

# **Precautionary Allergen Labelling (PAL): a science- based approach based on Quantitative Risk Assessment**

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## Abstract/Executive summary

Allergens as ingredients have been regulated in the EU since 2005. Due to the realities of food production there are situations where it is not possible to avoid the unintended presence of allergens, which in some cases might pose a risk to susceptible people. Precautionary allergen labelling (PAL) has evolved as an essential tool both to communicate and manage this risk.

Mounting evidence indicates that PAL is increasingly losing credibility among stakeholders, including critically those for whom it is primarily intended, i.e. allergic consumers. This failure of PAL diminishes a valuable and necessary risk management tool and places allergic consumers at risk.

The current issues associated with PAL can be attributed to several factors, in particular the absence of generally agreed quantitative limits for the unintended presence of allergens. The lack of harmonised standards across Member States and industry also adds to confusion.

Currently PAL is not formally regulated in the EU, although the general principles of food safety law arguably apply to it. However, Article 36 of Regulation (EU) 1169/2011 (hereafter: the “FIC Regulation”) sets out a framework which can be used to implement a comprehensive, consistent, and science-based approach.

New methodologies as well as growing volumes of good quality data now exist that can be applied to assess the risk from unintended allergen presence.

This paper describes how adoption of quantitative limits (based on reference doses) could form part of an EU-wide approach aligned with the principles enunciated in Article 36 of the FIC Regulation. Such an approach would greatly strengthen the protection of allergic consumers by making PAL meaningful and transparent. It would also benefit the European food industry by providing a comprehensive framework (“level playing field”), which would also strengthen the single market. FoodDrinkEurope would like to see a defined framework for the application of PAL which meets the requirements of article 36(2) of the FIC Regulation, namely:

- PAL should be clear: a single statement with a single meaning, easy to translate into EU languages, i.e. “may contain [allergen]”.
- PAL should not be misleading: it should only be applied where a defined, appreciable risk has been identified, including (where it is relevant and possible) through a quantitative risk assessment.
- PAL should be applied based on transparent quantitative limits derived using the most up to date, relevant, peer-reviewed and robust scientific data.
- Consumers need to know that products have been through a risk assessment and that the presence or absence of PAL is a consequence of that process.

## Summary Recommendations on PAL

FoodDrinkEurope would like to see a defined framework for the application of PAL which meets the requirements of Article 36(2) of the FIC Regulation, namely:

- Clear: a single statement with a single meaning, easy to translate into EU languages, i.e. “may contain [allergen]”
- PAL should not be misleading: it should only be applied where a defined, appreciable risk has been identified, including (where it is relevant and possible) through a quantitative risk assessment.
- PAL should be applied based on transparent quantitative limits derived using the most up to date, relevant, peer-reviewed, and robust scientific data.
- When Quantitative Risk Assessment (QRA) relies on analytical data, it should be noted that sampling procedures and analytical methods have limitations regarding sensitivity, specificity, and accuracy. The applicability of analytical data as an input into QRA requires harmonization.
- In addition, consumers need to know that products have been through a risk assessment and that the presence or absence of PAL is a consequence of that process.

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## 1. Introduction

Allergens are common constituents of consumer products with valuable functional and/or nutritional attributes. Food allergy refers to an inappropriate immune response to a food constituent (almost always a protein), causing the food to provoke an allergic reaction when it is eaten again. The nature and type of reactions, as well as the numbers of people with food allergies make allergens an important food safety issue.

Allergen incidents can arise for many reasons along the food chain, including unintended presence of allergens which are not part of the recipe. Despite the most serious efforts to manage allergens during manufacturing and other operations, this unintended presence of small amounts of allergens, which can pose a risk to susceptible individuals, cannot always be avoided. Precautionary allergen labelling (PAL) was introduced as one of the measures to mitigate and manage this risk.

While current practices in the management of major allergens (according to Annex II of the FIC Regulation) have increased the safety of food products for allergic consumers, the lack of an agreed, consistent approach to quantitative risk assessment for unintended allergen presence has led to divergent standards applied by different manufacturers, as well as divergent approaches by enforcement authorities across Europe and the world. These factors have led to the extensive use of PAL, that may not be related to the actual risk the product poses, does not always cover the right allergens and restricts the food choices of allergic consumers while damaging its credibility. This, in turn has led to a significant proportion of these consumers taking risks and to allergic consumers suffering accidental reactions, as documented in various publications (Barnett *et al.* 2011, Blom *et al.* 2018, Cochrane *et al.* 2013, DunnGalvin *et al.* 2015, Michelsen-Huisman *et al.* 2018).

PAL remains a necessary and useful tool to manage and communicate risk to allergic consumers but, in order to restore its value and maximise consumer protection, an urgent need exists for the adoption of a comprehensive EU approach to quantitative risk assessment for PAL purposes.

The European Food Safety Authority addressed the issue of food allergens in an [Opinion in 2014](#) (EFSA 2014). While the Opinion discussed risk assessment approaches, it was limited only to (regulated) allergens used as ingredients. Thus, it did not consider how the risks arising from unintended allergen presence might be assessed, which would have provided a sound scientific basis for risk managers to implement PAL.

The FIC Regulation requires implementing acts to be adopted by the Commission concerning rules for the use of PAL. These include that the information provided must not be misleading, must be clear and that it must be based on relevant scientific data. In this paper, FoodDrinkEurope proposes an approach to PAL based on quantitative risk assessment, guided by the principles set out in the Regulation<sup>1</sup>. The approach is aimed at the application of PAL to pre-packaged retail food products for normal consumption, although elements could be applied to other sectors.

