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# Towards the Quantitative Management of Food Allergens in the Food Industry

**Gustavo A. Polenta**[1,2,3]

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## Abstract

**Purpose of Review** This paper reviews different aspects related to recently proposed threshold values for priority food allergens, which are expected to guide food business operator (FBO) and regulatory agencies towards a quantitative management of allergens, providing transparency and trust to the different stakeholders, especially in controverted aspects such as the (over) use of precautionary allergen label (PAL) in food products, and the potential application of quantitative risk analysis, to improve the current management of food allergens.

**Recent Findings** Recently, groups of reports were published from an Expert Committee on Risk Assessment of Food Allergens convened by FAO and WHO, to provide the Codex Committee on Food Labelling (CCFL) scientific advice on different topics related to allergen management such as the establishment of threshold levels for priority allergens, recommendations on the potential use of these thresholds by the food industry, and the proposal of a risk-based process to scientifically support the inclusion of precautionary allergen labelling (PAL) in foods. These reports are expected to provide internationally harmonized basis to ensure that food labelling is accurate and informative for consumers with food allergies, and that food companies would be able to comply with food safety standards.

**Summary** Quantitative allergen management will be increasingly important for different stakeholders such as the food industry and regulatory agencies. In this regard, allergen thresholds, defined as the levels of allergens in food products below which the risk of an allergic reaction is considered negligible, can help ensure that food products are safe for consumers with food allergies. FAO and WHO have recently addressed this topic and proposed allergen thresholds for the priority allergens. One of the most important uses of thresholds is in the implementation of PAL, which can help allergic consumers make an informed decision. The use of sound analytical methods represents a key element, which allows to measure the amount of allergens in raw materials, finished products, and food processing environments. This information can be used to identify and address any potential allergen risks. Quantitative risk assessment allows the food industry to identify and assess the risks of allergen cross-contamination. This information can be used to develop, implement, and improve control measures to reduce the risk of cross-contamination and comply with regulations.

**Keywords** Quantitative risk assessment · Food allergen thresholds · Cleaning validation · Precautionary allergen labelling (PAL)

## Introduction

Food allergies have emerged as one of the most relevant food safety hazards of the last decades, with an important impact on public health. In fact, in countries such as the UK, food anaphylaxis admissions in hospitals experimented an annual increase of around 6%, from 1.23 to 4.04 per 100,000 population per year (from 1998 to 2018) [1]. Although current allergen management practices have made food products safer for allergic consumers, there is not yet a harmonized approach to risk assessment and

✉ Gustavo A. Polenta
polenta.gustavo@inta.gob.ar

1 Instituto Nacional de Tecnología Agropecuaria (INTA), Instituto Tecnología de Alimentos, Nicolás Repetto y de los Reseros S/N (B1686) Hurlingham, Buenos Aires, Argentina

2 Instituto de Ciencia y Tecnología de Sistemas Alimentarios Sustentables (ICyTeSAS), UEDD INTA CONICET, Buenos Aires, Argentina

3 Instituto de Biotecnología, Universidad Nacional de Hurlingham (UNAHUR), Buenos Aires, Argentina

management among different manufacturers. This has led to an increase in precautionary allergen labelling (PAL), eroding consumer trust and making people more likely to take unnecessary risks. Minimizing the risk of allergenic foods is a shared responsibility of all stakeholders. Allergen cross-contact leading to unintended allergen presence (UAP) constitutes a relevant challenge for food business operators (FBO), for which priority allergens must be effectively managed throughout the manufacturing process [2].

A recent report of FDA comprising the period 2013–2019 indicates that allergens were responsible for most regulated recalls, with milk being the most involved allergen (37.5%). Most allergen recalls (89.4%) were classified as class I, which means that they posed a serious or life-threatening health hazard [3]. These data are coincident with other global food safety incidents reported by different regulatory agencies (CFIA — Canada, FSANZ — Australia and New Zealand, FSA — UK, etc.), where almost half of the identified hazards ending in recalls were related to allergens (1354 out of 2932) [4].

The evaluation of quantitative data related to UAP leads to the conclusion that the detected amounts undoubtedly represent a serious concern. In this regard, a study with dark chocolate bars found that 87% of chocolate products with a PAL for milk contained levels of this allergen above 100 parts per million (ppm), and more than half even above 1000 ppm [5]. These high levels represent a serious risk of triggering anaphylactic reactions.

