

Research article

Allergen management under a voluntary PAL regulatory framework – A survey of Canadian food processors



Silvia Dominguez^{a,*}, Jérémie Théolier^a, Beatrice Povolo^b, Jennifer Gerdtz^b, Samuel Benrejeb Godefroy^a

^a Food Risk Analysis and Regulatory Excellence Platform (PARERA), Institute of Nutrition and Functional Foods and Department of Food Science, Université Laval, Quebec, Quebec, G1V 0A6, Canada

^b Food Allergy Canada, 505 Consumers Drive, Suite 507, Toronto, Ontario, M2J 4A2, Canada

ARTICLE INFO

Keywords:

Food allergen management
Canada
Survey
Food manufacturers
Precautionary allergen labelling

ABSTRACT

Canadian regulations require food business operators (FBOs) to implement preventive controls to manage allergens and ensure their accurate declaration. However, the use of precautionary allergen labelling (PAL) is voluntary and competent authorities provide limited guidance on its use. The objective of this study was to present an overview of Canadian FBOs' current allergen management practices, including the mechanisms used to evaluate the need for PAL in finished products, and to investigate potential areas for improvement. Canadian FBOs were invited to answer an online survey of 48 questions covering allergen management practices and perceptions. Eighty-four full survey responses (margin of error of 9% at a 90% confidence level) were obtained. Differences in responses to multiple choice questions per company size were determined using chi-square and Fisher's exact tests. Kruskal-Wallis tests were used to analyse responses to rating or forced ranking questions. Survey respondents' allergen management practices were based on a combination of recognized best practices, third-party quality systems' standards, and regulatory requirements. Concerning practices related to the criteria used to reach PAL decisions were noted, which could be addressed with increased awareness and use of risk-based approaches and a clearer regulatory policy. Analytical testing applicability and interpretation, access to information on unintentional allergen presence in raw materials, and clarity on the expectations related to the current regulatory framework on food allergens and its enforcement, were identified as challenges faced by Canadian FBOs. The results of this survey and its analysis could be used by regulators – to inform potential policy changes, by FBOs – to map industry practices, and by allergic consumers – to better understand how manufacturers manage allergens in their operations.

1. Introduction

Food allergy affects approximately 6% of Canadians and this number has remained stable during the last decade (Clarke et al., 2020). However, an increasing incidence of anaphylaxis cases at Canadian hospitals was reported at the beginning of the 2010s (Hochstadter et al., 2016), with food as the main cause (Lee et al., 2017; O'Keefe et al., 2017). Although new therapies are under investigation, there is currently no definitive cure for food allergy. For the long-term management of this condition, the primary treatment for patients is strict avoidance of their allergens. As most allergic patients consume pre-packaged foods, accurate allergen information on product labels is essential for the identification of safe food options (Blom et al., 2021). Mandatory declaration of

allergenic ingredients is embedded in the regulatory framework of most industrialized countries, with specific requirements for priority allergens, in accordance with Codex Alimentarius guidelines (Gendel, 2012; Codex Alimentarius Commission, 2020). In Canada, the allergen labelling regulation was amended in 2011 to add this provision (Government of Canada, 2022a,b). In addition to regulatory requirements, Food Business Operators (FBOs) that adhere to third-party quality systems (e.g., GFSI-endorsed systems) must comply with specific allergen management requirements – often an important item in this type of certification.

From the consumers' standpoint, it is expected that FBOs accurately declare the presence of allergens in their products when they are used as ingredients. The difficulty lies in the growing use of Precautionary Allergen Labelling (PAL) since the mid-1990s (Government of Canada,

* Corresponding author.

E-mail address: silvia.dominguez.1@ulaval.ca (S. Dominguez).

<https://doi.org/10.1016/j.heliyon.2022.e11302>

Received 27 June 2022; Received in revised form 4 October 2022; Accepted 24 October 2022

2405-8440/© 2022 The Author(s). Published by Elsevier Ltd. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

2012b). In Canada, PAL is used on a voluntary basis by FBOs and is not covered by a specific legislation. *De facto*, it is outside the jurisdiction of regulatory authorities (Canadian Food Inspection Agency or provincial agencies) as long as it is not in contradiction with Canadian legislation – notably, the requirement under subsection 5(1) of the Food and Drugs Act for information to be “truthful and not misleading” (Government of Canada, 1985). Health Canada has outlined general recommendations for the use of PAL on pre-packaged foods; specifically, PAL should only be used when the presence of allergens in food is unavoidable despite all reasonable measures, and it must not be considered a substitute for Good Manufacturing Practices (Government of Canada, 2012b). Nevertheless, the use of PAL under this type of framework is confusing for allergic consumers, as it does not provide information in terms of risk of presence of unintentional allergens (occurrence and/or quantity) (Holleman et al., 2020). For example, as pointed out by prospective articles (Manny et al., 2021a,b; Touma et al., 2021), in some products with PAL, there is no detectable level of the unintentional allergen (e.g., milk in candies) while others are frequently contaminated at levels that may pose a risk to allergic consumers (e.g., milk in dark chocolate). As a result, some allergic consumers may unnecessarily limit their food choices (i.e., strictly avoiding products with PAL for their allergens) while others take risks that may have serious health consequences (i.e., consuming products with PAL for their allergens). Furthermore, the globalization of the food supply chain introduces a heterogeneity factor; since other countries apply different criteria for the use of PAL, products carrying the same type of label (e.g., “May contain [specific allergen]”) may represent varying levels of risk for allergic consumers (Fiocchi et al., 2021).

In general, the credibility of PAL is at stake and its usefulness as a tool for food allergen management is eroded (DunnGalvin et al., 2015). The management of food allergens and the prevention of food allergy incidents is a shared responsibility among allergic consumers, FBOs and competent authorities. However, the current lack of a regulatory framework for the use of PAL in pre-packaged foods places FBOs at a pivotal point, as they take on the responsibility if reported allergic reactions are linked to consumption of their products. Considering this, the objectives of this article were to investigate the current allergen management practices of Canadian FBOs, including the mechanisms used to evaluate the need for PAL in finished products, and to identify areas where harmonization could improve the use of PAL.

2. Methodology

2.1. Survey design

An online questionnaire was designed by Food Allergy Canada (a food allergic consumer association) with stakeholders' collaboration to determine the Canadian food industry's food allergen management practices. A first version of the survey was pre-tested with a small sample ($n = 5$) of FBOs for relevance and readability purposes. The final version of the survey was composed of 48 questions (Appendix), divided in 6 main sections: (1) use of food allergens; (2) use of PAL; (3) allergen management plan; (4) cleaning/sanitation; (5) allergen thresholds; and (6) demographics. The survey was issued in both French and English, and translations were checked to ensure accuracy. A consent was also obtained individually at the beginning of each survey and was a requirement for continuation.

Food Allergy Canada disseminated the questionnaire to industrial processors across Canada using a snowball strategy. An email, with a brief message explaining the study and a link to the survey using Survey Monkey, was sent to 5 food industry associations. They were asked to distribute the questionnaire to their members, representing more than 1500 FBOs. Reminders were also used to reengage potential respondents. The survey was open from June 10th, 2021 to August 31st, 2021. Anonymized answers were collected by Food Allergy Canada and shared for statistical analysis.

2.2. Data analysis

Statistical analysis was conducted on full survey responses only. Responses were analysed globally, and per company size (Table 1). Differences in responses to multiple choice questions per company size were determined using chi-square and Fisher's exact test (for contingency tables with values < 5). The non-parametric Kruskal-Wallis test, followed by Dunn's test for post-hoc analysis, when applicable, were used to analyse responses to rating (i.e., Likert scales) or forced ranking questions. All statistical analyses were conducted in RStudio (RStudio Team, 2019), R version 3.6.2, and figures were produced using the *ggplot2* (Wickham, 2009) and *likert* (Bryer and Speersneider, 2016) packages.

3. Results

3.1. Margin of error

The total population was estimated to be 6279 FBOs (Government of Canada, 2021) (Table 1). It was assumed that all FBOs in Canada manage allergens. The sample size of 84 full survey responses provides a margin of error of 9% at a 90% confidence level.

3.2. Respondents' characteristics

Most respondents represented food companies that manufacture their own lines of products (64%) and that trade in both the domestic and international markets (68%). The most represented manufacturing sector was “Meat products manufacturing” (29%) (Table 2). Respondents who selected “Other [manufacturing sector]” (32%) were prompted to specify their manufacturing sector; most listed more than one choice. “Spices” processors were mostly (64%) represented among small companies.

3.3. Allergen management in the Canadian food industry

This section's results are first presented as a global summary. Significant differences between large companies with small and/or medium companies are then noted, where applicable. Full responses, as well as the results of all pairwise comparisons, are available upon request.

3.3.1. Priority allergens use

Priority allergens were used as ingredients by 87% of respondents. Large companies (41/43) were more likely ($p = 0.04$) to use allergens than small companies (16/22). Most large companies (66%) used more than 7 and up to 12 different allergens. Most small (63%) and medium (56%) companies used more than 1 and up to 7 different allergens. Overall, soy (86%) and milk (82%) were the allergens most frequently used, and crustaceans/molluscs (18%) the least (Question 2). The same pattern was observed for medium and large companies. Among small companies, mustard (81%) and wheat and triticale (81%) were the most prevalent allergens.

Table 1. Survey characteristics: population, sample size and margin of error.

	Company size			Total
	“Large”	“Medium”	“Small” ²	
Number of employees	≥500	100–499	<100	All sizes
Population size ¹	55	573	5662	6279
Sample size	43	19	22	84
Margin of error (90% confidence level)	6%	21%	18%	9%

¹ Statistics Canada (Government of Canada, 2021).

² Statistics Canada's employment size categories “Micro” (1–4 employees) and “Small” (5–99 employees) are grouped under one single category (<100 employees) in this study.

