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Survey of peanut levels in selected Irish food products bearing peanut allergen advisory labels

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Peanut allergy affects up to 2% of consumers and is responsible for the majority of fatalities caused by food-induced anaphylaxis. Peanut-containing products must be clearly labelled. Manufacturers are not legally required to label peanut if its inclusion resulted from unintentional cross contact with foods manufactured in the same facility. However, the use of allergen advisory statements alerting consumers of the potential presence of peanut allergen has increased in recent years. In previous studies, the vast majority of foods with precautionary allergen statements did not contain detectable levels of peanut, but no data are available on Irish food products. Thirty-eight food products bearing peanut/nut allergen-related statements were purchased from multiple locations in the Republic of Ireland and analysed for the presence of peanut. Peanut was detected in at least one lot in 5.3% (2 of 38) of the products tested. The doses of peanut detected ranged from 0.14 mg to 0.52 mg per suggested serving size (0.035–0.13 mg peanut protein). No detectable levels of peanut were found in the products that indicated peanut/nuts as a minor ingredient. Quantitative risk assessment, based on the known distribution of individual threshold doses for peanut, indicates that only a very small percentage of the peanut-allergic population would be likely to experience an allergic reaction to those products while the majority of products with advisory labels appear safe for the peanut-allergic population. Food manufacturers should be encouraged to analyse products manufactured in shared facilities and even on shared equipment with peanuts for peanut residues to determine whether sufficient risk exists to warrant the use of advisory labelling. Although it appears that the majority of food products bearing advisory nut statements are in fact free of peanut contamination, advice to peanut allergy sufferers to avoid said foods should continue in Ireland and therefore in the wider European Union.

Keywords: food allergy; peanut; labelling; advisory labelling

Introduction

Peanut allergy is prevalent and known to cause severe reactions worldwide (Bock et al. 2007; Hourihane 2007; Pumphrey & Gowland 2007; Rona et al. 2007; Ben-Shoshan et al. 2010; Sicherer et al. 2010). Peanut-allergic consumers rely heavily on food manufacturers to provide accurate, non-misleading allergy information on food packages.

European Union (EU) Directive 2000/13/EC, as amended in 2003, mandates that certain allergenic ingredients including peanuts and products thereof must be clearly labelled on food products in which they are present (European Parliament and Council 2000, 2003). Manufacturers are not legally required to declare peanut if its inclusion was as a result of unintentional cross contact with foods manufactured in the same facility. However, many food manufacturers choose to voluntarily include statements advising consumers on its potential content (e.g., “may contain peanut”) in such situations. While the corporate intent may be to inform consumers, consumers consider such labels as at least confusing and often unhelpful.

Hefle et al. (2007) recognised that there are three main types of advisory allergen statements used, the “may contain [allergen]”-type, the “manufactured in the same facility with [allergen]”-type and the “manufactured on shared equipment with [allergen]”-type. Wording can vary greatly between different manufacturers. In addition, advisory statements may declare the presence of an allergen as a minor ingredient (e.g., contains traces of peanut or peanuts stated as the final ingredient in the ingredient listing).

Studies to date have revealed that the vast majority of foods with precautionary allergen statements do not contain detectable levels of peanut. For 75 foods purchased in the Republic of Ireland, the Food Safety Authority of Ireland (FSAI) found that only five products (7%) with advisory nut statements tested positive for peanut (Food Safety Authority of Ireland 2011). These results are similar to those found in the United States in several studies where 4.5–7.3% of the products bearing advisory peanut statements tested positive for peanut (Hefle et al. 2007; Ford et al. 2010; Remington et al. 2010). In the EU, a higher percentage of products (25%) with advisory nut/peanut labelling had detectable peanut levels in a survey

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of 333 biscuits and chocolates purchased in 10 European countries (Pele et al. 2007). This study also documented that products without an advisory statement contained peanut on occasion, an even riskier situation due to the lack of any advisory about peanut in these products (Pele et al. 2007). Because the various studies tested different food categories, it is difficult to compare the results. If these statements are overused, they reduce the diversity of products available to peanut-allergic consumers.

