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Occurrence and risk assessment of sesame as an allergen in selected Middle Eastern foods available in Montreal, Canada

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ABSTRACT

Sesame allergy is a public health problem in many countries around the world. The purpose of this study is to determine the occurrence of sesame allergen in unlabelled or labelled free-sesame Middle Eastern foods with or without Precautionary Allergen Labelling (PAL) 'may contain' and estimate the risk incurred by the Canadian population allergic to sesame with a focus on products purchased in Middle Eastern grocery stores and bakeries in Montreal, Canada. A total of 571 samples were analysed to determine the level of sesame protein. Of the 571 samples analysed, 19% (109/571) contained sesame (results >LOQ) with concentrations of sesame proteins varying between 0.5 and 1,875 mg kg⁻¹ and 35% (199/571) contained traces (a value between LOD and LOQ). Unpackaged products were found to present the highest proportion of sesame containing samples (36%). For packaged products, 16% (27/173) of samples with PAL and 3% (5/173) without PAL were found to contain sesame. A probabilistic approach was used to estimate the risk incurred by the Canadian consumers allergic to sesame. Our evaluation estimated that 33 to 308 allergic reactions may occur out of 10 000 individuals ingesting one type of bakery product contaminated at a level of 0.6–74 mg kg⁻¹ sesame proteins. The incidence and level of sesame cross-contact reported in this study demonstrate that sesame allergic consumers could react if they ignore the precautionary allergen statements on product labels. Attention to sesame as a potential cross-contact agent and as a priority allergen calls for better management, given the growing interest in this ingredient to be included in food formulations. Enhanced risk management efforts must be coupled with targeted risk communication covering both producers and consumers as to the need to adopt and an approach for the application of precautionary allergen labelling based on risk.

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Food allergen; sesame; modelling; precautionary allergen labelling; probabilistic approach

Introduction

Food allergy is a significant public health problem that has been on the rise for years (Renz et al. 2018; De Martinis et al. 2020). According to the World Health Organisation (WHO), it is considered, worldwide and in particular in industrialised countries, among the five major foodborne illnesses (FÆste et al. 2011). Over the past two decades, the prevalence of food allergies has increased in Western countries (Western Europe, North America, Australia and New Zealand), to reach 10% in preschool children (Soon 2019; De Martinis et al. 2020). Allergens can be present as ingredients in food, or accidentally end up in them as a result of contamination during transport, storage or even during processing. In order to protect the health

of allergic consumers from an accident, several countries follow the allergen labelling requirements of the Codex General Standard for the Labelling of Pre-Packaged Foods (Codex Stan 1–1985 [CXS-001 F]), which imposes provision of the necessary information when allergens are present in food. These countries have introduced into their laws and regulations the obligation to indicate the presence of certain ingredients defined as 'priority allergens' on food packaging labels.

In the United States, the Food Allergen Labelling and Consumer Protection Act was enacted as a law in 2004 (Marchisotto et al. 2017) and requires 'priority allergens' to be identified in clear language on labels, if

they are ingredients in the recipe. These allergens are wheat, egg, milk, peanuts, fish, shellfish, soybeans and nuts. In Canada, allergen labelling regulations came into effect on 4 August 2012. It required a similar mandatory labelling, but it also included sesame, molluscs and mustard in the list (Health Canada 2012). In fact, sesame has to be declared as ingredient in several countries, including those of the European Union and Australia (Gendel 2012). Sesame allergy is a growing public health problem, particularly due to the globalisation of eating habits and the increase in sesame consumption in the Western world, partly because of the current trend towards vegetarian and vegan diets (Mühlenbein and Pfützne 2018). Sesame is mostly eaten in the Middle East as a paste called ‘Tahini’, mixed with ingredients to make traditional Lebanese dishes or as a sweet compound called ‘Halva’. Similarly, sesame paste is also used in several Chinese dishes (noodles, etc.). Most of these preparations have long been present in Europe and the United States because of the ‘internationalisation of meals’ (Della-Torre et al. 2013). At the same time, concerns have emerged about the risk of allergies caused by sesame seeds. These are often reported around the world (Li et al. 2017) and their prevalence is estimated at 0.1–0.2% of the general population (Patel and Bahna 2016). Compared, for example, to those by milk and eggs, common in children, the prevalence of sesame allergy is low, but varies regionally (Li et al. 2017). This is probably due to the different eating habits observed in each country (Patel and Bahna 2016). Sesame allergies in Canada impact about 0.3% of children (0–17 years) and 0.2% of adults (18 years and older) (Clarke et al. 2020). In the United States, estimates were at 0.1–0.2% (Sokol et al. 2020). The Food and Drug Administration (FDA) is currently considering a petition to include sesame in the list of allergens to be on food labels, as is currently required in Europe, Australia/New Zealand and Canada (Warren et al. 2019).