Table 2. Number of complete survey responses per manufacturing sector and company size.

Manufacturing sector ¹	Company size		
	“Large”	“Medium”	“Small”
Other	16	6	5
Meat product manufacturing	16	4	4
Fruit and vegetable preserving and specialty food manufacturing	10	0	6
Dairy product manufacturing	11	3	1
Bakeries and tortilla manufacturing	12	1	2
Beverage manufacturing	7	4	2
Spices	4	0	9
Animal slaughtering and processing	6	3	2
Grain and oilseed milling	4	2	4
Sugar and confectionery product manufacturing	6	1	2
Seafood product preparation and packaging	6	0	2

¹ Food manufacturing sectors per North American Industry Classification System Version 3.0. “Animal food manufacturing” was excluded; “Spices” was added. The sum (161) is larger than the total number of full responses obtained (84) because respondents could select more than one sector.

Overall, 67% of respondents processed finished products with PAL. Large companies (36/43) were more likely ($p < .01$) to use PAL than small companies (9/22). Soy was the most prevalent PAL allergen (68%), followed by milk (63%), and crustaceans/molluscs (13%), the least prevalent (Question 5). This pattern was maintained for medium and large companies. Small companies reported gluten from sources other than wheat (78%) and mustard (67%) as the most prevalent PAL allergens. Among all respondents who produced finished products with PAL, 73% used only one type of PAL statement, predominantly (84%) “May contain [specific allergen]” (Question 4).

3.3.2. Allergen management

A defined allergen management approach was in place in 92% of the companies surveyed. Federal competent authority guidelines (97%) and third-party quality systems (91%) were identified as the sources most frequently consulted. Globally, the most prevalent approach was to integrate allergen management into other quality programs without having a designated allergen management team (56%), followed by having a dedicated allergen management team formed by selected employees from different departments (35%) (Question 9). Among large companies, “Designated employees are responsible for the specific aspects of allergen management in their work or assigned areas, but there is no designated allergen management team” was the second most common (45%) approach.

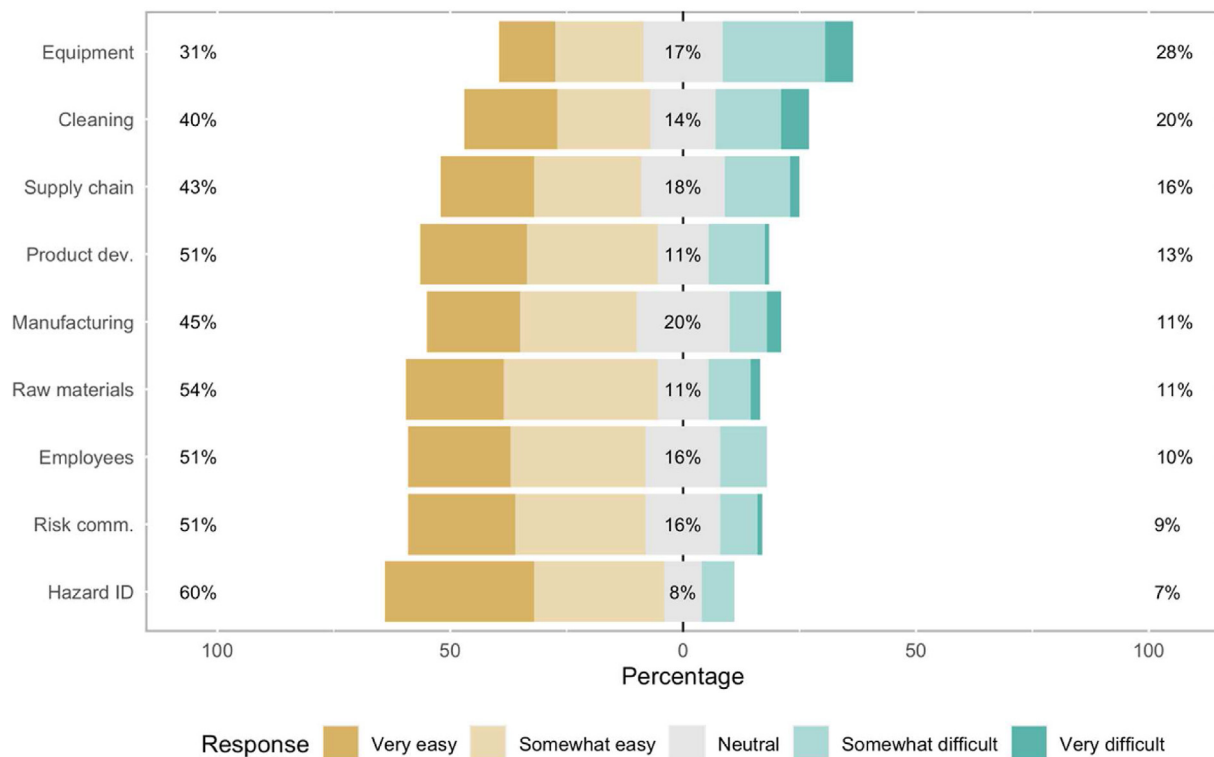
Companies that had a defined allergen management approach ($n = 77$) were asked to identify the elements included, and to rate them with respect to their ease of implementation (Question 10). Overall, “Equipment and factory design” was rated as more difficult to implement than all other elements ($p < .05$), except “Cleaning” and “Supply chain” (Figure 1).

Seven respondents (4 small and 3 large companies) indicated not having an allergen management approach; they all represented companies trading in the domestic or provincial/local markets only. No patterns were identified among the reasons for not having an allergen management approach (Question 14).

Supplier control was included in the allergen management approach of most companies surveyed (96%) and involved different requirements (Figure 2).

According to 74% of respondents who applied supplier controls, their suppliers routinely provided complete allergen ingredient information, including any potential cross-contact information (Figure 3).

Cleaning and/or sanitation procedures addressing allergens were applied by 79% of respondents, predominantly (81%) confirmed using equipment/surfaces specific allergen swabs (Question 23). Equipment/

**Figure 1.** Allergen management elements¹ rated by food processors with respect to their ease of implementation ($n = 77$).

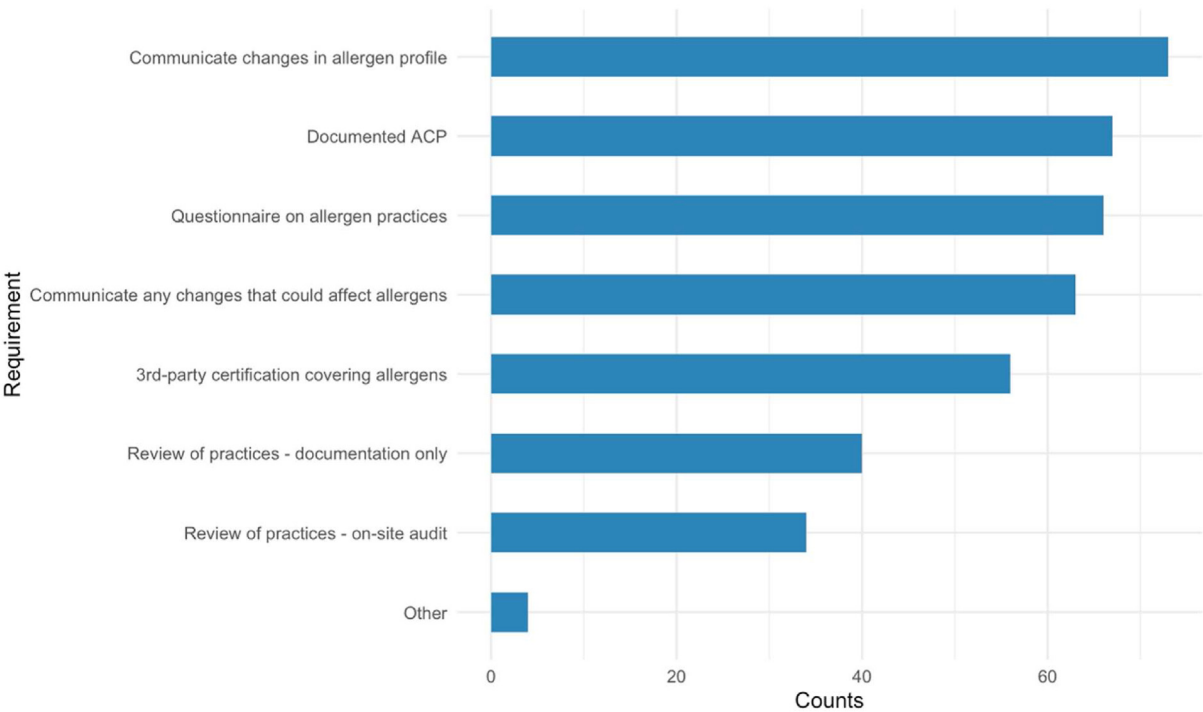


Figure 2. Supplier control requirements¹ (n = 78).