One of the most relevant aspects of allergens, leading to consistent and transparent managing and clear communication of the allergenic status, would be the establishment of globally accepted threshold values, which should be based on scientifically sound methodologies [2]. In this regard, the recurrent question referred to allergens “how much is too much?”, first posed by Taylor et al. [6], has thereafter received considerable attention. Despite its increasing concern, this topic had not been officially addressed until recently [7•, 8], when an Expert Committee on Risk Assessment of Food Allergens was convened by FAO and WHO to provide the Codex Committee on Food Labelling (CCFL) with scientific advice on different topics related to allergen management, such as the establishment of threshold levels for priority allergens and recommendations on the potential use of these thresholds by the food industry [9, 10••, 11]. The general approach on this subject as well as different recommendations from the FAO/WHO committee is currently being evaluated by different regulatory agencies [12, 13]. From these and other international discussions, it becomes clear that scientists have currently enough information on threshold doses for the most relevant allergenic foods, to guide food manufacturers on how to protect allergic consumers.

Globally harmonized regulations based on threshold values are expected to improve the quality of life for food-allergic consumers, focussing on the real risks that exist to these consumers. Therefore, considering that PAL is a voluntary labelling system that informs consumers with food allergies about the potential presence of allergens in food, the establishment of harmonized allergen threshold values will allow for a more rational assessment of the real need to include it. However, up to the present, PAL has not always been effective in mitigating risks, due to inconsistencies in its application. This paper reviews several aspects related to threshold values for priority food allergens, which can now guide FBO and regulatory agencies towards a quantitative management of allergens, providing transparency and trust to the different stakeholders.

## Rational Use of PAL in Food Products

It is important to consider that allergen management has two main protection goals: minimizing the risk of allergy episodes in sensitive people (food safety objective) and maximizing the possibilities of choice for healthy foods by allergic consumers (food security objective). In this regard, stakeholders agree that PAL should be used based on the actual risk of allergic reaction, with transparent and consistent decision-making criteria, when there is an unacceptable risk of significant but unavoidable allergen cross-contamination, without unduly restricting food choices to allergic consumers [2, 14•]. Contrarily, current use of PAL has shown limited effectivity to protect people with food allergies. Therefore, different studies recommend a risk-based approach to decide its inclusion, which should be based on the amount of allergen likely to cause a reaction as well as in the potential severity of reactions [15]. In this regard, it was reported that reactions to small amounts of allergens are usually mild, while the most severe allergic reactions are usually caused by significant quantities of allergens, added intentionally as an ingredient to the food [16, 17].

PAL was developed by the food industry as an ultimate tool to mitigate the risk of unavoidable UAP due to the complexity of food manufacturing (different ingredients and raw materials, shared equipment, cleaning protocols that could be not entirely effective to remove all traces of allergens) [18]. Ideally, the inclusion of PAL should be decided according to the so-called action levels, objectively determined (a topic that will be later discussed in more detail). Thus, a concentration of the potential UAP higher than the action level would trigger the use of PAL, while no PAL would be necessary for concentrations equal to or lower than this cut-off [16].

According to this conception, the conduction of a formal allergen risk assessment can be considered as an improvement in the use of PAL, since it will provide the basis for a more informative labelling scheme, ultimately contributing to a transparent allergen management and communication [19]. One of the first and most widely used schemes using this approach has been the VITAL program (Voluntary Incidental Trace Allergen Labelling), established by the Allergen Bureau of Australia and New Zealand [20].

In summary, the rational use of PAL is important to ensure that it be used in a transparent, clear, and concise way, avoiding unnecessary risk or confusion to consumers. Therefore, FBO should only use PAL when there is a genuine risk of cross-contamination and, in turn, allergic consumers should be aware of the limitations of PAL and not rely on it as the only way to avoid food allergies, for which they should be educated about the real meaning of precautionary labelling [11].

## The Way for Threshold Values of Food Allergens

Allergen threshold is defined as the minimum amount of an allergenic food that can trigger an allergic reaction. One of the problems associated to allergen threshold is that this expression may have different significance and connotation for the different stakeholders such as allergic individuals, health professionals, the food industry, and regulatory authorities. For allergic individuals and health professionals, threshold data can help them manage allergies by identifying safe food choices and preventing allergic reactions [21], since they provide information on how much allergen can be tolerated by (most of) allergic individuals before they experience a reaction. In turn, the food industry and regulatory authorities can use thresholds to assess the public health risk of food allergies and design appropriate food safety measures [22].