Since 1976, Lebanese food chains and bakeries have gradually opened across Quebec, Canada. Almost 50% of the customers in these shops are Quebecers (Annabel 2017). This has allowed, on the one hand, the expansion of products consumed from Lebanese bakeries throughout Quebec and may have, on the other hand, contributed to the increase of allergic risks associated with sesame because it is an ingredient widely used in Lebanese cuisine. The guidelines for

managing allergens from cross-contact are similar in many countries. These include the declaration of sesame through Precautionary Allergen Labelling if the company has identified a risk of accidental exposure to allergens in the final product despite all preventive measures put in place. In Japan, where PAL is not allowed, and in Switzerland, sesame must be reported when the concentration in food exceeds 10 mg/kg and 1 g/kg respectively (Comit et al. 2013). In other countries, preventive labelling (with a ‘may contain’ mention) is not regulated (Gendel 2012; [EFSA] 2014; Marchisotto et al. 2016). When firms decided to use PAL on product labels, the risk and levels of allergens due to cross-contact are low (Blom et al. 2018). This leads therefore to possible overuse (without prior analysis of contamination during processing) and loses some of its credibility with allergic consumers (Agostoni et al. 2014; DunnGalvin et al. 2015). However, about 8% of consumers indicate having had reactions following ingestion of products with preventive labelling (Allen and Taylor 2018). Also, consumer knowledge of PAL varies considerably (Marchisotto et al. 2017). In recent requirements set by the Government of Canada in 2017, manufacturers were asked to clearly label packaged, processed as well as non-packaged products containing one of the priority allergens (Health Canada 2017). Canadian regulators have decided to reduce the confusion by recommending a single phrase for PAL like ‘may contain [X]’ to be used by manufacturers, rather than the multiple statement forms describing manufacturing conditions, such as ‘manufactured in a facility that uses [X]’, ‘produced on the same line where [X] is used’, etc., because the distinct risk levels encountered in allergic consumers did not correspond to these different references.

To date, no international studies have been conducted on sesame seeds accidentally present in food products that should not contain this allergen because it is not part of the recipes. This study is the first to survey labelled and unlabelled Middle Eastern food products such as canned foods, jams, spices and baked goods for the presence of sesame due to cross-contact. This potential incidental presence of sesame could trigger reactions in consumers allergic to this ingredient. Thus, it becomes clear that the non-compliance with good manufacturing practices (GMP) and the absence of

segregation (separation of different productions and/or material with or without sesame) may lead to its involuntary presence in processed products and a reduction in food choices for allergic consumers (Crevel et al. 2014). Manufacturers and regulators need to adopt a transparent approach based on risk analysis and assessment associated with potential cross-contact that may occur in the production chain.

The present study uses a probabilistic approach to estimate the risk incurred by the Canadian population allergic to sesame when consuming a Lebanese product purchased in Middle Eastern grocery store in the great Montreal area. The quantitative risk assessment model incorporates input variables to predict the risk associated with exposure to residual sesame proteins in food. The three main variables included were: distribution of consumption (consumed quantity of a suspected contaminated product), distribution of contamination (quantity of sesame present in a contaminated product) and threshold distribution (quantity of allergens to which allergic consumers react). The methodology used a second-order Monte Carlo simulation incorporating variability and uncertainty as proposed by Rimbaud et al. (2010), to estimate the potential risks for the targeted population.

Materials and methods

Occurrence data

Sampling

Samples of Middle Eastern products were purchased from supermarkets, bakeries and other retail

outlets in the greater Montreal area (Quebec, Canada) between August and December 2018. Five large bakeries and two major food industries of Lebanese origin were targeted due to the frequency of their sales and the distribution of their products in various regions of Quebec. Samples consisted of various food categories and included unlabelled or labelled oriental products with or without PAL. For unlabelled products, the absence of sesame as ingredients was confirmed on site, during the purchase. Ten types of baked goods (bites [pizza, cheese, and spinach], cake, croissant, 'kaak' (a type of cracker), 'kaak' with milk (similar to brioche), bread, French bread, oriental pastry, 'petit four', 'sfouf') and four types of other products (jam, canned foods [beans, chickpeas, etc.], spices (ground spices), and other cooking ingredients such as semolina, flour, etc.) were selected. The target number of lots was five for bakery products and three for processed foods. A total of 571 samples were analysed at the allergen laboratory of Laval University – Quebec (Table 1).

Preparation and analysis of samples

The first step consisted in ensuring good homogeneity of each sample to be analysed. For food products of 30 g to 250 g, the whole sample was mixed or ground according to the base of its matrix. For samples weighing 250–500 g, half the product was sampled, mixed or ground. For products of more than 500 g, only one quarter was sampled, mixed or ground (Bolin and Lindeberg 2016). Food samples were analysed in duplicates using the RIDASCREEN® FAST Sesame

Table 1. Food product categories analysed.

Type of industries	Category	Unlabelled products	Labelled products with PAL	Labelled products without PAL	Total products per category
Bakeries	Bites	95	0	0	95
	Cake	5	5	10	20
	Croissant	40	10	5	55
	Kaak	15	5	5	25
	Kaak with milk	0	15	15	30
	Bread	0	0	36	36
	French bread	0	15	10	25
	Oriental pastry	20	15	0	35
	Petit four	30	0	3	33
	Sfouf	10	0	0	10
Food Industries	Jam	0	0	12	12
	Canned foods	0	0	42	42
	Spices	0	78	27	105
	Other (semolina, flour, etc.)	0	30	18	48
Total		215	173	183	571