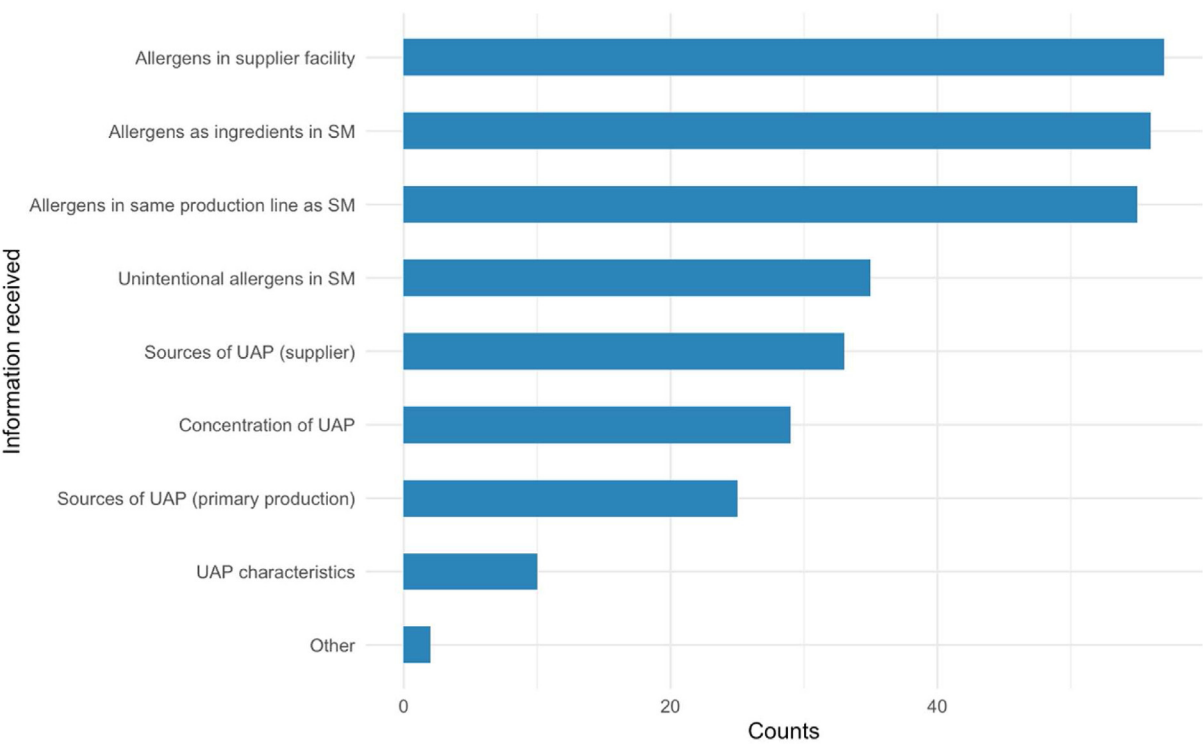


Figure 3. Allergen information routinely received from suppliers^{1,2} (n = 60).

surfaces adenosine triphosphate (ATP) and/or general protein swabs (75%) and visibly clean standards (75%) were the second most common methods for confirming allergen cleaning/sanitation. Overall, 86% of the companies surveyed conducted allergen testing (either in-house or through external laboratories), predominantly for cleaning validation (79%) and verification (67%) (Figure 4).

According to 87% of respondents, the analytical methods used for allergen testing were validated for use in their specific products and processes. A protocol for deciding the appropriate number of samples to analyze for allergen testing was followed by 81% of these respondents. Internal sampling protocols (90%) were more common than standard food sampling protocols (25%).

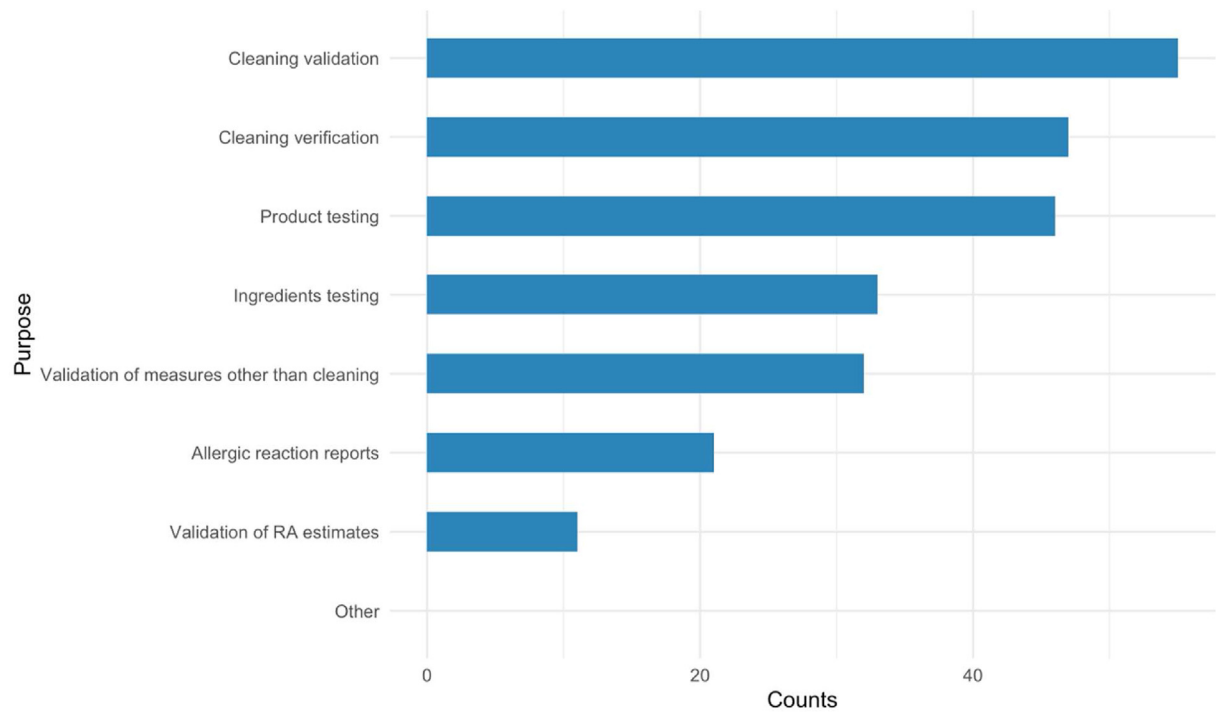


Figure 4. Allergen testing purpose¹ (n = 70).

Among companies who indicated producing finished products with PAL (n = 56), 88% indicated they based the decision to use PAL on a risk assessment process. The different criteria applied to establish the need for PAL are presented in Figure 5.

3.3.3. Allergen thresholds

Allergen thresholds were used as part of the allergen management approach of 48% of all the companies surveyed (n = 39). Globally, thresholds for gluten from sources other than wheat (77%) and for

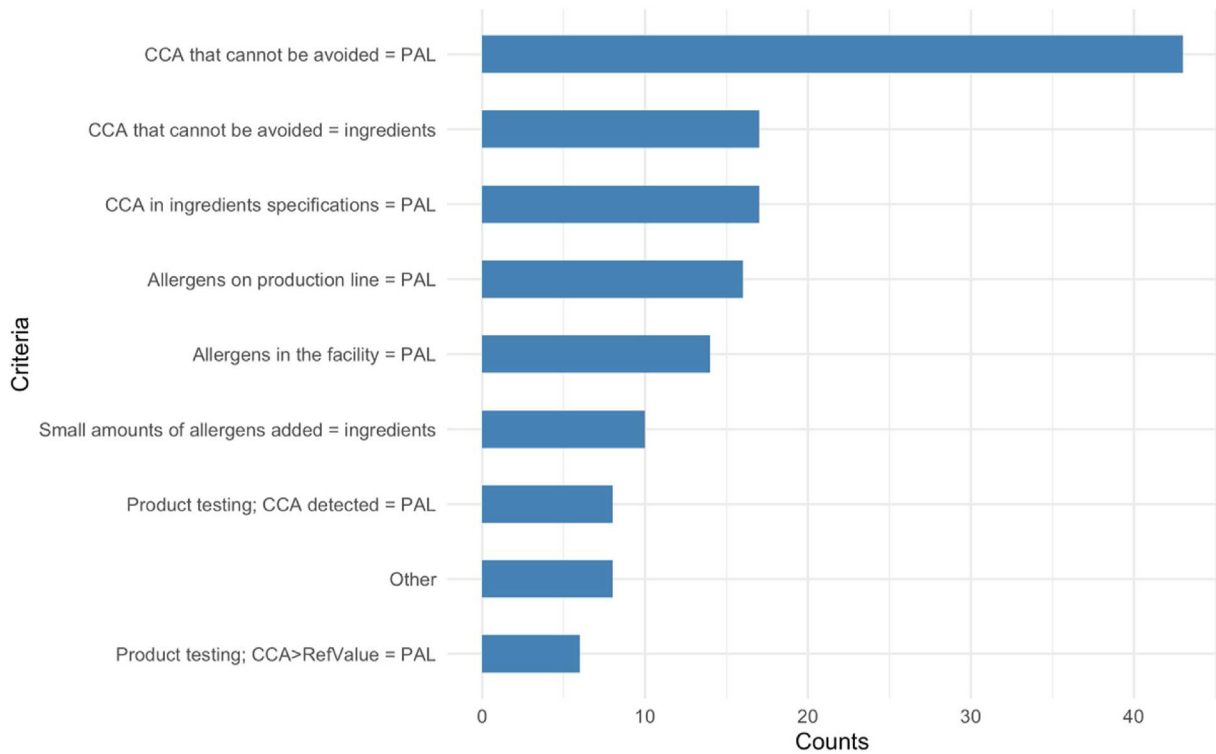


Figure 5. Decision criteria¹ related to the use of PAL in finished products (n = 56).

sulphites (64%) were the most common (Question 31; Figure 6). Among the tools used to quantify allergen levels (Question 35), commercially available allergen tests (e.g., ELISA kits) were the most popular (92%). The Voluntary Incidental Trace Allergen Labelling (VITAL) program was used by 15% of companies who reported using allergen thresholds (Question 35).

