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Quantitative risk assessment of foods containing peanut advisory labeling

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ABSTRACT

Foods with advisory labeling (i.e. "may contain") continue to be prevalent and the warning may be increasingly ignored by allergic consumers. We sought to determine the residual levels of peanut in various packaged foods bearing advisory labeling, compare similar data from 2005 and 2009, and determine any potential risk for peanut-allergic consumers. Of food products bearing advisory statements regarding peanut or products that had peanut listed as a minor ingredient, 8.6% and 37.5% contained detectable levels of peanut (>2.5 ppm whole peanut), respectively. Peanut-allergic individuals should be advised to avoid such products regardless of the wording of the advisory statement. Peanut was detected at similar rates and levels in products tested in both 2005 and 2009. Advisory labeled nutrition bars contained the highest levels of peanut and an additional market survey of 399 products was conducted. Probabilistic risk assessment showed the risk of a reaction to peanut-allergic consumers from advisory labeled nutrition bars was significant but brand-dependent. Peanut advisory labeling may be overused on some nutrition bars but prudently used on others. The probabilistic approach could provide the food industry with a quantitative method to assist with determining when advisory labeling is most appropriate.

1. Introduction

Peanut is one of the most common allergenic foods with a worldwide prevalence of 0.6–2.9% (Osborne et al., 2011; Rona et al., 2007; Sicherer et al., 2010; Sicherer and Sampson, 2010). Peanut allergies are potentially life-threatening and the most common cause of food allergy-related fatalities in the United States (Bock et al., 2007; Keet and Wood, 2007; Rona et al., 2007). Peanut-allergic consumers must adhere to a strict avoidance diet and carefully examine ingredient labels (Hefle et al., 2007; Pieretti et al., 2009; Taylor et al., 1986; Yu et al., 2006). The presence of peanut in mislabeled or unlabeled packaged products has led to allergic reactions in consumers relying on clear and accurate ingredient statements (Kemp and Lockey, 1996; Yu et al., 2006).

In the US, the Food Allergen Labeling and Consumer Protection Act (FALCPA) that protects allergic individuals from unclear or unlabeled products was passed in 2004 and became effective January 1, 2006 (FDA, 2006). Similar allergen labeling laws have been implemented in 18 other national regulatory frameworks to address the issue of improved labeling of allergens in food (Gendel, 2012). For public health authorities, the primary strategies have been to develop lists of priority allergenic foods and enact regulations to assure that any ingredients derived from these foods are declared on the labels of packaged foods (Gendel, 2012). FALCPA requires that companies must declare ingredients derived from the major allergenic foods including peanuts. Labeling of peanut is required by all 19 international regulatory frameworks that address allergen labeling (Gendel, 2012). However, advisory labeling for allergens is voluntarily used by the food industry and not directly regulated or addressed by FALCPA or most similar regulations elsewhere. The U.S. Food, Drug, and Cosmetics Act does require that label statements be "truthful and not misleading" (Chapter II, Sec. 201). Since advisory label statements are voluntary, a variety of advisory labels are used which can cause confusion and lead to weighted opinions of differing label statements. In a report by the U.S. Food and Drug Administration (FDA), both allergic and non-allergic consumers indicate that shorter "may contain" advisory labels are more likely to contain peanuts or other listed allergens. Additionally, both allergic and non-allergic consumers were more likely to serve a product with a longer "shared

Abbreviations: DBPCFC, Double-blind, placebo-controlled oral food challenge; FAAN, Food Allergy & Anaphylaxis Network; FALCPA, Food Allergen Labeling and Consumer Protection Act; FDA, U.S. Food and Drug Administration; LOAEL, Lowest Observed Adverse Effect Level; NHANES, National Health and Nutrition Examination Survey; NOAEL, No Observed Adverse Effect Level.

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facility" or "shared equipment" statement to an allergic individual than a product with a shorter "may contain" label (FDA, 2006). Allergic consumers are more likely to avoid products that state they "May contain" or were "Manufactured on the same/shared equipment" than products that state they were "Manufactured in a facility that also processes/uses" (Barnett et al., 2011; Hefle et al., 2007). However, peanut may be present in products that contain any form of advisory label for peanut (Hefle et al., 2007; Pele et al., 2007).

A US supermarket survey found 17% of products in 24 standard food industry categories contain an advisory label statement for food allergens (Pieretti et al., 2009). The wording of such statements was split evenly among products as 38% had "May contain", 33% had "Same/shared equipment", and 29% had "Shared facility" labels. Certain categories, such as chocolate candy, cookies, and baking mixes, had the highest prevalence of advisory statement usage with 40–54% of the products having an advisory label (Pieretti et al., 2009). While the use of advisory labeling is high, Hefle et al. (2007) found in a 2005 survey that only 7.3% of products with peanut advisory statements tested had detectable levels of peanut. Consumer avoidance of advisory labeled products has decreased and the prevalence of detectable peanut is low, but a risk of an allergic reaction still exists when consuming advisory labeled products (Hefle et al., 2007).

The current study surveyed packaged foods with an advisory label for peanut for the presence of peanut. Special attention was paid to the difference between foods with peanut advisory labeling and peanut labeled as a minor ingredient. Comparisons to a similar study conducted in 2005 by Hefle et al. (2007) were done. High levels of peanut in nutrition bars tested in 2005 and 2009 led to a second market survey focused on nutrition bars which sought to determine the levels of peanut in products with and without peanut advisory labeling. The potential risk to peanut-allergic consumers of nutrition bars was determined through the use of probabilistic risk assessment.