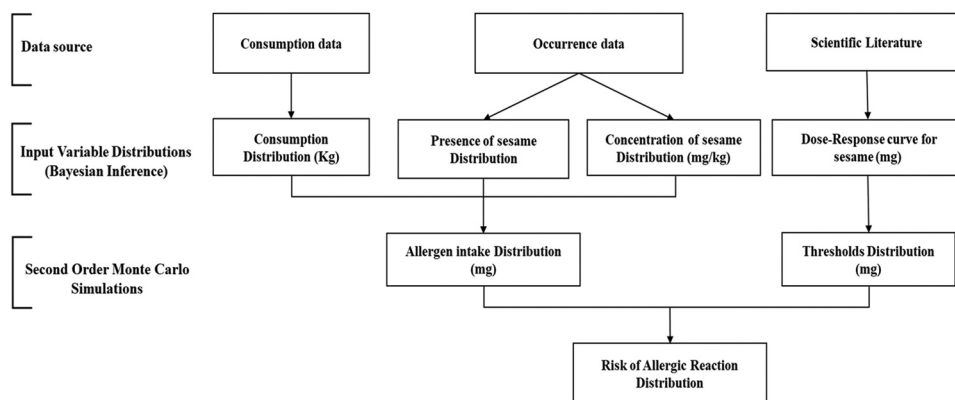


Figure 1. The concept of probabilistic food allergy risk assessment (adapted from Madsen et al. 2013).

enzyme immunoassay (R-Biopharm A.G., Darmstadt, Germany) sandwich-type ELISA method. The limit of detection (LOD) of the kit using reference material available from suppliers is 0.14 mg kg^{-1} sesame and the range of quantification is $2.5\text{--}20 \text{ mg kg}^{-1}$ sesame. The doses obtained were converted from mg kg^{-1} sesame to mg kg^{-1} sesame protein by multiplying the amount of sesame by 0.17 since this is the fraction present on average in sesame seeds (Taylor et al. 2014). Any sample with a concentration of these proteins above the LOQ (0.43 mg kg^{-1}) is considered positive. Sesame was extracted and quantified according to instructions in the manual provided by the ELISA kit. The results were read with a Stat Fax 4200 spectrophotometer from Awareness Technology and the RIDA®SOFT Win software from R-Biopharm was used to determine the concentration of sesame. Standard curves were plotted using the curve fit (cubic spline) recommended by the manufacturer. Samples with concentration greater than the highest point (20 mg kg^{-1}) on the standard curve were diluted to determine the level of sesame.

Method validation

In order to ensure the effectiveness of the ELISA method, its performance evaluation was carried out to verify the method's ability to detect sesame in processed products. To do this, sesame seeds cooked in bread and cookie matrices were directly collected, crushed and mixed with Phosphate-Buffered Saline (PBS) and carboxymethylcellulose (CMC) to obtain a homogeneous solution, with a known concentration of cooked sesame seeds. This solution was directly added (spiked) to sesame-free food matrices, such

as crackers, oriental pastries, or bread, that were similar to those purchased for the study.

Different concentrations of sesame proteins were analysed with the ELISA kit (RIDASCREEN® FAST Sesame). The test kit was able to accurately detect sesame testing material in the form most commonly found in a food matrix.

Probabilistic risk assessment model

The risk assessment model was built using a stochastic approach, as described by Madsen et al. 2013. First, the model estimates consumer exposure. This was calculated from the 'distribution of the consumed quantity' and the 'distribution of the allergen concentrations' in the food product under investigation (Figure 1). The risk is then estimated by combining the 'distribution of allergen exposure' and the relationship giving the probability to trigger an allergic reaction based on this exposure. This model uses a second-order Monte Carlo simulation to separately propagate variability (heterogeneity within the population) and uncertainty (lack of knowledge about the true value) (Pouillot and Delignette-Muller 2010; Rimbaud et al. 2010; Remington et al. 2013).

Distribution of the concentration of allergens found in tested foods

The risk assessment was carried out using R statistical software (version 3.6.2). The 'fitdistrplus' package (Pouillot and Delignette-Muller 2010) was used for exploratory data analysis and to model the distribution of sesame proteins in bakery and industrial food

products. This package provides a dedicated set of functions for fitting univariate parameter distributions to various types of data, including censored ones.

Distribution of the consumed quantity

Data from national food consumption surveys were used in the risk assessment of food allergens. No database specific to the use of resources from consumers with food allergies is currently available. The general hypothesis is that allergic and non-allergic people consume a product at the same rate and that their reasons for non-consumption are likewise retained (Madsen et al. 2013; Remington et al. 2013). If no data is available, a specified serving size can be replaced with the probability that more than one can be consumed (Remington 2013). Thus, for each bakery product, the portion consumed was determined by calculating the average across five bakeries. It was assumed that the number of servings consumed per person followed a Poisson distribution with mean = 3, which allows to calculate consumption per individual in a random and independent manner.

Dose-response relationship

The dose-response curve is defined by the relationship between the intake of a given quantity of sesame proteins and the proportion of allergic people likely to react (Rimbaud et al. 2013).

Table 2. Sesame threshold data from five published studies as reported in Dano et al. 2015.