Finished product testing was the most frequently (67%) reported context of use of allergen thresholds, when considering all survey respondents (Figure 7). However, large companies were significantly less likely to apply allergen thresholds to finished products testing than small ($p < .01$) and medium ($p = .01$) companies. For large companies, the most common uses of allergen thresholds were cleaning validation/

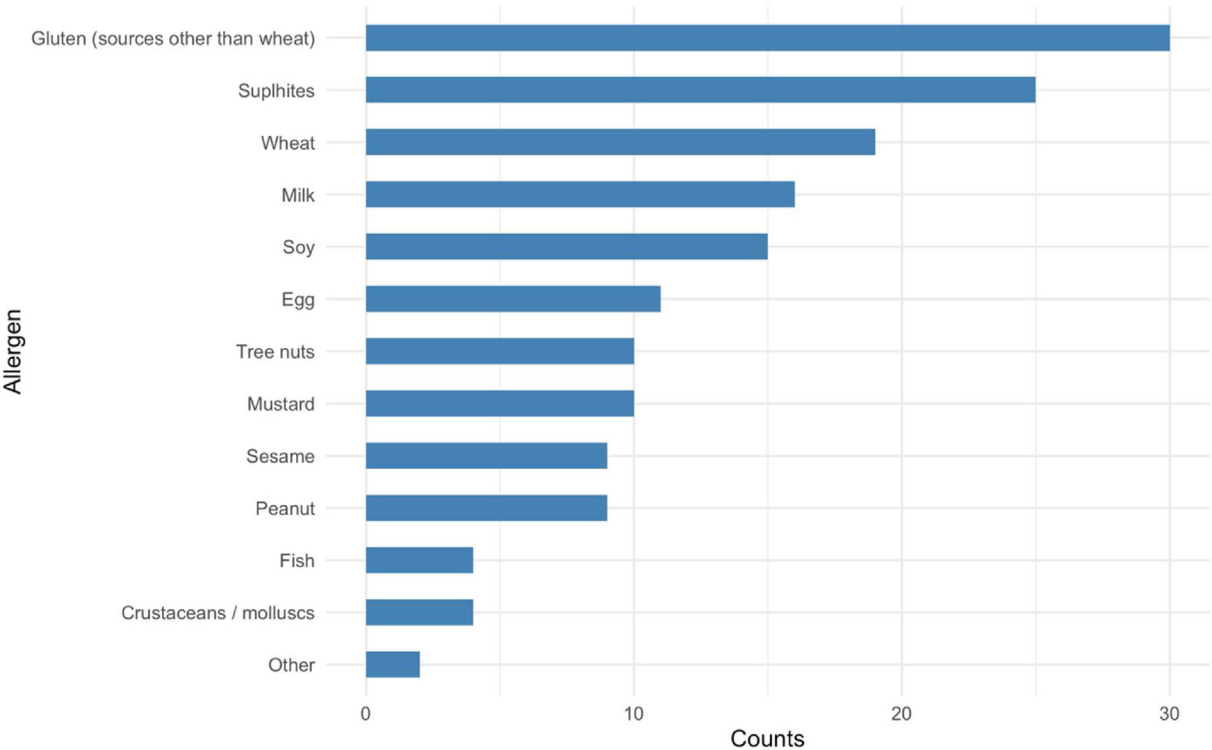


Figure 6. Thresholds used as part of the company's allergen management approach (n = 39).

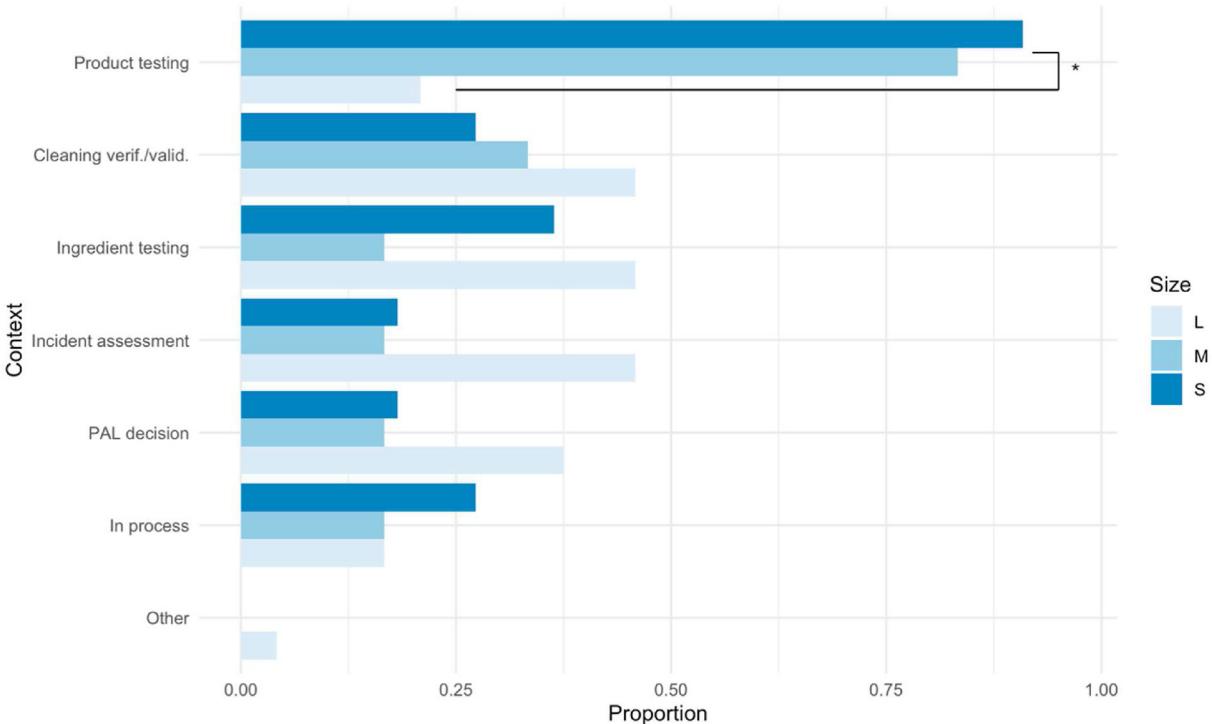


Figure 7. Context of use of allergen thresholds per company size (n = 39)^{1,2}.

verification, ingredient testing, and risk assessment in response to incidents (46% each).

In total, 12 respondents (9 large, 1 medium, and 2 small companies) indicated using allergen thresholds to establish the need for PAL. They were asked to rank seven elements considering the *challenges* their company may face when using these thresholds (Question 34). The element most frequently ranked as “least challenging” was “financial” (46%), and the one most frequently ranked as “most challenging” was “legal liability” (27%). Comparisons per company size were not attempted due to the limited sample size.

Respondents who indicated not using thresholds to establish the need for PAL ($n = 69$) were asked to rank the same elements but consider their level of *concern* (Figure 8). “Legal liability” was the element most frequently ranked as “most concerning” (30%) and “financial” as “least concerning” (29%). Overall, “regulatory” was ranked as more concerning (i.e., more frequently ranked at concern levels 1, 2, 3) than “financial” ($p < .001$). “Financial” was ranked as significantly less concerning (i.e., more frequently ranked at concern levels 5, 6, 7) by large companies than by small companies ($p < .01$).

All surveyed companies were asked whether they thought allergen thresholds are or could be a useful tool when deciding whether to apply PAL (Question 36). Seventy-seven percent of respondents answered “yes” (significant differences are shown in Figure 9).

Almost half of respondents (48%) indicated their current allergen management practices would be modified if government agencies *adopted* allergen thresholds for PAL (Question 38; “no” = 20%; “I don’t know” = 32%). The potential effect of *recommendation* of voluntary allergen thresholds for PAL by industry guidance was unclear; 36% of respondents did not know if their current allergen management practices would be altered under this scenario (Question 39; “yes” = 33%; “no” = 31%).

3.3.4. Regulatory framework

Most survey respondents (92%) were familiar with the Canadian Food Inspection Agency’s (CFIA) guidelines “Preventive controls for food

allergens, gluten and added sulphites” (Government of Canada, 2022b) and found them helpful (88%).

When asked if minimum standards for allergen management should be required for all food manufacturers (Question 15), 94% of survey respondents agreed. Large companies were significantly more likely to agree than small companies ($p = 0.03$).

Out of 15 options listed (Question 40), respondents were asked to select 4 that they thought it would be beneficial for industry if government agencies were to provide or enhance. More than half of respondents (58%) selected “Clarity on government agencies’ expectations related to the current regulatory framework on food allergens and its enforcement” (Figure 10). Small companies’ top choices also included general and sector-specific allergen management guidelines and consumer education on allergen risk management.

4. Discussion

Use of priority allergens as ingredients was widespread among the surveyed companies (87%), and 67% produced finished products with PAL. More than 90% of the surveyed companies had a defined allergen management approach, which included multiple elements (Figure 1) and was developed based on various sources of information (Question 8), suggesting they consider allergen management an important part of their overall food safety programs. Resources developed by federal competent authorities and third-party quality systems were consulted by more than 90% of respondents. The strong presence of third-party quality systems across all company sizes, almost in line with that of regulatory bodies, likely reflects the requirements to operate in a global market, and could be leveraged as a mechanism for harmonization of best practices in allergen management. In addition, enhanced allergen management seems to be a requirement for global trade, as all seven companies who declared not having a clearly defined allergen management approach operated in the provincial or domestic markets only. This also suggests that local competent authorities could further strengthen their industry outreach and surveillance activities related to allergen management.