Materials and methods

Thirty-eight wrapped, shelf-stable food products were purchased from multiple locations in the Republic of Ireland and tested in Lincoln, NE, USA. The 38 food products represent a spectrum of packaged snack foods available in Ireland and were further categorised as baked goods, biscuits, cereal/granola bars, chocolates or nutrition/meal bars. The 38 food products included 30 with advisory statements of various types and 8 with peanut or nut listed as a minor ingredient. The “chocolates” category included chocolate bars, share-size bags of miniature chocolates and chocolate confections. All products were selected in the stores on the basis of visible allergen statements that made reference to either peanut or nuts (label reference to nuts was taken to refer to peanuts, tree nuts or both). Despite efforts to obtain as many as four different lot numbers for each product, this was accomplished for only four of the products. Three different lot numbers were acquired for 13 of the products, 2 different lot numbers for 11 products and only 1 lot number for 5 products. Four samples (same or different lot numbers) of each product were attainable for the majority of the products tested (30 of 38).

A total of 136 samples were analysed. Each sample was homogenised. Two sub-samples were taken from each homogenous sample and subjected to an extraction procedure before being analysed for peanut residue by using the Neogen Veratox™ Quantitative Peanut Allergen Test kit (Neogen Corporation, Lansing, MI, USA). Both extractions were analysed in duplicate for the presence of peanut protein. The results were expressed in parts per million (micrograms of whole peanut per gram). The test kit is able to reliably detect peanut residues above $2.5 \mu\text{g g}^{-1}$, and a result found to be below this level is referred to as being below the limit of quantification; results are expressed as $\mu\text{g g}^{-1}$ of whole peanut.

Samples that tested positive were subjected to probabilistic risk assessment as described (Spanjersberg et al. 2007; Kruizinga et al. 2008) to determine the health risk to peanut-allergic individuals consuming that brand of product. This risk assessment uses a modified Monte Carlo approach, incorporating the mean and standard error associated with parameters of the peanut threshold log-normal probability distribution and the frequency of peanut being

present into a Bayesian framework to better estimate the confidence of the risk of allergic reaction (Rimbaud et al. 2010). The log-normal probability distribution of individual threshold doses (in mg whole peanut) for 450 peanut-allergic individuals was reported by Taylor et al. (2010). The Monte Carlo program (50 runs, 10,000 iterations each) randomly sampled from the peanut threshold distribution determined whether the sample contains peanut, selected from the observed $\mu\text{g g}^{-1}$ whole peanut levels whether the sample is positive and selected a consumption amount to determine the possibility of an allergic reaction. An allergic reaction is predicted if the consumed amount and the concentration of peanut lead to a dose (of whole peanut) over the predicted allergen threshold; this is the user risk for peanut-allergic consumers who decide to eat the particular product. Consumption amounts for this study were based on the serving size for each product in question. Multiple simulations were run with the consumption amount restricted to one, two, three or four serving sizes. One simulation combined the probabilities of consuming one or more serving sizes on the basis of similar products (cereal bars and chocolate confections) in the United States National Health and Nutrition Examination Survey (NHANES) to better estimate the actual risk to a peanut-allergic consumer.

Results

Table 1 shows the number of products tested for each category, the types of allergen statements observed and the number of products that tested positive for detectable peanut contamination. In this sample of food products, the most common type of allergen label observed was the “may contain”-type label, with 55% (21 of 38) of the products using this type of labelling. Thirty-four percent (13 of 38) of the products carried labels that made reference to nuts (which may include peanuts); none contained detectable levels of peanut. Peanut was detected in at least one lot in 5.3% (2 of 38) of all the products tested, including 8.0% (2 of 25) with advisory labels specific for peanut. A detectable peanut level of $25.8 \mu\text{g g}^{-1}$ was found in one out of three lots of one brand of miniature chocolate bar (Table 2). At this level of peanut, the dose per suggested serving size (one bar) was 0.52 mg of whole peanut. The allergen statement on the packaging of this chocolate product warned consumers that the product “may contain traces of peanut”. All four lots of one particular brand of cereal bar had detectable levels of peanut, ranging from 2.8 to $7.4 \mu\text{g g}^{-1}$ (Table 2). At this level of peanut, the dose per suggested serving size (one bar) ranged from 0.14 mg to 0.33 mg of whole peanut. A “manufactured in the same facility”-type label was used to advise consumers of the potential for peanut contamination in this cereal bar. Only a single product was found with a label bearing “manufactured on shared equipment”

Table 1. Label types observed on packaged foods and number of samples with detectable levels of peanut.

Product category	“May contain” labelling ^a		“Shared equipment” labelling		“Shared facility” labelling		Minor ingredient labelling		Total
	Peanut	Nuts	Peanut	Nuts	Peanut	Nuts	Peanut	Nuts	
Baked goods	–	2	–	–	1	–	–	–	3
Biscuits	5	1	1	–	2	–	–	–	9
Cereal/granola bars	–	2	–	–	1 (1)	–	1	–	4 (1)
Chocolates	3 (1)	6	–	–	–	–	5	1	15 (1)
Nutrition/meal bars	5	–	–	–	–	–	1	1	7
Total	13	11	1	–	4	–	7	2	38 (2)

Note: ^aNumber of samples tested (number of samples with detectable peanut in one or more lots).