Study	Total number with objective symptoms	Population	Lowest LOAELS (mg of protein)	Highest LOAELS (mg of protein)
Kanny et al. (1996)	7	6 adults 1 children	30.78	3078
Kolopp-Sarda et al. (1997)	1	Age not reported	1208.7	—
Morisset et al. (2003)	1	Age not reported	5.1	—
Leduc et al. (2006)	12	7 adults 5 children	1.02	1190
Dano et al. (2015)	14	9 adults 5 children	2.55	340
Total	35	22 adults 11 children 2 unknown	1.02	3078

Based on data from literature, the distribution of individual threshold doses from DBPCFC ('double-blind, placebo-controlled food challenge') of 35 individuals allergic to sesame was undertaken and presented in Table 2 (Kanny et al. 1996; Kolopp-Sarda et al. 1997; Morisset et al. 2003; Leduc et al. 2006; Dano et al. 2015). According to Dano et al. (2015), the eliciting dose (ED) to induce an allergic reaction in 5% of a specific population with allergies (ED05) can be estimated on the basis of statistical modelling for sesame proteins. In this study, the ED05 was found to be 1.0 mg of sesame proteins when using the Weibull model. The lower 95% confidence interval of this ED05 (0.1 mg) has been recommended as a sesame reference dose for risk assessment of food allergens.

Exposure and quantification of risk

Exposure is defined by the quantity of allergens, expressed in milligrams, ingested by the consumer while eating a product (Rimbaud et al. 2013). It depends on the distributions of the allergen concentrations, the quantity of food ingested, and the likelihood of the product getting contaminated. The risk, which is the probability that an allergic consumer will react to sesame after eating a serving of food, is obtained by combining exposure with the dose-response relationship. A two-dimensional Monte-Carlo simulation method was used to estimate the risk for 1,000 scenarios, each including 10,000 portions, in order to characterise uncertainty and variability (Birod 2017). In the Remington 2013 study, risk simulation results are presented in three ways: allergic risk per serving, risk per serving for the peanut allergic population, and total risk for the general population. In the proposed model, the allergic risk for the consumer assumes that each individual is allergic to sesame and consumes products packaged or not, with or without preventive labelling.

Results

Occurrence data of sesame in tested foods

The ELISA kit used in this study present recoveries meeting AOAC requirements, between 50 and

150% for the different food matrices that were tested (Data not shown). Regarding the purchased food samples, of the 571 samples analysed, 19% (109/571) were contaminated i.e., to contain sesame (results > LOQ) with levels of sesame proteins varying between 0.5 and 1,875 mg kg⁻¹ and 35% (199/571) contained traces (a value between LOD and LOQ) (Table 3). The 97 of 109 positive samples came from 10 different baked products containing sesame in at least one lot out of five. Of the 571 samples, 215 were unlabelled and 356 were labelled. Of the labelled products without sesame listed as an ingredient, 173 of them had a PAL for sesame and 183 had not. It should be noted that some products were sold in packaging (with and without PAL) and others without packaging, i.e. in bulk at retail, such as 'Croissant' or 'Kaak'.

Unpackaged products were found to be the most contaminated, since 36% of products sampled contained a level of sesame protein between 0.5 and 1,875 mg kg⁻¹ and 49% had traces of sesame protein (between LOD and LOQ). The 'Sfouf' product category, with a recipe similar to 'Cake', had the highest concentration (132–1,875 mg kg⁻¹), with 100% of products found to be contaminated. The 'Bites' came second with 36 contaminated products (0.5–3.3 mg kg⁻¹) out of 95 analysed (37.9% of all). For 'Petit four', 33 samples were subjected to analysis, 3 packaged without PAL and found to be not contaminated (at the level of determination), as well as 30 without packaging, 4 of which had

sesame contamination (0.5–3.2 mg kg⁻¹) and 20 containing traces of sesame. The 'Croissant' presented 40 samples without packaging, of which 16 were contaminated (0.5–10.4 mg kg⁻¹), 10 carried PAL, one of which had contamination (1.2 mg kg⁻¹) and 5 with packaging, without PAL, found to be not contaminated. Likewise, for 'Cake', out of 20 samples analysed, 5 without packaging and 10 packaged products, but without PAL, none was found to be contaminated; and of the 5 with a PAL, only one had contamination (3.1 mg kg⁻¹). For 'Kaak', a type of crackers, out of 15 samples without packaging that were subjected to analysis, 8 were contaminated (0.6–34 mg kg⁻¹), and out of 5 units packed with PAL all had contamination (2.4–74 mg kg⁻¹), as well, for 5 without PAL, only one was contaminated (0.9 mg kg⁻¹). Finally, for 'Oriental pastry', out of 20 samples without packaging, there were 3 contaminated (0.6–10.3 mg kg⁻¹) and out of 15 with PAL, only one had contamination (10.2 mg kg⁻¹).

For packaged products, 16% (27/173) of samples with PAL were contaminated and 3% (5/173) without PAL. For 'Bread', which is a Lebanese bread used in the Middle East, out of 32 samples packed without PAL analysed, 2 were contaminated (1.2–4.5 mg kg⁻¹) and 10 contained traces. For 'Kaak with milk', having a recipe similar to brioche, out of 15 samples with PAL that were subjected to analysis, 6 were found to be contaminated (0.7–20 mg kg⁻¹) and out of 15 without PAL, only one had sesame contamination (0.8 mg kg⁻¹). With

Table 3. Concentration of sesame proteins in labelled and unlabelled products on the Quebec market.