A term closely related to allergen threshold and useful for public health purposes, i.e. eliciting dose (ED), can be used to set safety limits for foods potentially containing allergens [23]. With this purpose, standardized clinical challenges from a large number of allergic patients can help estimate population thresholds through statistical modelling of the dose-distribution of individual responses to the target allergen. From these models, ED or population threshold can be therefore defined as the amount of the allergenic food which will cause an objective reaction in a specified proportion of an allergic population (EDp). Thus, the ED05 is the dose predicted to elicit an allergic reaction in the 5% most sensitive individuals. For example, if the ED05 for peanuts is 1 mg, then a portion of food (to be consumed in one eating occasion) containing 1 mg of peanuts would be safe for 95% of people with peanut allergies. Although the ED acknowledges that it is impossible to guarantee absolute safety, a value that protects a certain percentage (ideally the vast majority) of allergic people could be agreed [10••, 23].

Several bibliographic references addressed the topic of threshold values. The following list includes the most significant and representative publications in the way to a global consensus:

- Alternative criteria to establish threshold values for food allergens [24]
- Establishment of reference doses for different allergenic foods based on oral provocation studies and probabilistic models [25]
- Establishment of population minimal eliciting dose-distributions of priority allergens based on clinical data with a more extensive database [26]
- Full range of population eliciting doses for priority allergenic foods also based on the previous database [7•]
- International scientific consensus on reference values, action levels, and current analytical capabilities in relation to the recommended thresholds for priority allergens [10••]

Some of these thresholds have been already used with success in Australia and New Zealand, to develop reference dose limits for the voluntary, risk-based VITAL program for food manufacturers [20].

## The Concepts of Reference Dose and Action Level

Four main components should be addressed for the establishment of allergen thresholds in food: (a) the estimation of reference doses from the modelling of dose–response curves of individual allergens, obtained from a sufficient numbers of allergic individuals subjected to provocation tests; (b) the agreement of the required level of (minimum) eliciting dose obtained from these models (ED01, ED05, etc.); (c) sound consumption databases for different types of food; and (d) commercially available analytical methods to quantify allergens at the required levels [10••].

Based on EDp values, risk managers can set reference doses (RfD) at any risk level considered to be acceptable [8]. Remington et al. [26] reported ED01 and ED05 values (considered the candidate values for the establishment of thresholds) for fourteen different allergenic foods. Based on these values, the VITAL program chose the ED01 (protection levels of 99%) as the basis for the RfD for taking risk management decisions within the VITAL 3.0 framework [27]. Other regulatory agencies such as the Belgium Federal Safety Agency adopted the lower limit of the 95% confidence interval of ED05 [28], while the Dutch Office BuRO established the ED01 value [29]. Recently, FAO/

WHO [10••] agreed a tolerable safety objective associated to a threshold value as that capable (literally) "to minimise, to a point where further refinement does not meaningfully reduce health impact, the probability of any clinically relevant objective allergic response as defined by dose-distribution modelling of minimum eliciting doses (MED) …". The committee responsible for this publication agreed that ED05 values will meet this objective. Full range of allergic population dose-distributions such as those presented by Houben et al. [7•] can be further used for characterizing the risk and number of predicted reactions for different scenarios or specific situations [8].

Table 1 presents the most important threshold values (RfDs), either expressed as absolute amounts (mg) of concentrations (ppm), presented by different regulatory agencies and/or organizations such as FAO/WHO and VITAL. It becomes evident that there is a wide range of values and different ways of expression (mg or ppm) for each individual allergen among the different agencies, organizations such as FAO/WHO, and programs like VITAL. However, it has been recognized, after the publication of FAO/WHO reports, the validity of methodologies such as the dose-distribution analysis to determine the reference values, and the consumption database to calculate action levels. It is also acknowledged that data sources reported in the studies from Remington et al. [26] and Houben et al. [7•] constitute the best described and most comprehensive bibliographic sources available up to the present, in terms of content and curation and validation by highly regarded peer-reviewed publications. The main difference is due to what can be considered by the regulatory agencies and organization as a tolerable risk to protect consumers, according to the concept of Madsen et al. [15], and the difficulty to find a right compromise between the food safety and food security protection goals, as previously described.