(Table 1), suggesting that this advisory labelling format is less frequently used in Ireland than in the United States (Hefle et al. 2007; Remington et al. 2010). Products with peanut/nut indicated as a minor ingredient were also surveyed, and none had detectable levels of peanut (Table 1), which could be interpreted as either suggesting that it is easier/cheaper to inaccurately label a product as containing peanut than it is to guarantee that it does not contain peanut, or as an attempt to dissuade peanut-allergic consumers who would otherwise ignore precautionary labelling.

Table 3 displays the results of all probabilistic risk assessment simulations for the cereal bar and miniature chocolate bar products. The user risk to peanut-allergic consumers of the cereal bars is 1.4, 3.2 and 4.8 predicted reactions per 1000 consumptions (eating occasions) of one, two or three servings, respectively. Consumption patterns for cereal bars in the NHANES predicted that 75% of the consumers would eat one cereal bar serving, 20% would eat two and 5% would eat three; the assumption was made that Irish consumption patterns would be similar because the food consumption survey available for Ireland (<http://www.iuna.net/>) does not include a specific category for cereal bars. The overall risk to peanut-allergic

consumers based on the combination of these various consumption levels (one, two or three bars) was 2.0 predicted reactions per 1000 eating occasions of this cereal bar brand. The miniature chocolate bar product presented a risk of 1.6, 3.8, 6.0 and 7.8 predicted reactions per 1000 consumptions of one, two, three or four servings, respectively. Candies with serving sizes close to 20 g produced consumption patterns that estimated that 75% would consume one serving, 10% would consume two, 10% would consume three and 5% would consume four based on the NHANES. These percentages were consistent with mean and 95% percentile serving sizes in an Irish food consumption survey for the chocolate confectionery category. The overall risk to peanut-allergic consumers based on the combination of various consumption levels of these miniature chocolate bars (one, two, three or four servings) was 2.6 predicted reactions per 1000 eating occasions using the realistic consumption pattern.

Discussion

Enzyme-linked immunosorbent assays detected peanut residues in 5.3% (2 of 38) of food products with advisory labels purchased in the Republic of Ireland including 8.0%

Table 2. Concentration and serving-size doses of peanut in packaged foods with advisory labels for peanut/nut that tested positive for peanut in at least one lot.

	Product category	Labelling	No. ^a	Concentration ^b	Dose ^c (mg)
1	Chocolates	“May contain traces of peanut”	3 (1)	25.8 µg g ⁻¹ BLQ	0.52 <0.05
2	Cereal/granola bar	“Shared facility”-type	4 (4)	BLQ 3.0 µg g ⁻¹ 2.8 µg g ⁻¹ 7.4 µg g ⁻¹ 6.2 µg g ⁻¹	<0.05 0.14 0.13 0.33 0.28

Notes: BLQ, below the limit of quantification.

^aNumber of different lots tested (number of positive lots).

^bConcentration in µg g⁻¹ (micrograms whole peanut per gram).

^cDose in milligrams of whole peanut per suggested serving.

Table 3. Results of the probabilistic modeling simulations.

	Cereal/granola bar				
Consumption amount	45 g	90 g	135 g	45–135 g	
Lots tested (positive)	4 (4)				
$\mu\text{g g}^{-1}$ range	2.8–7.4				
Probability of peanut in product ^a (%)	83 ± 16	84 ± 12	84 ± 13	84 ± 13	
Peanut-allergic user risk ^b	1.4 ± 0.6 per 1000	3.2 ± 1.1 per 1000	4.8 ± 1.5 per 1000	2.0 ± 0.8 per 1000	
	Chocolates				
Consumption amount	20 g	40 g	60 g	80 g	20–80 g
Lots tested (positive)	3 (1)				
$\mu\text{g g}^{-1}$ range	25.8				
Probability of peanut in product (%)	34 ± 20	43 ± 23	41 ± 17	40 ± 20	37 ± 21
Peanut-allergic user risk ^b	1.6 ± 1.1 per 1000	3.8 ± 2.1 per 1000	6.0 ± 2.9 per 1000	7.8 ± 4.4 per 1000	2.6 ± 1.5 per 1000

Notes: ^aAs part of the Bayesian Monte Carlo simulation, the probability that a detectable level of peanut is present in the product can be modelled by a binomial distribution with parameters of the number of positive samples (p) and the number of samples tested ($n1$). Using the conjugate Beta(1,1) prior distribution, the posterior distribution of the parameter p is the Beta ($1 + x$, $1 + n1 - x$). Therefore, if a product contains four positive samples out of four tested products, there is not 100% chance that the product is contaminated but an average probability of contamination of 83–84%.