Product category	No.	Labelled Products with PAL(a)			No.	Labelled Products without PAL			No.	Unlabelled Products		
		< LOD(c)	LOD-LOQ	> LOQ(d)		< LOD	LOD-LOQ	> LOQ		< LOD	LOD-LOQ	> LOQ
		< 0.02	[0.02–0.43]	Dose (ppm)		< 0.02	[0.02–0.43]	Dose (ppm)		< 0.02	[0.02–0.43]	Dose (ppm)
Bites	-	-	-	-	-	-	-	-	95	4	55	36 [0.5–3.3]
Sfouf	-	-	-	-	-	-	-	-	10	-	-	10 [132–1875]
Petit Four	-	-	-	-	3	2	1	-	30	6	20	4 [0.5–3.2]
Croissant	10	5	4	1 [1.2]	5	3	2	-	40	3	21	16 [0.5–10.4]
Cake	5	-	4	1 [3.1]	10	8	2	-	5	5	-	-
Kaak	5	-	-	5 [2.4–74]	5	-	4	1 [0.9]	15	3	4	8 [0.6–34]
Kaak with milk	15	-	9	6 [0.7–20]	15	2	12	1 [0.8]	-	-	-	-
French bread	15	6	8	1 [0.98]	10	8	2	-	-	-	-	-
Oriental pastry	15	-	14	1 [10.2]	-	-	-	-	20	11	6	3 [0.6–10.3]
Bread	-	-	-	-	36	24	10	2 [1.2–4.5]	-	-	-	-
Spices	78	59	11	8 [0.7–55]	27	20	6	1 [0.6]	-	-	-	-
Jam	-	-	-	-	12	12	-	-	-	-	-	-
Canned foods	-	-	-	-	42	42	-	-	-	-	-	-
Other	30	25	1	4 [0.7–1.3]	18	15	3	-	-	-	-	-
Total (%)	173	95 (55%)	51 (29%)	27 (16%)	183	136 (74%)	42 (23%)	5 (3%)	215	32 (15%)	106 (49%)	77 (36%)

(a) Precautionary allergen labelling

(b) Number of samples tested

(c) Limit of Detection

(d) Limit of Quantification

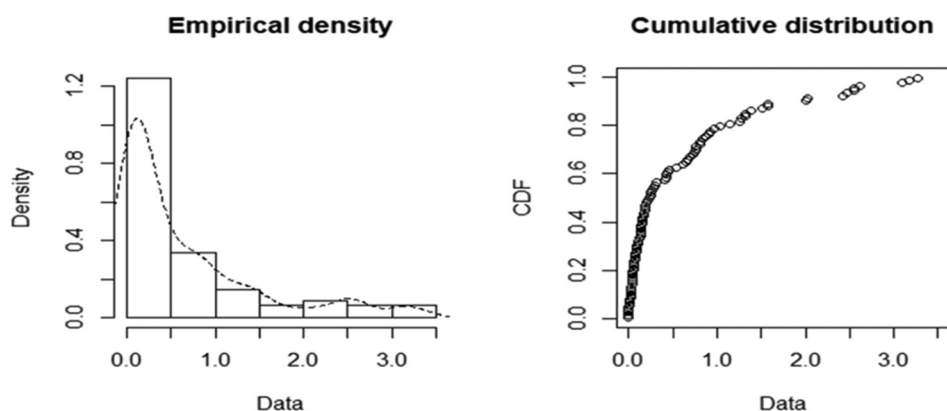


Figure 2. Empirical density and cumulative distribution plots of sesame proteins in observed data from 'Bites'.

regard to 'French bread' (baguette type), 15 samples with PAL are analysed, only one was contaminated (0.98 mg kg^{-1}) and 10 without PAL had no contamination. For processed products such as jam and canned foods, no product was found to have sesame contamination (0/54). While for spices, out of 78 samples with PAL analysed, 8 were found to have significant amounts of sesame ($0.7\text{--}55 \text{ mg kg}^{-1}$) and of the 20 without PAL, only one had contamination (0.6 mg kg^{-1}).

Finally, products designated as 'Various', such as semolina and flour, for 30 samples with PAL analysed, 4 were contaminated ($0.7\text{--}1.3 \text{ mg kg}^{-1}$) while out of 8 without PAL, none was. In total, 45% of samples with PAL contained sesame proteins above the limit of detection ($0.02\text{--}74 \text{ mg kg}^{-1}$), a significantly higher number of products labelled with PAL for these allergens compared to products without PAL (26%, $0.02\text{--}4.5 \text{ mg kg}^{-1}$) ($p < .01$).

Estimation of contamination and consumption

Contaminated samples were retained for risk assessment. Only bakery products were modelled for the distribution of sesame protein data. As an example of distribution fitting for one of these products, empirical density and cumulative distribution of the observed data for 'Bites' from bakeries are shown in Figure 2. It is observed that the distribution of values is not symmetrical. Based on its initial estimation, observed contamination data (concentration of sesame proteins) was fitted to three distributions: the gamma distribution, the Weibull distribution and the log-normal distribution.

The quality of the fit was assessed using classical goodness-of-fit statistics (Chi-squared, Kolmogorov-Smirnov and Anderson-Darling tests) and graphs (empirical and theoretical cumulative distribution functions, P-P and Q-Q plots, obtained using the 'fitdistrplus' package for R) (Pouillot and Delignette-Muller 2010).