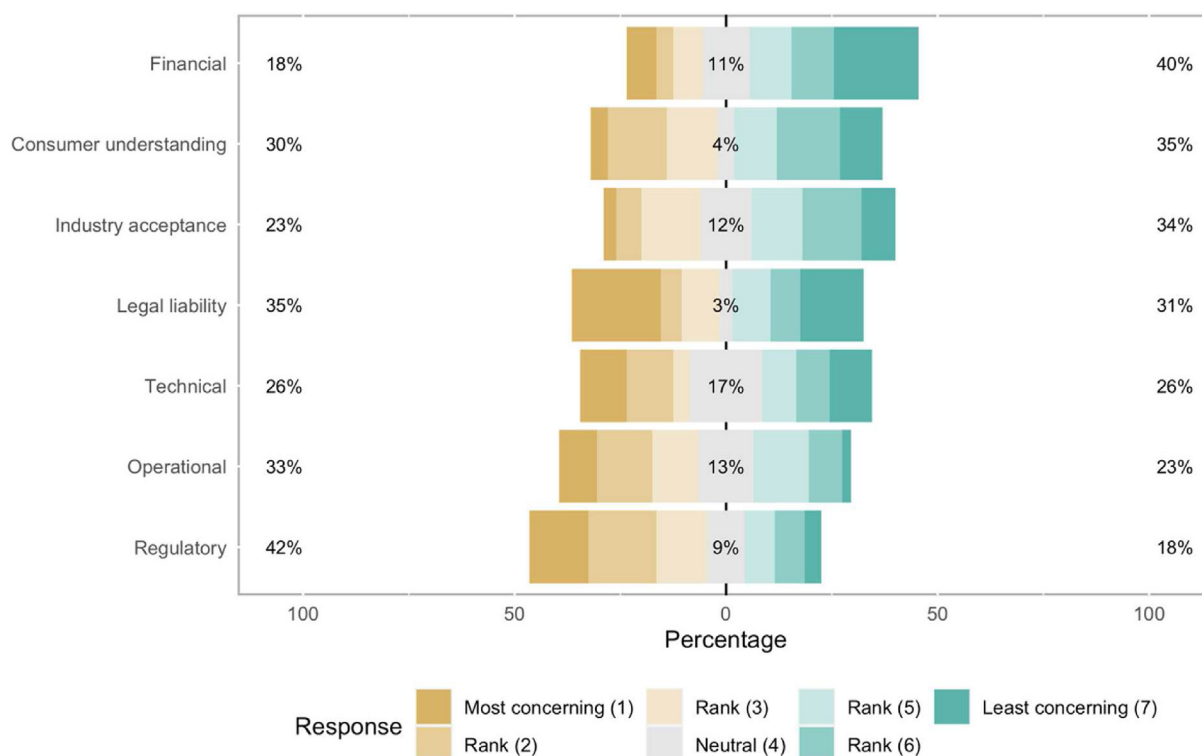


Figure 8. Elements¹ ranked by food processors considering their level of concern regarding the use of allergen thresholds for PAL ($n = 69$).

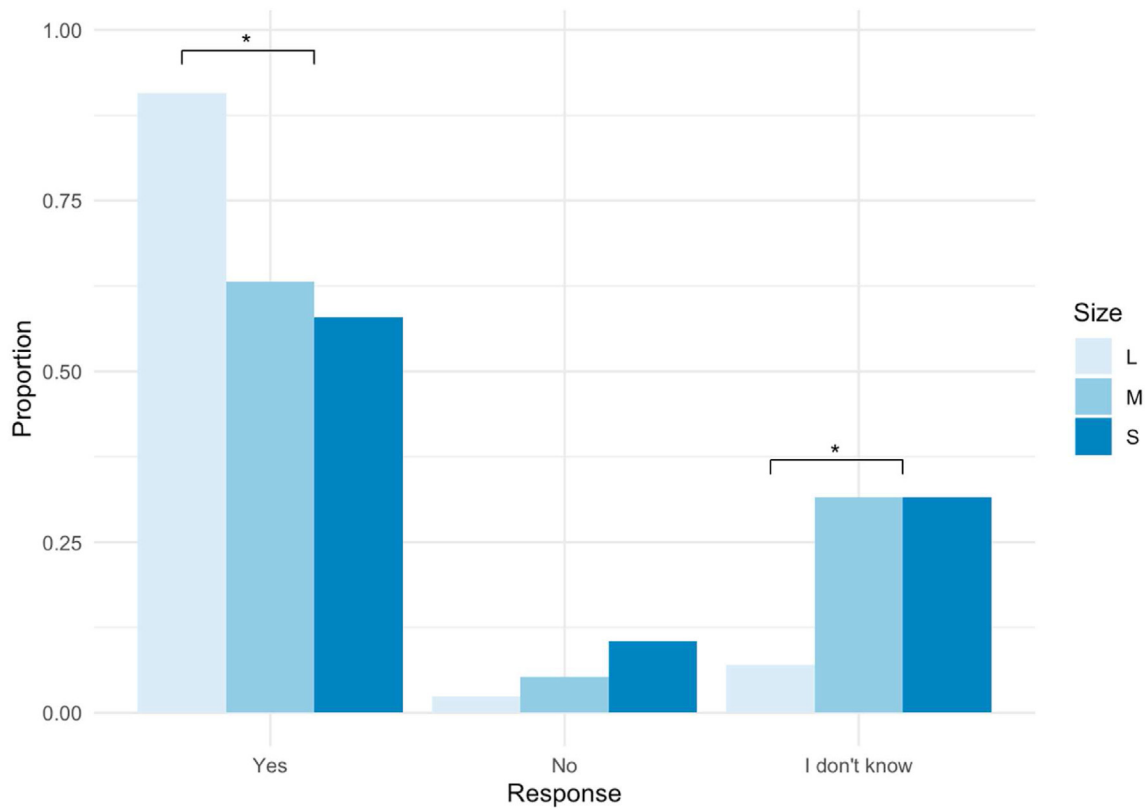


Figure 9. Perception of allergen thresholds as a useful tool when deciding whether to apply PAL (n = 81)^{1,2,3}.

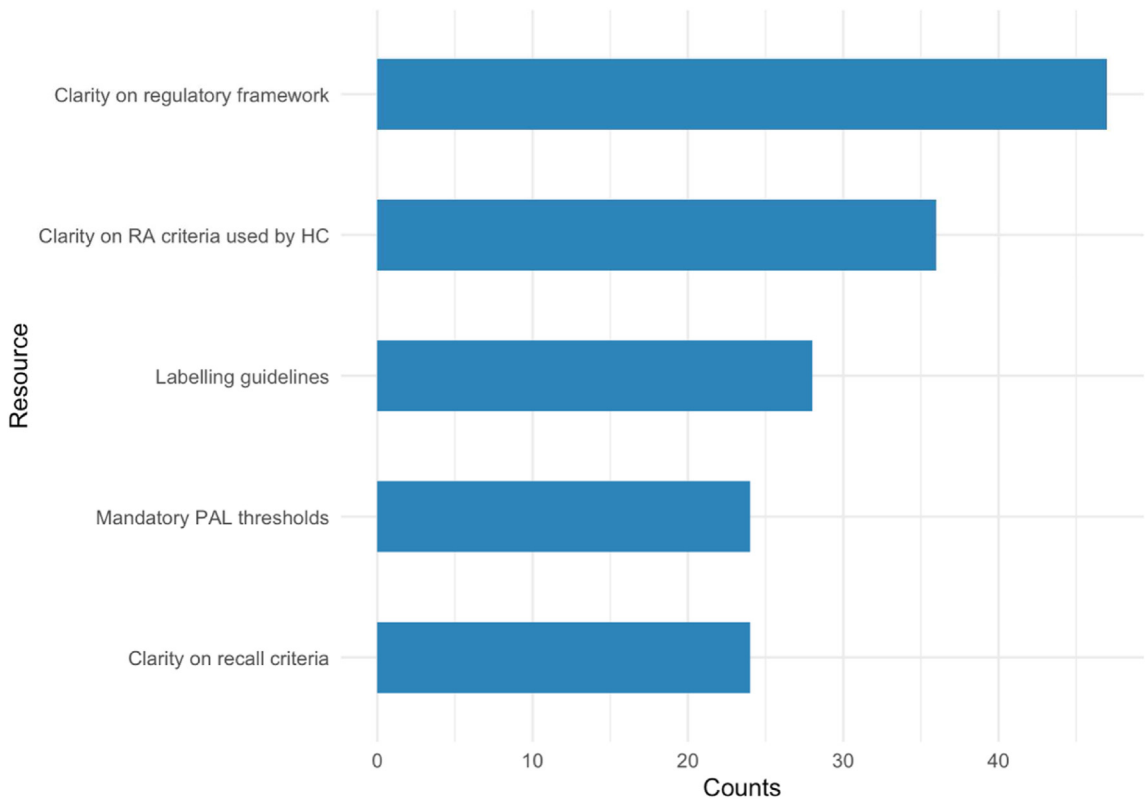


Figure 10. Resources most frequently selected among respondents' top 4 choices as beneficial to industry if government agencies were to provide or enhance (n = 81)^{1,2,3}.

In general, the surveyed companies appear to be familiar with allergen management. Survey respondents rated most allergen control elements predominantly as easy to implement (Figure 1). “Hazard identification and assessment” was rated as the easiest, despite it being one of the most time and resource intensive steps of the development of an allergen control plan (ACP). Indeed, allergen hazard identification requires a cross-functional team reviewing all raw materials and processing steps to identify allergens intentionally/unintentionally added from raw materials, and allergens potentially present from cross-contact during receiving, handling, storage and processing. Respondents may have rated this element as “easy” due to their familiarity with this type of exercise in the context of generic preventive control plans (e.g., HACCP), without being aware of the additional effort an enhanced allergen hazard identification process requires.

There seemed to be no consensus among the surveyed companies regarding the need for a dedicated, cross-functional team responsible for allergen management. According to most respondents (56%), integrating allergen management into other quality programs, without having a dedicated team was the preferred approach. This was clear among large companies, where the second most common approach also implied not having a dedicated team. Indeed, allergen management must be integrated into the facility's quality programs, especially in its operational stage. However, a dedicated team remains essential for overseeing the development of the facility's ACP and its implementation, and for conducting audits, reviews and updates as needed. Furthermore, the CFIA guidelines consider having an allergen prevention team as good practice, especially for larger food businesses (Government of Canada, 2022b). Given the pivotal role of third-party quality systems in the development of the surveyed companies' allergen management approach, it can be inferred that not all these certifications require the establishment of an allergen management team. In this case, they appear as more likely to influence food manufacturing practices than recommendations by competent authorities.