^bUser risk involves the expected frequency of reactions among peanut-allergic consumers of the product.

(2 of 25) of food products with advisory labels specifically mentioning peanut. Although none of the 13 food products with advisory labels mentioning nuts was found to contain detectable peanut residues, the meaning of the term *nuts* on such advisory statements is unclear. Nuts might be taken to mean peanuts and any of several tree nuts. Peanut residues were not detected in any nutrition/meal bars in this study, whereas nutrition/meal bars purchased in Lincoln, NE, USA, were found to have the highest levels of peanut compared with foods from other categories (Remington et al. 2010). Twenty-five percent of chocolates purchased from 10 European countries tested positive for peanut (Pele et al. 2007), and in this study, only 7% (1 of 15) of products from the “chocolates” category tested positive, including 12.5% (1 of 8) of products with an advisory statement specific to peanut. The particular product categories were chosen for analysis because they were postulated to have a higher risk of peanut contamination compared with other food categories based on previous US data (Hefle et al. 2007; Remington et al. 2010). Therefore, it seems that a more comprehensive survey including more food categories would produce a smaller percentage of positive results. However, the FSAI study in Ireland did not bear out this assumption: a greater number of different food categories was analysed, and the proportion of positively tested products was actually higher than the percentage in this study. While the randomness of sampling in the FSAI survey is unknown, both this study and the FSAI survey involved limited numbers of samples and product categories. Thus, results of this study indicate that the detection of peanut residues in products having advisory labelling for peanut is lower

in Ireland than in other EU countries (Pele et al. 2007) although this may be reflective of industry changes in labelling practices between the time of selection of the products in the two surveys. Our survey did not compare products with advisory labels to similar products without advisory labels. In previously published surveys (Pele et al. 2007), peanut residues were also found in products without advisory labels. However, with the increased food industry awareness of peanut allergy, the probability of finding detectable levels of peanut in products without direct ingredient or advisory statements about peanut has hopefully decreased in recent years.

Analysis for peanut contamination was carried out only on selected food categories, and so these results do not represent all food categories in the Irish market that have advisory peanut/nut statements. Most of the companies whose products we tested are large international organisations whose good manufacturing practices (GMP) may be better than that of more local or regional producers. Although there are limitations to this study, the positive analytical results were found in one of three lots of one particular product and four of four lots of another product. Using quantitative risk assessment based upon the dose-distribution relationship of individual threshold levels of 450 peanut-allergic subjects (Taylor et al. 2010), the risk to peanut-allergic consumers of these products is, respectively, 1.6 and 1.4 per 1000 one serving eating occasions. Of course, as shown in Table 3, the risk increases proportionately if more product is consumed. Based upon NHANES and consistent with the Irish food consumption survey for the chocolate confectionery category, many product types are consumed in amounts in

excess of the serving size, although amounts as large as four serving sizes would capture the vast majority of all consumers. The risk calculation was based upon serving sizes rather than a more detailed consumption distribution because such a distribution was not available for these two product categories from Ireland and the particular products are sold as individual packages, which enhances the likelihood that they will be consumed in serving size multiples. For chocolate confections, the mean and 95% intake from the Irish survey match the serving size multiples used in this analysis reasonably closely. The amount of peanut per serving in these products ranges from 0.14 to 0.52 mg, which is well below the predicted eliciting dose for 5% of this peanut-allergic population, 5.2 mg of peanut (Taylor et al. 2010). The risk expressed in Table 3 is the user risk or the risk to peanut-allergic consumers if they choose to ingest this product. The overall population risk would be much smaller because only a fraction of the population is allergic to peanut and chooses to consume these particular products. Even among peanut-allergic consumers, only a small percentage would experience any risk from the ingestion of these two products. The highest dose per serving size observed in our study was 0.52 mg whole peanut, just above the minimal eliciting dose of 0.4 mg whole peanut noted for 1 of 450 subjects in the study of Taylor et al. (2010). The minimal eliciting dose refers to the lowest dose that triggered an objective reaction in a controlled clinical challenge (Taylor et al. 2010). Typically, the objective symptoms noted at the minimal eliciting dose are mild or moderate; severe reactions are not encountered at such low doses. Thus, the ingestion of 0.52 mg whole peanut would not be predicted to provoke a severe reaction.