As an example, Figure 3 shows the graphical analysis of the fitted distributions (Weibull, gamma and lognormal) to sesame concentration data for 'Bites'. A comparison of empirical CDFs (cumulative distribution functions, black dots) and theoretical (distinct colour for respective distributions) provides an overall picture of the fit.

Based on goodness-of-fit statistics and graphic analysis (Figure 3), Weibull was selected as the most appropriate distribution to describe sesame contamination in 'Bites'. Sesame contamination in other bakery products was modelled following this methodology. Uncertainty on the fitted parameters was obtained by bootstrapping using the 'bootdist' function of the 'fitdistrplus' package (Delignette-Muller and Dutang 2015).

The number of 'Bites' consumed per person was described using a Poisson distribution with mean = 3 and was based on serving size recommended on the packaging. The largest portion consumed was on average 104 g (95% CI 35 g – 210 g) (Table 4).

Dose-response relationship

Figure 4 shows the dose-response curve for sesame proteins constructed using published NOAEL and

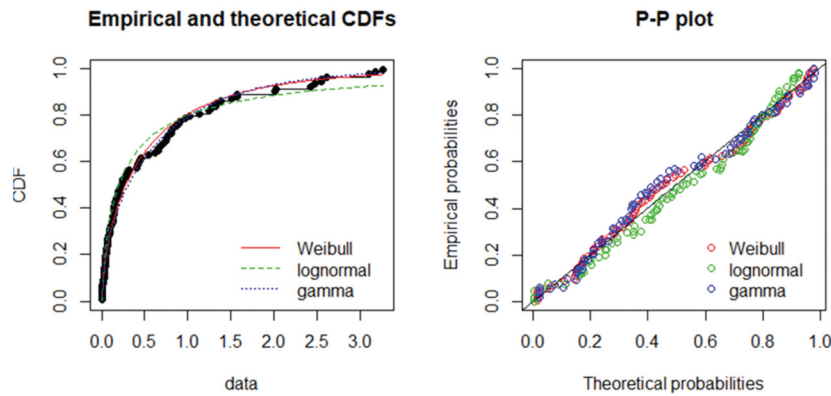


Figure 3. Examples of plots used for evaluation of fitted distributions (Weibull, Gamma and Lognormal) to sesame concentration data for 'Bites'.

LOAEL values and fitted to a Weibull distribution. The estimated ED05 obtained from this model (0.93 mg sesame protein) is in agreement with the value reported by Dano et al. 2015 (1.0 mg sesame protein).

According to this curve, 99% of the population allergic to sesame will not respond to a protein level ≤ 0.05 mg (ED01 = 0.05 mg). Likewise, at least 90% of consumers allergic to sesame will react to a dose equal to 1,500 mg of sesame protein (ED10 = 1,500 mg) and 97.5% to a dose of 3,500 mg (ED02.5 = 3,500 mg).

Table 4. Descriptive statistics of portions consumed (g).

Product category	Mean	2.5% ^(a)	Median	97.5% ^(a)
Bites	104	35	105	210
Cake	136	45	135	270
Croissant	243	80	240	480
Kaak	54	18	54	108
Kaak with milk	194	65	195	390
Bread	107	36	108	216
French bread	228	75	225	450
Oriental pastry	150	50	150	300
Petit four	53	17	51	102

(a) 2.5th and 97.5th percentiles of the distribution

Exposure and quantification of risk

The risk assessment model was constructed as described in Table 5, for each of the products simulated. The average level of exposure for 'Bites' was estimated as 0.08 mg of sesame proteins. On the other hand, the highest average exposure was observed for 'Kaak' with 1.1 mg,

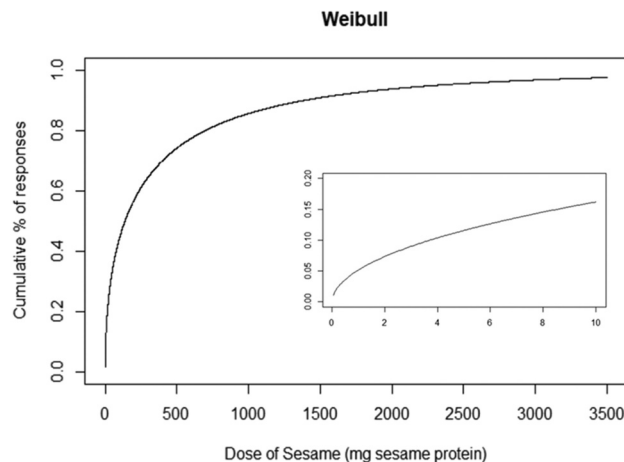


Figure 4. Adjustment for dose-response curve for sesame allergic patients, ranging from 0 mg to 3,500 mg, established from DBPCFC studies: median proportion of allergic individuals who are likely to react to ingested quantities of proteins (in milligrams). The window shows an enlarging of the dose-response curve to the range 0 mg to 10 mg.

Table 5. Risk assessment model for sesame proteins in the product 'Bites'.