To apply RfD in practical terms and determine the limits for different types of foods, these values should be converted into concentrations (ideally expressed as mg of total protein of the allergenic food per kg food product) by simply dividing them by the estimated serving size of food eaten in a single occasion. This would provide the target concentration limit to decide a PAL inclusion and the required limits of quantification of analytical methods to monitor compliance of food products [10••, 11]. These target values, termed action levels, can be defined as the maximum concentration of each specific allergen that can be present in a food

**Table 1** Reference doses (threshold values) either expressed as absolute amounts (mg) or concentrations (ppm) proposed by different different regulatory agencies and/or organizations such as FAO/WHO and Allergen Bureau's VITAL® (Voluntary Incidental Trace Allergen Labelling) Program

| Allergen | FAO/WHO (10) | Scientific Committee — Federal Agency for the Safety of the Food Chain — Belgium (8) | VITAL 2.0 (20; 25) | VITAL 3.0 (27) | Japan (47) | Switzerland (30) | Office for Risk Assessment & Research (BuRO) Netherlands Food and Product Safety Authority (29) |
|---|---|---|---|---|---|---|---|
| Walnut | 1.0 mg | 0.5 mg | | 0.03 mg | 10 ppm | 1000 ppm | |
| Pecan | 1.0 mg | 0.5 mg | | 0.03 mg | | 1000 ppm | |
| Almond | 1.0 mg | 0.5 mg | | | | 1000 ppm | |
| Milk | 2.0 mg | 1.2 mg | 0.1 mg | 0.2 mg | 10 ppm | 1000 ppm | 0.016 mg |
| Peanut | 2.0 mg | 1.1 mg | 0.2 mg | 0.2 mg | 10 ppm | 1000 ppm | 0.015 mg |
| Egg | 2.0 mg | 0.3 mg | 0.03 mg | 0.2 mg | 10 ppm | 1000 ppm | 0.0043 mg |
| Sesame | 2.0 mg | 0.4 mg | 0.2 mg | 0.1 mg | | 1000 ppm | 0.10 mg |
| Hazelnut | 3.0 mg | 0.5 mg | 0.1 mg | 0.1 mg | | 1000 ppm | 0.011 mg |
| Wheat | 5.0 mg | 1.3 mg | 1.0 mg | 0.7 mg | 10 ppm | 1000 ppm | 0.14 mg |
| Fish | 5.0 mg | | | 1.3 mg | | 1000 ppm | |
| Crustacea | 200 mg | 12.1 mg | 10 mg | 25 mg | 10 ppm | 1000 ppm | 3.7 mg |
| Cashew | | 0.6 mg | 2.0 mg | 0.05 mg | | 1000 ppm | |
| Pistachio | | 0.5 mg | 1.0 mg | 0.05 mg | | 1000 ppm | |
| Mustard | | 0.1 mg | 0.05 mg | 0.05 mg | | 1000 ppm | 0.022 mg |
| Lupin | | 4.5 mg | 4.0 mg | 2.6 mg | | 1000 ppm | 0.83 mg |
| Soybean | | 2.9 mg | 1.0 mg | 0.5 mg | | 1000 ppm | 0.078 mg |
| Celery | | | | 0.05 mg | | 1000 ppm | |
| Buckwheat | | | | | 10 ppm | | |
| Sulphites | | | | | 10 ppm | 10 ppm | |

product without causing a severe reaction in most people with allergies to that allergen. The allergen concentration unintentionally remaining in a product, even with the best allergen management practices, can be estimated by different methodologies. These estimated concentrations can then be compared to allergen threshold values [2]. Different information sources and calculus related to these values have been recently proposed by the International Life Science Institute (ILSI) [14•].

To provide reference serving amounts, Birot et al. [29] combined data from consumption surveys accomplished in different European countries (France, Denmark, and Netherlands) into a common database, which resulted in 61 food groups. They calculated for each food group the mean consumption value, as well as the 75th percentile (P75) and the 90th percentile (P95), which are useful for allergen risk assessment. The 50th percentile is considered as the optimal consumption amount to be used confidently for probabilistic risk assessments with an acceptable risk level [30, 31]. Intake data from the general population can also be used for food allergen risk assessment since, as evidenced, no statistically significant difference of consumption exists between the allergic and the general populations [32].

## Quantitative Management of Food Allergens

As previously explained, the use or absence of PAL currently shows a limited correlation with the real level of UAP and the consequent risk of an allergic reaction. This concomitant risk after the consumption of a product that unintendedly contains an allergen can be estimated by quantitative risk assessment (QRA) [33]. This tool complements allergen management practices by quantitatively estimating the risk that face an allergic consumer due to an UAP in a food. It can thereby provide information as input into the risk management decision-making process, such as whether a PAL inclusion is necessary [14•].

