steve Gendel, FDA CFSAN

Attachments:

- GMA and the food associations who have joined this letter and Food Allergy Issues Alliance comments on Docket No. 00P-1322 [2000-P-0134], Food Labeling and Allergen Contamination Control, submitted May 31, 2001.
- GMA and the food associations who have joined this letter and other associations comments on Docket No. 2005D-0490 [2005-D-0227], Guidance for Industry: "Questions and Answers Regarding Food Allergens, including the Food Allergen and Consumer Protection Act 2004", submitted May 14, 2007 and Attachment I, "Tree Nut allergy Review"