In 2011, Australian Allergen Bureau assembled an expert panel to establish appropriate reference doses for residues of allergenic foods as a part of the Voluntary Incidental Trace Allergen Labeling (VITAL) program. In turn, the food industry is recommended to use these reference doses as a guide with advisory labelling decisions. The expert panel recommended a reference dose of 0.8 mg whole peanut (0.2 mg peanut protein) as a level to help limit advisory labelling while still protecting 99% of the peanut-allergic population. The dose of peanut provided by these products is under the VITAL reference dose for peanut and suggests that advisory labelling may not be warranted in this instance. However, the analysis of only a small number of samples of each product does not allow us to deduce that these products will never contain levels of peanut that would have more profound adverse effects on a larger percentage of the peanut-allergic population. The use of product analysis with quantitative risk assessment and the use of consensus reference doses such as the VITAL approach have the potential to restrict the use of advisory labelling while still serving to protect peanut-allergic consumers.

For the majority of the food products (30 of 38), it was possible to analyse four samples (same or different lot numbers) of each product. Previous studies have analysed fewer samples for each product. For example, Hefle et al. (2007) analysed two samples of each product, and Ford et al. (2010) analysed only one sample for each. The negative results for our samples do not infer that all samples of the same product on the market are free from detectable peanut contamination.

Interestingly, no detectable levels of peanut were found in the products that indicated peanut/nuts as a minor ingredient, and so it is unclear why the products are labelled as containing peanut. The results from our study and from US studies (Hefle et al. 2007) indicate that the majority of packaged foods with minor ingredient labelling do not contain detectable levels of peanut residue. Both EU and US legislation require that the information on packaged foodstuffs should not be misleading to the consumer. It is likely that either the levels of peanut added are too low to be detectable by even sensitive enzyme-linked immunosorbent assay-based techniques (which we think is unlikely) or food manufacturers choose to use this type of labelling to further dissuade allergic consumers who might otherwise ignore precautionary labelling. This implies that food manufacturers are using advisory allergen labelling and “contains [allergen]” labelling in lieu of or, more likely, in addition to GMP. Thus, our study provides further evidence that advisory labelling is over-used. This makes the whole concept of such labels and warnings less reliable and relevant for food-allergic consumers in terms of assisting actual risk avoidance.

Almost half of the products tested in this study have advisory labels that make reference to nuts (e.g., may contain nuts) and fail to disclose the specific type of nut the food may contain. The use of more generic advisory labelling forces peanut-allergic consumers to avoid a wider range of food products than may be necessary.

It appears that nut allergy sufferers or caretakers of nut allergy sufferers may associate different advisory nut labelling statements with different levels of risk. For example, a greater percentage of parents of nut-allergic children in the United Kingdom would ignore the precautionary advice of a food labelled “may contain traces of nuts” than a food labelled “may contain nuts” (Noimark et al. 2009). Another study found that when purchasing foods with advisory labelling, US consumers were more likely to ignore the advice from foods bearing the “manufactured in the same facility with [allergen]”-type and the “manufactured on shared equipment with [allergen]”-type statements than the “may contain [allergen]”-type statement (Hefle et al. 2007). In actuality, this graduated risk for differently labelled foods, as perceived by consumers, may not always reflect reality. An example of this was shown when Pele et al. (2007) analysed European biscuits for traces of hazelnut. Analytical results were found to be

similar for both the biscuits with the “may contain”-type label and those bearing the “present in environment”-type label (e.g., “manufactured in a facility that processes hazelnut”, “processed on equipment that also processes hazelnut”). Similar results have also been observed in the United States (Hefle et al. 2007; Remington et al. 2010). Our smaller study in Ireland (EU) supports the literature, which demonstrates that this graduation of possible risk on labels has no basis of demonstrably differing levels of peanut between the different types of allergen labels.

Although it appears that the majority of food products bearing advisory nut statements are in fact free of peanut contamination, advice to peanut allergy sufferers to avoid said foods should continue in Ireland. The small percentage of products that tested positive justifies the avoidance of such products. Hefle et al. (2007) observed that food-allergic people or parents of food-allergic children were less likely to follow advisory allergen warnings in 2006 than in 2003 (Hefle et al. 2007). We suspect that the increased tendency for people to overlook advisory allergen warnings corresponds with the increased use of these warnings (which we have termed “label fatigue”).

Our results would suggest that there is a small but definite risk of peanut-allergic people consuming peanut-contaminated confectionary and cereal bar products that carry advisory peanut labelling.

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