Steps	Distribution/ Equation
A Number of 'Bites' consumed	Poisson ($\lambda = 2$) + 1
B Weight of one serving (kg)	0.035
C Quantity of sesame consumed (kg)	$A \times B$
D Sesame proteins per serving (ppm)	Weibull (0.68, 0.48)
E Probability of the product being contaminated	Bernoulli ($p = .38$)
F Exposure to sesame proteins (mg)	$C \times D \times E$
G Dose-response relationship	Weibull (0.52, 279.23)
H Risk (probability of allergic reaction given exposure)	G(F)
I Occurrence of allergic reaction	Bernoulli ($p = G$)

and where 97.5% of the population is exposed to a level below 8.3 mg (Table 6). According to the dose-response curve (Figure 4), this value is sufficient to trigger a reaction in 15% of individuals allergic to sesame. For the other products analysed, the average exposure varied from 0.0003 mg sesame proteins for 'Bread' to 0.5 mg for 'Croissant'.

The risk for the entire Canadian population (Table 7) was extrapolated assuming that individuals allergic to sesame consume these products as

established in the risk assessment model. Thus, the product 'Kaak' was found to induce the highest risk, followed by 'Croissant', 'Bites', 'Kaak with milk', 'Oriental pastry', 'Petit four', 'French bread' and 'Cake', and finally 'Bread'. For example, for 'Kaak', we estimated that, on average, 131 individuals allergic to sesame out of 10,000 would have a reaction when consuming this product (95% CI 33–308).

Discussion

The increasing introduction of sesame seeds or its by-products into the diet, even in small quantities, may have contributed to the increase in prevalence of sesame allergy. Studies have discussed the increased incidence of sesame allergy over the past five decades (Adatia et al. 2017; Li et al. 2017). Therefore, it is essential to protect Canadian consumers exposed to foods containing sesame that is present intentionally or unintentionally. In this context, this study applied a model to quantify the risk due to the accidental presence of sesame allergens in labelled and unlabelled foods. Results showed that products labelled with PAL

Table 6. Mean exposure to sesame (in mg) and uncertainty associated following the consumption of different contaminated products.

Product Category	Exposure = C(a) X D(b)					Exposure = C(a) X D(b) X E(c)				
	Mean	SD(d)	2.5%(e)	Median	97.5%(e)	Mean	SD(d)	2.5%(e)	Median	97.5%(e)
Bites	0.08	0.14	3.00E-04	0.03	0.45	0.02	0.08	0	0	0.22
Cake	0.01	0.04	1.16E-05	0.004	0.08	0.0004	0.01	0	0	0.001
Croissant	0.5	0.48	1.06E-05	0.02	3.16	0.08	0.43	0	0	0.79
Kaak	1.1	1.6	9.20E-05	0.2	8.3	0.24	0.90	0	0.001	2.13
Kaak with milk	0.16	1.1	1.40E-04	0.02	1.1	0.03	0.26	0	0	0.2
Bread	0.003	0.02	3.30E-06	0.0004	0.04	0.0004	0.01	0	0	0.0005
French bread	0.02	0.03	9.50E-06	0.004	0.1	0.001	0.02	0	0	0.002
Oriental pastry	0.18	0.57	3.40E-05	0.006	1.02	0.02	0.35	0	0	0.04
Petit Four	0.02	0.05	1.70E-06	0.003	0.12	0.003	0.08	0	0	0.02

(a) Quantity of sesame consumed (kg)

(b) Sesame proteins per serving (ppm)

(c) Probability Whether the product is contaminated or not

(d) Standard deviation

(e) 2.5th and 97.5th percentiles of the uncertainty distribution

Table 7. Estimated risk (number of sesame-induced allergic reactions per 10,000 individuals) associated with consumption of different bakery products.

Product Category	Risk = DR(a)(Exposure = C(b) X D(c))				Risk = DR(Exposure = C X D X E(d))			
	Mean	2.5%(e)	Median	97.5%(f)	Mean	2.50%	Median	97.50%
Bites	104	22	93	258	40	7	35	102
Cake	33	4	26	99	2	0	1	6
Croissant	164	39	156	370	41	9	37	95
Kaak	232	53	213	500	131	33	119	308
Kaak with milk	136	29	118	336	31	1	28	78
Bread	22	2	18	69	1	0	1	5
French bread	44	4	35	136	2	0	1	13
Oriental pastry	83	14	71	214	11	0	9	29
Petit Four	39	4	33	112	5	0	4	15

(a) Dose-response curve

(b) Quantity of sesame consumed (kg)

(c) Sesame proteins per serving (ppm)

(d) Probability Whether the product is contaminated or not

(e) 2.5th and 97.5th percentiles of the uncertainty distribution

for sesame contain more of the allergen (16%) than those without such labelling (3%). This could be interpreted by the fact that PAL is adequately used on a risk assessment basis rather than simply due to the presence of sesame in the food production environment. As a result, this labelling provides important information for consumers allergic to sesame. On the other hand, as expected, the products without packaging were the most contaminated (36%), with the highest concentration of sesame proteins reported for 'Sfouf'. This product was not subject to an allergen risk assessment due to the small number of samples analysed (10, not allowing for simulations) but its high concentration (132–1,875 mg kg⁻¹) makes it a high risk product even if consumed in small quantities. This high sesame concentration may be explained by the fact that traditions in Lebanon use 'Tahini' in the preparation of cakes and 'Sfoufs', so that they do not adhere to moulds used during their production.