Monte Carlo simulations have become popular in the quantitative assessment of microbial and chemical risks (EU, 2003; Kroes et al., 2000; Lammerding and Fazil, 2000; Larsen, 2006; Notermans et al., 1995) but their use with food allergens is a recent development. Probabilistic risk assessment of food allergens was introduced by TNO in the Netherlands and used to investigate the risk associated with undeclared hazelnut in chocolate spreads (Spanjersberg et al., 2007). Additional research conducted by the same group, and others in France, has shown the robust capabilities of the probabilistic models and expanded the concept to products with advisory labels for milk and peanut (Kruizinga et al., 2008; Rimbaud et al., 2010; Spanjersberg et al., 2010).

The current study uses a probabilistic risk assessment approach to estimate the risk of an allergic reaction to the peanut-allergic population. The risk assessment couples the Bayesian inference of input variables from the model and 2nd Monte Carlo simulations to separately propagate the variability and the uncertainty of these variables (adapted from Rimbaud et al. (2010)). Parametric distributions describe each input variable, i.e. the prevalence of peanut allergy, reflecting natural heterogeneity and diversity. In a Bayesian framework, model parameters are random variables with their own distributions and not fixed as in other standard statistical approaches. These distributions reflect uncertainty in each parameter due to measurement errors or model hypothesis and are incorporated as they reflect the state of knowledge available before data set analysis (Pouillot et al., 2003; Rimbaud et al., 2010). To date, probabilistic risk assessment of food allergens based on packaged products found in the US has not been done. This study aims to assess the risk to a peanut-allergic consumer who intentionally purchases nutrition bars with advisory labeling for peanut.

2. Methods and materials

2.1. Peanut advisory labeling studies

2.1.1. 2009 Packaged food samples

A total of 202 packaged food products bearing advisory statements regarding peanut (186) or products that had peanut listed as a minor ingredient (last three ingredients on statement; 16) were purchased in Lincoln, Nebraska, USA. Products were categorized as baked goods/mixes, baking ingredients, candy/confectionery, cereals/cereal bars, frozen desserts, instant meals, nutritional/meal bars, or snack foods. Two different lot numbers of each product were obtained leading to a total of 404 samples. Sampling was designed in an effort to replicate the 2005 study (Hefle et al., 2007) and 54 identical products were available to purchase again in 2009. If identical products (manufacturer/flavor) were not available, similar products from the same manufacturers were targeted.

2.1.2. 2010 Nutrition bar market survey

Due to the level of peanut in nutrition bars with advisory labeling in the 2005 and 2009 surveys, an in depth survey of nutrition bars available in Lincoln, Nebraska, USA was conducted. Products were categorized by the nature of the declaration of peanut on the labeling including contains peanut, minor ingredient, advisory statement for peanut, unique advisory labeling (may contain nuts, contains + advisory statement, minor ingredient + advisory statement), declaration of peanut free, and no mention of peanut on the label. A total of 399 nutrition bars were recorded over all categories. Products stated to contain peanut before the last three ingredients on the statement were not tested (120). Subsequently, 279 were purchased for testing including 49 with minor ingredient declaration, 166 with advisory labeling statements, 15 declared peanut free, and 49 with no mention of peanut. In an effort to sample as many unique brand and flavor combinations as possible, a single lot number of each nutrition bar was tested in this study.

2.1.3. Peanut analysis

A representative sample from a single package was homogenized (1/2 of package) and then analyzed (5 g) for the presence of peanut using a commercial enzyme-linked immunosorbent assay (Peanut Veratox®, Neogen) with a lower limit of quantification of 2.5 ppm (ppm, μg/g) whole peanut (0.63 ppm peanut protein). Samples were prepared and analyzed according to instructions provided with the kit. Identical analytical methods were used in the 2005 market survey.

2.2. Nutrition bar consumption

Consumption data for nutrition bars were extracted from the U.S. National Health and Nutrition Examination Survey (NHANES) using a combination of the 2003–2004, 2005–2006, and 2007–2008 surveys (CDC, 2004, 2006, 2008). Only individuals completing both of the 24 h dietary recall interviews were included in the dataset. Within the NHANES data, USDA food codes specific to high protein nutrition and meal replacement bars, PowerBar™, and Snickers™ Marathon bars (41435110, 53541200, 53544450, 91780010, and 91781010) were used to create the nutrition bar product category. Individuals were considered consumers if they ate nutrition bars during one of the two recall days. For individuals consuming multiple nutrition bars in a 24 h period, the intakes were summed to a daily consumption level. As there is no consumption database describing the dietary habits of allergic consumers, the assumption was made that allergic and non-allergic individuals consume nutrition bars at the same rate and quantities and their reasons for nonconsumption are the same.

2.3. Threshold doses

The distribution of individual threshold doses from DBPCFC of 450 peanut-allergic individuals based on objective symptoms was taken from Taylor et al. (2010). A Log-Normal probability distribution function was fitted to the No Observed Adverse Effect Levels (NOAELs) and Lowest Observed Adverse Effect Levels (LOAELs) from each individual to describe the population threshold dose expressed as mg whole peanut, as previously described (Taylor et al., 2009).

2.4. Quantitative approach to risk assessment

The probabilistic risk assessment model for food allergens was described by Spanjersberg et al. (2007) and Kruizinga et al. (2008). Briefly, data inputs for prevalence of food allergy, allergen thresholds, consumption patterns, and product test results can be fitted to statistical distributions for use in a Monte Carlo simulation. The current risk assessment incorporates a Bayesian framework into a 2nd order Monte Carlo simulation to estimate the risk of an allergic reaction from consumption of nutrition bars with advisory labeling for peanut (adapted from Rimbaud et al. (2010)). The simulation scheme can be seen in Fig. 3.1. The simulation will set and hold distribution parameter inputs for a single run and then resample to achieve a new set of parameter inputs for the next run. Each run consists of 100,000 iterations that randomly sample from each set distribution and match if the individual is allergic, a consumer of the type of product, and if the product con-