Supplier control is recognized as one of the pillars of food allergen management, and was considered by 96% of the surveyed companies. The most common supplier requirements (Figure 2) were related to communication and indirect verification of supplier practices. Direct verification of supplier practices (i.e., audits) was the least common. Especially for large companies – likely to manage hundreds of suppliers – this may reflect a risk-based approach to supplier auditing, where only suppliers assessed as high risk are subject to audits. Supplier questionnaires are also a valuable tool but, unlike audits, they are limited in scope and do not allow for direct verification of practices (i.e., details of the implementation of control measures). Since most FBOs audit their suppliers as part of other, not allergen-specific quality processes (e.g., approval of new suppliers, renewal of approved supplier status), allergen management aspects could be added to these audits (e.g., issues related to allergen cross-contact within the suppliers' operations, suppliers' management of raw materials with PAL).

Information related to unintentional allergen presence (UAP) in the supplied raw materials appears to be rarely accessible to FBOs (Figure 3). This type of information (e.g., frequency and potential sources of cross-contact, physical characteristics of cross-contact allergens) is necessary when assessing the need for PAL in finished products. Characteristics of UAP originating within the supplier's operation could be collected during supplier audits, for example. However, UAP in raw materials originating earlier in the food supply chain (i.e., agricultural co-mingling) poses challenges to all FBOs (including those supplying ingredients). Accurately establishing if a cross-contact allergen is likely to be present in a specific production of a given commodity (as opposed to listing it by default as “May contain” or equivalent in all specifications) requires assessing factors going as early as primary production. Awareness of crops cultivated in the same or adjacent fields in the preceding season, and of farm practices and/or transport conditions that could introduce cross-contact allergens are examples of relevant information that could guide PAL decisions (Allergen Bureau, 2021). This implies a change in

current practices, as it would require a more thorough information collection effort than what is usually expected from commodity suppliers, with the intent of limiting the prevalence of PAL to instances where UAP cannot be avoided. Since in undeclared allergen incidents, the food manufacturer bears significant legal responsibility, it is in their interest to enhance cross-contact allergen information collection from their raw materials suppliers. For example, if possible agricultural co-mingling is reported by the supplier at a given step, mitigation measures implemented and documented by the supplier to limit UAP should be communicated to the food manufacturer. Yet, even if the UAP source is identified, the probability of occurrence in the supplied material and the expected amount of the unintentional allergen likely to be present are difficult to estimate. In addition, the presence of allergen residues in agricultural commodities requires an assessment to establish the level of risk they may pose (e.g., Remington et al., 2013). Thus, considering the size of agricultural commodity lots and the lack of sampling plans for allergen testing, analytical tools are unlikely to provide meaningful information. These limitations may explain, at least partially, the automatic transfer of raw materials' PAL into finished products – a practice applied by 30% of respondents who produce finished products with PAL (Figure 5). The actual percentage of PAL that is currently applied in Canada based on this practice, however, is unknown. Nevertheless, this approach must be regarded as temporary, and the use of PAL should be reviewed as more information and/or more accurate data, that could be incorporated into a risk assessment process, become available.

Supplier control is crucial for the identification of allergens allowed into a food processing facility. Cleaning, on the other hand, is one of the main strategies for preventing the unintentional transfer of allergens within the facility. It is well-established that cleaning procedures designed for other purposes (e.g., to eliminate microorganisms) may not be effective for removing allergen residues (Jackson et al., 2008). Most respondents seemed aware of this, as 79% indicated having cleaning procedures that addressed allergens, and that were validated as such by testing equipment/surfaces and/or with a visibly clean standard. Finished product testing was also applied at a relatively high ratio (61%). Technically, finished product testing, when based on a representative sampling plan and conducted using fit-for-purpose analytical methods, provides reliable information regarding allergen presence/absence. Nevertheless, in general, an upstream, preventive approach to food safety is preferred. Testing finished products for allergens presents significant challenges. For example, 25% of respondents reported using standard food sampling protocols for deciding the number of samples to analyze when conducting allergen testing. However, contrary to testing for microorganisms, standard sampling plans specifically developed for allergen testing are not available (Yeung and Robert, 2018; Remington et al., 2022a). The majority (90%) of respondents reported using internal sampling protocols, but this survey did not investigate how representative they may be. If indeed robust sampling plans for allergen testing have been developed by food companies, an exchange of information would benefit the industry as a whole. Moreover, 14% of respondents used both standard and internal sampling protocols, showcasing the need for guidance on this matter. Another challenge relates to the analytical methods' ability to detect and quantify allergen proteins in different food matrices. For example, ELISA kits' performance – the most common tool for allergen testing in industrial settings – is influenced by multiple factors (van Hengel, 2007; Török et al., 2015), and needs to be validated for use in every allergen and food matrix. For large companies, with hundreds of different product formulations, this would seem practically impossible. Yet, 87% of respondents indicate using analytical methods validated for use in their specific products and processes, which questions whether survey respondents understand what analytical validation entails. Adding to the confusion, Health Canada proposes a compendium of allergen detection methods, but it is not exhaustive and has not been updated since 2011 (Government of Canada, 2011), and there are no official allergen detection methods used by CFIA. Due to the lack of reference methods for food allergens, technical consultation with the kit

manufacturer and/or the external laboratory conducting the analyses is critical when identifying the most adequate method and establishing validation requirements. Considering the challenges posed by allergen testing of finished products, visibly clean standards, supported by equipment/surface testing when relevant, present an interesting alternative for the validation and verification of cleaning procedures due to their simplicity and reliability. This appears to be the preferred approach among survey respondents (Question 23).

Almost half (48%) of respondents incorporated thresholds in their allergen management approach, predominantly for gluten and sulphites (Figure 6). The latter have thresholds for declaration in prepackaged foods as per Canadian regulations (Government of Canada, 2012a). Thresholds for other allergens for which regulatory provisions do not exist in Canada (i.e., milk, soy) were also common. The actual values used as thresholds or the sources from which these values were obtained were not directly investigated in this survey – but 6/39 companies who use thresholds reported referring to the VITAL program. Also, population thresholds have not been established for all foods considered allergenic, which hinders their use as a risk management and risk assessment tool by food manufacturers (Graham and Fiocchi, 2022). For instance, FBOs may consider a kit's limit of detection or quantification as thresholds, but the validity of this approach would require further investigation. Overall, thresholds were predominantly applied when testing finished products (67%), but this was not the case for large companies (Figure 7). Large companies used thresholds mainly as part of preventive controls (cleaning validation/verification, ingredients testing) and incident management, suggesting they apply a risk-based approach to allergen management, aiming at limiting UAP. Enhanced FBOs' awareness of analytical considerations (e.g., interpretation of results, applicability of a given test to a given product/allergen combination, repeatability of results, representativity of samples) seems necessary, especially for small and medium manufacturers.

Few respondents (12/84) used thresholds to establish the need for PAL. In recent years, due to the eroded credibility of PAL as a risk communication tool, various stakeholders and experts have proposed regulation of PAL based on reference doses (e.g., Allen et al., 2014; DunnGalvin et al., 2015; Yeung and Robert, 2018; Madsen et al., 2020; FAO/WHO, 2021). Only a few countries (e.g., Japan, Switzerland) have adopted this approach so far. However, with more data available on individual allergen thresholds and population dose-response curves (e.g., Houben et al., 2020), along with clearer guidance on allergen risk assessment (e.g., Food Allergy Canada & Université Laval, 2022; Remington et al., 2022b), the way FBOs and competent authorities manage PAL is expected to change. When questioned about the use of allergen thresholds for PAL, respondents ranked legal liability and regulatory aspects as more concerning/challenging than other elements (Questions 34 and 37; Figure 8). These concerns align with the nature of the voluntary PAL framework in Canada, which does not consider PAL thresholds. Furthermore, it is recommended to use PAL only when there is a real risk of allergen presence (Government of Canada, 2012b); however, guidance on how to conduct an allergen risk assessment and what its outcomes would mean from a regulatory standpoint are not provided, making it difficult for FBOs to manage this responsibility. Financial aspects did not seem to pose challenges to FBOs (Figure 8), particularly among large companies. Interestingly, large companies were more likely ($p < 0.01$) to produce finished products with PAL than small companies. The increased use of PAL by large companies may be simply associated with their wider use of allergenic ingredients. Yet, considering previous studies reporting high prevalence of products with PAL but without detection of the PAL allergens (Manny et al., 2021a; Manny et al., 2021b) a potential overuse (e.g., driven by legal concerns) cannot be discarded.

Issues related to the technical implementation of allergen thresholds to establish the need or not for PAL, and the costs related to this process, are not expected to hinder a hypothetical application of regulatory thresholds for PAL in Canada. Survey respondents clearly perceived

thresholds as a useful tool for PAL (78%), and this was significantly more pronounced among large companies (Figure 9). Negative responses were limited, demonstrating an overall openness towards this tool. Again, the limited use of thresholds for PAL recorded in this survey reflects the current regulatory environment. Health Canada (Government of Canada, 2012b) indicates that the use of PAL “where there is no real risk of an allergen being present in the food is contrary to the Department's goal of enabling a variety of safe and nutritious food choices for the allergic consumer”. This guidance focuses on risk of *presence* of unintentional allergens, and does not refer to exposure dose or the risk of the UAP leading to an allergic reaction. Thus, Canadian FBOs applying a quantitative risk-based approach to PAL (i.e., estimating whether an unintentional allergen potentially present in a food may lead to an allergic reaction, based on reported eliciting doses) are not legally protected. If enforcement bodies, as part of their surveillance activities, analytically detect an allergen in a prepackaged food with no declaration of this allergen in the ingredients list or in PAL, they will be subject to investigation and potentially recall, regardless of the amount of allergen present. In this context, FBOs are more likely to apply approaches other than thresholds as decision criteria for the use of PAL, as shown in Figure 5.