The high concentration of sesame allergens found in baked goods could also be an indicator of insufficient or inadequate cleaning. Indeed, bakeries face several challenges in terms of risk management related to sesame. The same equipment is used to manufacture sesame-based foods as well as products that do not contain it, as it is the case with 'French bread' and 'Kaak', whose seeds are visible to the naked eye. The electrostatic characteristics of sesame make the removal of sesame seeds arduous, which facilitates cross-contact (Koppelman et al. 2015).

Packaged processed products were found to be the least contaminated. No trace of sesame has been detected in canned products and jams (packaged without PAL) made by industries also manufacturing some products containing sesame in their recipes. On the other hand, spices were more frequently contaminated, especially the packaged products with PAL, where concentrations ranging from 0.7 mg kg⁻¹ to 55 mg kg⁻¹ were detected. Industrial preparations, especially for fast food and exotic cuisines, have contributed to the spreading of allergens from spices, which can be described as an emerging allergen in food processing (Gomez-Gomez et al. 2010). These considerations are not taken into account in our study because the information available is limited and allergic reactions due to the consumption of spices containing sesame appear to be rare, although they are probably underestimated (Chen and Bahna 2011).

However, this should not prevent future work that will attempt to assess exposure-response relationships for each type of spice in order to characterise their potential effects on sesame allergic consumers.

Some sources of risk overestimation have to be considered. Exposure was established considering the distributions of the allergen concentrations and the quantity of food ingested. However, the prevalence of products contaminated with sesame must also be taken into account in the risk analysis model since not all the products consumed are contaminated. It is possible that a consumer consumes a product without sesame.

The economic cost of food allergen management is important for the industrial sector (Hefle and Taylor 2004). Industries need to make significant investment to improve allergen control. Cleaning procedures, employee training, design of equipment and premises, and the possibility of recalls due to cross-contact with various allergens were most often seen as major factors requiring great expense in the management of these substances in food (Gupta et al. 2017).

This study was able to show that the majority of baked goods contained sesame proteins even though sesame was not used as an ingredient. These products are becoming part of the diet of an increasingly large and varied clientele internationally. This increases the risk of allergic incidents, knowing that 50% of the customers coming to these bakeries are Quebecers of Middle Eastern descent. The probabilistic risk assessment indicates that these products pose a risk to many people with sesame allergies. For example, our evaluation estimates that 33 to 308 allergic reactions may occur, out of 10 000 individuals ingesting 'Kaak' in Quebec (Table 10). If we consider packaged products alone, we notice that those with PAL are the ones that, as expected, contain the greatest quantity of sesame proteins. The presence of PAL indicates that the food product has potentially been exposed to an allergen, but it is not known whether the amounts are capable of inducing a reaction. Almost half of allergic consumers or their caretakers in Canada believe that these labels are required by law, which is not the case since this precautionary labelling is voluntary. Despite their food allergy, up to 40% of allergic consumers buy food with PAL (Marchisotto et al. 2017).

Labelling is the most important prevention tool to reduce exposure to allergens. However, studies have shown that the current system is insufficient to prevent it (Marra et al. 2017). Seventy-three percent of Canadians said that knowing that risk analysis was used for products bearing such PAL would improve their confidence in a product labelled 'may contain' (DunnGalvin et al. 2019). Quantitative risk assessment aims to provide a standardised approach to determine whether the allergen that may be unintentionally present in a product is above a certain threshold or level of risk. Quantitative risk assessment also provides a flexible tool to inform decisions about labelling, product releases and recalls (Remington et al. 2013).

Conclusion

The percentage of sesame-positive samples in this survey was about 19 per cent, at levels estimated to represent a risk to the health of sesame allergic consumers. This study demonstrates that allergic consumers could experience allergic reactions if they ignore the precautionary allergen statements related to sesame on product labels. This study also demonstrates that some products with no allergen declaration or PAL also contained sufficient undeclared allergen residues to pose a risk to public health. Sesame is a potent allergen, even trace amounts can cause a severe allergic reaction (Dano et al. 2015). As edible seeds have become increasingly popular ingredients in food, the risk of unexpected reactions, often severe hypersensitivity, has also increased (Bianchi et al. 2019). Food industry and regulators must adopt a transparent, risk-based approach for the communication of the risk associated with potential cross-contact that could occur in the processing facility or production chain (Remington et al. 2015). The goal of risk communication is the dissemination of information in a way that presents the food allergic consumer with a clear and simple understanding of the process (Remington 2013). The main form of risk communication between a food producer and an allergic consumer is the product label, in this instance the precautionary labelling for allergens. In order to increase consumer confidence and reduce the

chance of accidental intake of allergens, it is necessary to clarify the requirements of the application of such PAL and improve the education level of consumers. In addition, allergens management must not only be based on general guidelines and descriptions, but a clear explanation is also needed (Fu et al. 2019). The credibility of PAL, and therefore its value as a risk management tool, will only be restored if it communicates a clear and consistent message about risk regarding the amount of allergen present in a food and the resulting risk of an allergic reaction. Additionally, the absence of a PAL should imply a clear and agreed level of safety. Risk assessment can be used to predict the expected number of reactions in foods with or without PAL. This approach can help increase the sense of control and trust, increase effective communication among all stakeholders, and reduce uncertainty. Finally, agreed-upon risk assessment methodologies to be applied by food industry along with added harmonisation of allergen management and labelling regulations across the world will be important both to protect allergic consumers and help support effective trade in the global marketplace.

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Declaration of competing interest

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