QRA can be based on fixed numerical data (deterministic), probabilities (probabilistic), or a combination of both. In food manufacturing, deterministic assessments are often used because they are simple and provide enough information to make risk management decisions [34].

In practical terms, once established the different parameters previously mentioned (reference doses, real serving sizes, action levels), the next step is to review, in a comprehensive assessment, the potential for allergens to be present in a food product, which will constitute a relevant input to make decisions about allergen labelling. The review process should identify the presence of allergens either by direct incorporation or by (unintended) cross-contact, and should include the entire manufacturing process, from raw materials to the finished product, identifying and quantifying any accumulated residues within the manufacturing line. The output will be the establishment of the allergen status of all materials, including the estimation of the amount of unintentionally added allergens [14•, 35]. Based on this information, the likelihood and severity of reactions in allergic people who consume food containing allergens can be systematically evaluated.

It is expected that QRA be increasingly adopted by FBO because of its utility to develop more effective control measures, or eventually decide in a coherent and transparent manner the inclusion of PAL, both conducting to reduce the risk of allergic reactions without unnecessary and unrealistic warnings. Among the advantages for FBO to adopt a decision-making process based on QRA, it can be mentioned a reduced liability in the event of an allergic reaction, the enhancement of the brand reputation, an increased efficiency by identifying and eliminating inefficient practices, which can lead to cost savings, an improved compliance with government regulations on food allergens, and a more efficient and transparent communication with stakeholders.

In summary, a quantitative risk-based approach to allergen management considers the likelihood and severity of an allergic reaction when determining whether to use precautionary labelling, leading to a wider range of food choices for allergic consumers and a lower risk of nutritional deficiencies. By taking this approach, the vast majority of allergic consumers will be able to tolerate foods that do not carry precautionary labelling [2].

## Analytical Requirement for the Quantitative Management of Food Allergens

The establishment of thresholds for food allergens requires the availability of sound analytical methods, which constitute a critical component to support compliance with the established values, as potentially required by certification systems, internal standards, and/or regulations. Allergen analysis can assist in different activities such as verifying allergen profile and potential UAP in raw materials, assessing cleaning efficacy and validations, confirming assumptions of the risk assessment process, and monitoring the effect of critical changes [20].

Three techniques (polymerase chain reaction — PCR, ELISA, and mass spectrometry —MS) are currently considered as being the best options for compliance and enforcement related to allergen management [36]. Because the availability of reference material for the analysis of allergens is still scarce, one important problem is that different analytical methods for food allergen can lead to inconsistent quantification results, which can hinder accurate quantitative risk assessment and its regulatory implementation. Therefore, there is still a clear need to improve, standardize, and harmonize allergen analysis [37, 38]. Cubero-Leon et al. [39] proposed a concept called reference measurement system for food allergens. This system consists of three components: a primary reference measurement method, a certified reference material, and a reference laboratory. Recently, a European project addressed the development of a MS method able to analyse six priority allergens (milk, egg, peanut, hazelnut, almond, and soybean), validated by immunoassay and DNA-based methods. This method has the required sensitivity to quantify these allergens with the performance established by the recent FAO/WHO expert consultation [40].

A recent study investigated if current methods have the required analytical performance to assess the recommended doses established by VITAL 2.0 and 3.0 for different serving sizes (between 5 and 500 g). Data on published and commercial ELISA, PCR, and MS methods were reviewed for the analysis of peanuts, soy, hazelnut, wheat, milk, and egg. It was found that available methods can successfully detect peanut, soy, hazelnut, and wheat allergens at or below the doses of both versions of the VITAL program, even in large serving sizes. However, some difficulties can be found for milk and egg due to matrix/processing incompatibility. In coincidence with the above mentioned, this study also remarks the need for harmonized reporting units, available reference materials, and ring-trials to enable validation and the provision of comparable measurement results [38].

The report on the establishment of threshold levels published by FAO/WHO [10••] recommends assessing the method performance requirement on the limits of quantification (LoQ), which should be around threefold lower than the action level for each food. This would account for the practical variability, assuring that the analytical values obtained are at or below the action levels. This report provides a table showing the required LoQ recommended to meet the action levels, as calculated for the different allergens, and serving sizes of foods. It is important to mention that the study from Holzhauser et al. (39) considers limits of detection (LoD), which are lower than LoQ, but the assessment was made for ED01 reference doses of allergens.