The lack of standardized criteria for PAL results in FBOs applying a variety of approaches (Figure 5), some of which are concerning. Notably, the second most common one (i.e., “cross-contact allergens that cannot be avoided with cleaning and production scheduling are declared in the ingredients list even though they are not intentionally added into the product's recipe”), used by 30% of respondents, may attempt to compensate for deficient allergen management practices (e.g., those leading to very high UAP in finished products). Alternatively, it may reflect a lack of clarity on how regulations are enforced (e.g., there are no maximum limits for unintentional allergen concentration in finished products with PAL), and a need for enhanced education on regulatory requirements. Also, this approach does not comply with current regulations on food labelling and could qualify as fraud under Canadian food labelling laws. Some FBOs (18%), perhaps to circumvent this potential legal implication, indicated that “Small amounts of allergenic ingredients are intentionally added into the product's recipe and are therefore declared in the ingredients list, eliminating the need for PAL”. By doing so, they are legally protected from potential undeclared allergen recalls, but they are in direct contradiction with Health Canada's “goal of enabling a variety of safe and nutritious food choices for the allergic consumer” (Government of Canada, 2012b). These responses highlight how, potentially motivated by legal liability concerns, FBOs can resort to questionable practices, generating new regulatory deviations and unnecessarily limiting food choices to allergic consumers. The prevalence of other, not risk-based, decision criteria for PAL (Figure 5), such as automatically declaring in PAL all allergens used in the facility or in the same production line, suggests that, although 88% of respondents indicated applying PAL based on risk assessment, this may not always be the case. Furthermore, it is difficult to establish what manufacturers refer to as “risk assessment”, specifically in terms of structure, scope, and depth. This situation could be improved by enhancing allergen risk assessment awareness and training and/or by establishing regulatory requirements.

In agreement with Health Canada's recommendation (Government of Canada, 2012b), most (84%) respondents who applied only one PAL statement to their finished products used exclusively “May contain”. Nevertheless, the prevalence of FBOs using more than one type of PAL (27% of PAL users), including statements such as “May contain traces of [specific allergen]” or “Produced in a facility that also processes [specific allergen]”, suggests the need for enhanced standardization efforts by government agencies, potentially beyond recommendation. Notably, studies have shown that allergic consumers may attribute different levels of risk to different PAL statements (Hefle et al., 2007; Marchisotto et al., 2017; DunnGalvin et al., 2019; Gupta et al., 2021), a misconception that could lead to risky consumption habits.

In general, this survey's results suggest that Canadian FBOs, especially large companies, may be adequately equipped for and favorable towards

operating in a regulated PAL environment, potentially including thresholds. They have experience in this type of setting (i.e., gluten, sulphites) and, overall, seem to have a strong food allergen management awareness. However, the current scenario (i.e., absence of clear PAL regulatory requirements) does not appear as the most suitable option, since FBOs do not follow a standardized approach for PAL that prevents consumer choices from being unnecessarily limited. Incorporating risk assessment in PAL decisions, with or without thresholds, would be a logical first step towards enhanced PAL regulation. In this respect, enforcement rather than recommendation would have a more significant impact, based on observations on the use of PAL statements (27% non-compliance with recommendations) and the uncertain effect of thresholds recommendation versus adoption. Moreover, 94% of survey respondents thought that minimum standards for allergen management should be required for all food manufacturers, and mandatory PAL thresholds were among the top 4 resources survey respondents thought government agencies could provide or enhance (Figure 10). In addition, more than half of respondents indicated the current regulatory framework was not fully understood (Figure 10). Core items such as the expectations for FBOs under current regulations and its enforcement, risk assessment and recall criteria applied by government agencies, as well as labelling, were brought up by survey respondents as requiring further clarification. Together with enhanced education on existing regulatory requirements, these issues could be directly or indirectly addressed through a clearer PAL policy. For example, the requirement to apply PAL only when a well-defined and documented risk assessment process indicates that UAP cannot be consistently avoided and that, if present in the finished product, it may pose a risk to allergic consumers, could be envisioned. For such policy to succeed, guidance from competent authorities on what would be considered an acceptable allergen risk assessment (including details on how to conduct an exposure assessment), and how they would interpret its results (e.g., during surveillance, inspection, or investigation activities), would be instrumental. In addition, the upcoming full report from the Ad hoc Joint FAO/WHO Expert Consultations on Risk Assessment of Food Allergens, which is expected to include a quantitative and risk assessment basis for the use of PAL, will be essential for the improvement and harmonization of PAL practices globally – if approved by Codex.

Finally, although this study provides a good overall representation of Canadian FBOs, it is mostly reflective of large manufacturers' experiences. Small and medium manufacturers' practices and perceptions should be further investigated, and this would require a different strategy to reach a larger sample size. Nonetheless, important issues about this manufacturers group, which could be addressed by industry organizations or government agencies, were highlighted in this study (i.e., allergen risk assessment and management awareness, guidance on the use and interpretation of analytical methods, clarity on regulatory expectations).

5. Conclusions

Overall, survey respondents self-report strong allergen management awareness and practices. However, challenges related to the use of PAL were noted. A variety of criteria for the use of PAL, including concerning approaches (e.g., declaring cross-contact allergens as ingredients, intentionally adding small amounts of allergenic ingredients to avoid PAL), highlight the need for standardization and risk assessment awareness. Thresholds for PAL were regarded as useful, but their limited application may be linked to legal and regulatory concerns. The current allergen regulatory framework was not fully understood, particularly aspects related to its enforcement, and the risk assessment criteria applied by government agencies. Also, access to information on cross-contact allergens potentially present in raw materials appears to be limited and calls for a change in current practices, especially for agricultural commodities. Finally, the specific practices and concerns of small and medium manufacturers may differ from those of large manufacturers (highly represented in this survey) and should be further investigated.

Declarations

Author contribution statement

Silvia Dominguez: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Jérémie Théolier: Analyzed and interpreted the data; Wrote the paper.

Beatrice Povolo: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data.

Jennifer Gerds; Samuel Benrejeb Godefroy: Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data.

Funding statement

Samuel Benrejeb Godefroy was supported by AgriAssurance Program [CAP-AAPN-053].

Data availability statement

Data will be made available on request.

Declaration of interests statement

The authors declare the following conflict of interests: Samuel Benrejeb Godefroy's research activities are funded by the Ministry of Agriculture, Fisheries and Food, Government of Quebec; the Ministry of Science, Technology, and Innovation, Government of Quebec; Canada's Innovation Foundation; the U.S. Department of Agriculture Foreign Agriculture Service; R-Biopharm GmbH; and R-Biopharm Canada Inc. Samuel Benrejeb Godefroy acts as an expert advisor for members of the food and beverage industry, international organizations (the Food and Agriculture Organization of the United Nations, the United Nations Industrial Development Organization, and the World Bank), and international food regulators such as the China National Centre for Food Safety Risk Assessment and consumer organizations such as Food Allergy Canada. Samuel Benrejeb Godefroy is the Board President of the Global Food Regulatory Science Society (GFORSS).

Jennifer Gerds is the Executive Director of Food Allergy Canada whose organization receives funding from the National Peanut Board to support educational programming.

Additional information

Supplementary content related to this article has been published online at <https://doi.org/10.1016/j.heliyon.2022.e11302>.

Acknowledgements

The authors would like to thank the food manufacturers and members of industry associations who helped draft and review the questionnaire, and those who participated and provided feedback during the validation of the preliminary version. The authors would also like to thank Dr. Sébastien La Vieille, member of the Food Risk Analysis and Regulatory Excellence Platform (PARERA) at Université Laval, for critically reviewing the manuscript before its initial submission.

References

- Allergen Bureau, 2021. Unexpected Allergens in Food – Revised & Updated. <https://allergenbureau.net/wp-content/uploads/2021/08/Unexpected-Allergens-in-Food-Aug-2021.pdf>. Accessed 22 June, 2022.
- Allen, K.J., Turner, P.J., Pawankar, R., Taylor, S., Sicherer, S., Lack, G., Rosario, N., Ebisawa, M., Wong, G., Mills, E.N.C., Beyer, K., Fiocchi, A., Sampson, H.A., 2014.

- Precautionary labelling of foods for allergen content: are we ready for a global framework? *World Allergy Org. J.* 7, 1–14.
- Blom, W.M., van Dijk, L.M., Michelsen-Huisman, A., Houben, G.F., Knulst, A.C., Linders, Y.F.M., Verhoeckx, K.C.M., Holleman, B.C., Lentz, L.R., 2021. Allergen labelling: current practice and improvement from a communication perspective. *Clin. Exp. Allergy* 51 (4), 574–584.
- Bryer, J., Speerschnieder, K., 2016. Likert: Analysis and Visualization Likert Items. R Package version 1.3.5. <https://CRAN.R-project.org/package=likert>.
- Clarke, A.E., Elliott, S.J., St. Pierre, Y., Soller, L., La Vieille, S., Ben-Shoshan, M., 2020. Temporal trends in prevalence of food allergy in Canada. *J. Allergy Clin. Immunol. Pract.* 8 (4), 1428–1430.
- Codex Alimentarius Commission, 2020. Code of Practice on Food Allergen Management for Food Business Operators – CXC 80-2020.
- DunnGalvin, A., Chan, C.H., Crevel, R., Grimshaw, K., Poms, R., Schnadt, S., Taylor, S.L., Turner, P., Allen, K.J., Austin, M., Baka, A., Baumert, J.L., Baumgartner, S., Beyer, K., Buchhini, L., Fernandez-Rivas, M., Grinter, K., Houben, G.F., Hourihane, J., Kenna, F., Kruizinga, A.G., Lack, G., Madsen, C.B., Mills, E.N.C., Papadopoulos, N.G., Alldrick, A., Regent, L., Sherlock, R., Wal, J.-M., Roberts, G., 2015. Precautionary allergen labelling: perspectives from key stakeholder groups. *Allergy* 70, 1039–1051.
- DunnGalvin, A., Roberts, G., Regent, L., Austin, M., Kenna, F., Schnadt, S., Sanchez-Sanz, A., Hernandez, P., Hjorth, B., Fernandez-Rivas, M., Taylor, S., Baumert, J., Sheikh, A., Astley, S., Crevel, R., Mills, C., 2019. Understanding how consumers with food allergies make decisions based on precautionary labelling. *Clin. Exp. Allergy* 49 (11), 1446–1454.
- FAO/WHO, 2021. Ad Hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens. Part 3: Review and Establish Precautionary Labelling in Foods of the Priority Allergens. <https://www.who.int/news-room/events/detail/2021/10/18/default-calendar/ad-hoc-joint-fao-who-expert-consultation-on-risk-assessment-of-food-allergens-part-3-review-and-establish-precautionary-labelling-in-foods-of-the-priority-allergens>. Accessed 22 June, 2022.
- Fiocchi, A., Rizzo, D., DunnGalvin, A., González Díaz, S.N., Monaci, L., Fierro, V., Ansotegui, I.J., 2021. Food labeling issues for severe food allergic patients. *World Allergy Organization Journal* 14 (10), 100598.
- Food Allergy Canada & Université Laval, 2022. Allergen Management Guidelines for Food Manufacturers. https://parera.ulaval.ca/fileadmin/Fichiers/Formation_FAC/FAC_ManufacturersGuide_EN.pdf. Accessed 05 October, 2022.
- Gendel, S.M., 2012. Comparison of international food allergen labeling regulations. *Regul. Toxicol. Pharmacol.* 63 (2), 279–285.
- Government of Canada, 1985. Food and Drugs Act. <https://laws-lois.justice.gc.ca/PDF/F-27.pdf>. Accessed 22 June, 2022.
- Government of Canada, 2011. Allergen detection methods - the compendium of food allergen methodologies. <https://www.canada.ca/en/health-canada/services/food-nutrition/research-programs-analytical-methods/analytical-methods/allergen-detection-methods-compendium-food-allergen-methodologies.html>. Accessed 22 June, 2022.
- Government of Canada, 2012a. Health Canada's Position on Gluten-free Claims. <https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-allergies-intolerances/celiac-disease/health-canada-position-gluten-free-claims.html>. Accessed 22 June, 2022.
- Government of Canada, 2012b. The use of food allergen precautionary statements on prepackaged foods. <https://www.canada.ca/en/health-canada/services/food-nutrition/food-labelling/allergen-labelling/use-food-allergen-precautionary-statements-prepackaged-foods.html>. Accessed 22 June, 2022.
- Government of Canada, 2021. Businesses – Canadian industry statistics. <https://www.ic.gc.ca/app/scr/app/cis/businesses-entreprises/311>. Accessed 22 June, 2022.
- Government of Canada, 2022a. Food Allergen Labelling. <https://www.canada.ca/en/health-canada/services/food-nutrition/food-labelling/allergen-labelling.html>. Accessed 22 June, 2022.
- Government of Canada, 2022b. Preventive Controls for Food Allergens, Gluten and Added Sulphites. <https://inspection.canada.ca/preventive-controls/food-allergens-gluten-and-added-sulphites/eng/1517924742613/1528203218321>. Accessed 22 June, 2022.
- Graham, F., Fiocchi, A., 2022. The importance of threshold dose-distribution data for priority allergens and the need for future studies. *Allergy* 10 (77), 2886–2887.
- Gupta, R., Kanaley, M., Negris, O., Roach, A., Bilaver, L., 2021. Understanding precautionary allergen labeling (PAL) preferences among food allergy stakeholders. *J. Allergy Clin. Immunol. Pract.* 9 (1), 254–264.e1.
- Hefle, S.L., Furlong, T.J., Niemann, L., Lemon-Mule, H., Sicherer, S., Taylor, S.L., 2007. Consumer attitudes and risks associated with packaged foods having advisory labeling regarding the presence of peanuts. *J. Allergy Clin. Immunol.* 120 (1), 171–176.
- Hochstadter, E., Clarke, A., De Schyver, S., LaVieille, S., Alizadehfar, R., Joseph, L., Ben-Shoshan, M., 2016. Increasing visits for anaphylaxis and the benefits of early epinephrine administration: a 4-year study at a pediatric emergency department in Montreal, Canada. *J. Allergy Clin. Immunol.* 137 (6), 1888–1890.
- Holleman, B.C., van Os-Medendorp, H., van den Bergh, H., van Dijk, L.M., Linders, Y.F.M., Blom, W.M., Verhoeckx, K.C.M., Michelsen-Huisman, A., Houben, G.F., Knulst, A.C., Lentz, L.R., 2020. Poor understanding of allergen labelling by allergic and non-allergic consumers. *Clin. Exp. Allergy* 51, 1374–1382.
- Houben, G.F., Baumert, J.L., Blom, W.M., Kruizinga, A.G., Meima, M.Y., Remington, B.C., Wheeler, M.W., Westerhout, J., Taylor, S.L., 2020. Full range of population Eliciting Dose values for 14 priority allergenic foods and recommendations for use in risk characterization. *Food Chem. Toxicol.* 146, 111831.
- Jackson, L.S., Al-Taher, F.M., DeVries, J.W., Tippet, R., Swanson, K.M.J., Fu, T.-J., Salter, R., Dunaif, G., Estes, S., Albillos, S., Gendel, S.M., 2008. Cleaning and other control and validation strategies to prevent allergen cross-contact in food-processing operations. *J. Food Protect.* 71 (2), 445–458.
- Lee, A.Y.M., Enarson, P., Clarke, A.E., La Vieille, S., Eisman, H., Chan, E.S., Mill, C., Joseph, L., Ben-Shoshan, M., 2017. Anaphylaxis across two Canadian pediatric centers: evaluating management disparities. *J. Asthma Allergy* 10, 1–7.
- Madsen, C.B., van den Dungen, M.W., Cochrane, S., Houben, G.F., Knibb, R.C., Knulst, A.C., Ronsmans, S., Yarham, R.A.R., Schnadt, S., Turner, P.J., Baumert, J., Cavandoli, E., Chan, C.-H., Warner, A., Crevel, R.W.R., 2020. Can we define a level of protection for allergic consumers that everyone can accept? *Regul. Toxicol. Pharmacol.* 117, 104751.
- Manny, E., La Vieille, S., Barrere, V., Theolier, J., Godefroy, S.B., 2021a. Occurrence of milk and egg allergens in foodstuffs in Canada. *Food Addit. Contam.* 38 (1), 15–32.
- Manny, E., La Vieille, S., Barrere, V., Theolier, J., Godefroy, S.B., 2021b. Peanut and hazelnut occurrence as allergens in foodstuffs with precautionary allergen labeling in Canada. *npj Science of Food* 5, 11.
- Marchisotto, M.J., Harada, L., Kamdar, O., Smith, B.M., Wasserman, S., Sicherer, S., Allen, K., Muraro, A., Taylor, S., Gupta, R., 2017. Food allergen labeling and purchasing habits in the United States and Canada. *J. Allergy Clin. Immunol. Pract.* 5 (2), 345–351.e2.
- O'Keefe, A., Clarke, A., St. Pierre, Y., Mill, J., Asai, Y., Eisman, H., La Vieille, S., Alizadehfar, R., Joseph, L., Morris, J., Gravel, J., Ben-Shoshan, M., 2017. The risk of recurrent anaphylaxis. *J. Pediatr.* 180, 217–220.
- Remington, B.C., Baumert, J., Blom, W.M., Buchhini, L., Buck, N., Crevel, R., De Mooij, F., Flanagan, S., Hindley, J., Javed, B., Stavropoulou, D.S., van den Dungen, M.W., van Ravenhorst, M., Wang, S., Walker, M., Participants in the ILSI Europe Virtual Workshop of 29th October, 2022a. Allergen quantitative risk assessment within food operations: concepts towards development of practical guidance based on an ILSI Europe workshop. *Food Control* 138, 108917.
- Remington, B.C., Taylor, S.L., Marx, D.B., Petersen, B.J., Baumert, J.L., 2013. Soy in wheat – contamination levels and food allergy risk assessment. *Food Chem. Toxicol.* (62), 485–491.
- Remington, B.C., Baumert, J., Blom, W.M., Buchhini, L., Buck, N., Crevel, R., De Mooij, F., Flanagan, S., Hindley, J., Javed, B., Stavropoulou, D.S., van den Dungen, M.W., van Ravenhorst, M., Wang, S., Walker, M., 2022b. Practical Guidance on the Application of Food Allergen Quantitative Risk Assessment. Zenodo.
- RStudio Team, 2019. RStudio: Integrated Development for R. RStudio, Inc., Boston, MA. URL: <https://www.rstudio.com>.
- Török, K., Hajas, L., Horváth, V., Schall, E., Bugyi, Z., Kemény, S., Tömösközi, S., 2015. Identification of the factors affecting the analytical results of food allergen ELISA methods. *Eur. Food Res. Technol.* 241, 127–136.
- Touma, J., La Vieille, S., Guillier, L., Barrere, V., Manny, E., Théolier, J., Dominguez, S., Godefroy, S.B., 2021. Occurrence and risk assessment of sesame as an allergen in selected Middle Eastern foods available in Montreal, Canada. *Food Addit. Contam.* 38 (4), 550–552.
- van Hengel, A.J., 2007. Food allergen detection methods and the challenge to protect food-allergic consumers. *Anal. Bioanal. Chem.* 389, 111–118.
- Wickham, H., 2009. ggplot2: Elegant Graphics for Data Analysis. Springer.
- Yeung, J., Robert, M.-C., 2018. Challenges and path forward on mandatory allergen labeling and voluntary precautionary allergen labeling for a global company. *J. AOAC Int.* 101 (1), 70–76.