## The Relevance of Allergen Cleaning

Allergen QRA can provide critical allergen protein concentrations above which a risk can be verified. To attain such low or negligible amount of UAP, cleaning represents a key allergen control measure in food facilities. Allergen cleaning is the process of removing food allergens from surfaces, equipment, and other areas where they may have come into contact with food. However, it is usually difficult to link the results of allergen tests on non-food materials (such as surface swabs and rinse water) to the amount of allergen in finished products, since it is unclear how much of the allergen would be transferred. Current allergen tests for non-food materials are mostly used to validate and verify control measures. If allergens are detected, control measures need to be reviewed and improved [34].

In some situations, potential carry-over could be estimated through knowledge of the line(s) and equipment, together with easy measurements, such as the mass of preceding product that may be left within the equipment. Carry-over QRA can then be combined with analytical data to provide additional assurance [14•].

Appropriate analysis to assess cleaning efficacy plays an essential role for the effective risk management and harmonization of mitigation measures such as PAL. Four crucial issues to be addressed have been identified: (a) sampling method, (b) analysis accomplishment, (c) analysis performance, and (d) interpretation of the results [41]. Protocols designed to remove food allergens should include the following steps: identifying the allergens that need to be removed, selecting the appropriate cleaning methods and materials, cleaning surfaces and equipment thoroughly, and verifying that the cleaning has been effective.

## The Development of "Free-From Allergens" Products

Free-from-allergen foods are a special type of products initially devoted to a small number of highly sensitive and reactive allergic people. They would not provoke even mild reactions in the vast majority of highly sensitive allergic consumers, based on the guarantee of analytical absence of allergenic proteins and a robustly designed food safety system (GMP, HACCP, etc.) [2].

Free-from allergens is considered a claim, although its definition and requirements are not covered in most of the legislations of EU and countries such as the UK and Argentina, except for "gluten-free" products [42]. Because of its absolute connotation, a product should be labelled as "free-from" only after a stringent assessment of the ingredients, environment, and the assurance that processes and controls have been followed. According to the British Retail Consortium (BRC) [42], a "free-from" claim should observe the following principles: (a) no ingredient with the specified allergen should be included in the product recipe; (b) the production environment should observe strict manufacturing practices and the most stringent allergen management practices; (c) a robust analytical program with specified sampling and testing methods should be established and followed; and (d) a clear labelling and other communication tools should be considered, all of them complying with legal requirements. In some countries, these requirements are supported by independent (third-party) certification bodies. These products are particularly scrutinized and frequently monitored by regulatory authorities, and sometimes inconsistencies are found. For instance, products labelled as "milk- and gluten-free" has been detected to positively contain milk and gluten [43], and in 15% of chocolates with dairy-free statement and in 25% of vegan chocolates the presence of milk was detected [5].

In addition to more stringent management practices (for instance, some certification systems require that no ingredient with the target allergen be present in the powder form within the entire facility), the analytical absence of the allergen should be verified by any of the most sensitive commercial methods available. Actually, a very frequent use of analytical test kits by the food industry is in the context of certification or to support "free-from" labelling [44].

The market for free-from allergen foods has experimented a significant growth in the last years, especially in North America and Western Europe, mainly because of the increasing number of people with food allergies or intolerances. However, even non-allergic consumers wrongly perceive eating these products as a way to improve their overall health and digestion [45]. This suggests that the market for free-from foods will continue to grow and expand in the future, for which it will be increasingly important to have in place robust analytical programs, and a consistent quantitative management system for food allergens. In this case, a zero-risk approach would be particularly relevant, differently from regular foods, where a tolerable-risk approach would be more adequate.

## Conclusions

This review shows that quantitative allergen management will be increasingly important for different stakeholders such as the food industry and regulatory agencies. In this regard, internationally agreed allergen thresholds such as those proposed by FAO/WHO will be of utmost importance to ensure that food products are safe for allergic consumers. One of the most relevant uses of thresholds is in the process to assess the need to include PAL. Within this framework, the availability of sound analytical methods represents a key element. An increased adoption of QRA is therefore expected because of its efficacy to identify and address potential allergen risks, especially the existence and impact of cross-contamination and the consequent labelling decision. However, it should be emphasized that QRA does not substitute the compliance with good manufacturing practices (GMPs) and prerequisite programs (PRPs).

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**Data Availability** Not applicable.

## Declarations

**Ethical Approval** This article does not contain any studies with human or animal subjects performed by the authors.

**Conflict of Interest** Dr. Gustavo Polenta declares that he integrates the Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens convened by FAO/WHO.

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