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<sup>1</sup> The considerations on risk assessment included in this paper apply to substances or products causing allergies. Care needs to be taken to differentiate food allergy from food intolerance, which does not involve the immune system. However, the “PAL statements” are currently used also to inform consumers about the possible presence of substances or products causing intolerances. Therefore, the considerations on risk communication included in the section “Implementation of PAL: towards more consistent allergen risk communication” also apply to the communication about substances or products causing intolerances.

## 2. Definition and purpose of PAL

### Definition

Precautionary allergen labelling (PAL), also called advisory labelling, refers to the voluntary labelling to indicate that one or more regulated allergens could be unintentionally, but unavoidably, present in a product, and thus pose a risk to susceptible consumers. Currently, there are no formal legal definitions of Precautionary Allergen Labelling in the EU, nor a framework for its application, although the FIC Regulation details a possible basis for such a framework in Article 36, as discussed later. Guidance on good practice for its application has been published, for example by the UK Food Standards Agency and [FoodDrinkEurope](#).

### Purpose

PAL serves both to communicate risk, but also manage it, its ultimate purpose being to avoid reactions to allergens in susceptible consumers. The terminology used for PAL aims to convey to susceptible consumers the possibility that an allergen may be present in a product and therefore pose an appreciable risk to them, which the manufacturer wishes them to avoid. In other words, a food producer should be using PAL primarily to dissuade susceptible consumers from consuming their product.

Unintended allergen presence can occur in a number of ways, the most common and best known being through cross-contact during manufacture of either the product or one of its components, including agricultural raw materials. However, situations that can give rise to unintended allergen presence encompass the whole supply chain from the fields in which agricultural commodities are grown through the containers in which those commodities are transported, right up to storage at the manufacturing location. Unintended allergen presence can also manifest itself in several different ways depending on the production process, the source of unintended presence and the physical form of the allergen (readily dispersible or particulate). One situation can be a very low level of allergen present in all units of the product. Another can include presence of the allergen in a proportion of units only, due to carryover at changeover. In cases of allergen in particulate form, most units may not have any allergen, but where it occurs, it may be sufficient to provoke a severe reaction, so resulting in a rare event, but with serious consequences.

Inherent in the concept of PAL is a degree of uncertainty about the actuality of the risk (the allergen may or may not be present). There is also uncertainty about the exact nature of the risk to which allergic consumers may be exposed, such as likelihood of and severity of reaction if allergen is present, in part because of variability in their susceptibility, but also because currently, no quantitative limits have been agreed which are generally accepted by authorities, including national and Union authorities in the EU.

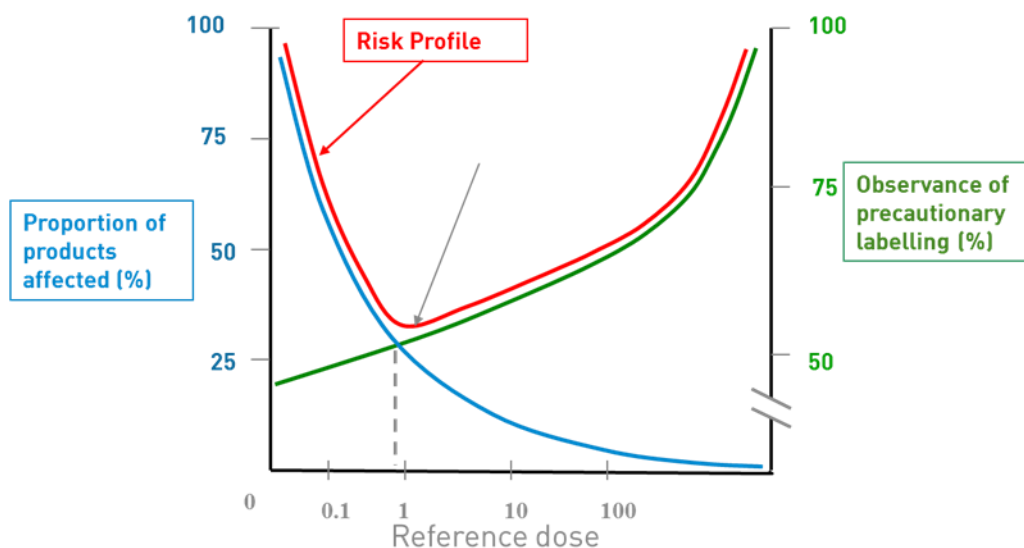
Precautionary allergen labelling is not an appropriate strategy to manage lack of Hazard Analysis and Critical Control Points (HACCP) during manufacturing, or lack of adherence to generally recognised Good Manufacturing Practices (GMP).

[Who are we trying to protect and against what? The challenges of making PAL meaningful.](#)

People with allergies vary over a very wide range in the minimum dose that will elicit a reaction, with data from controlled food challenges pointing to a million-fold range (micrograms to grams).

Manifestations of allergic reactions also vary considerably, from those barely perceptible to the affected person and not evident to an external observer (subjective reactions) through objective reactions of various degrees of severity to life-threatening anaphylaxis involving compromise to the cardiovascular and respiratory systems. These observations highlight the challenges in defining limits, based upon reference doses as the basis for the transparent and consistent use of PAL.

Using PAL in a meaningful way for consumers is not simply about setting limits so low that every allergic consumer is protected against every possible reaction, however mild, but being realistic that excessive use of PAL, which would ensue, in fact undermines its purpose in minimising the number of reactions among susceptible consumers. The challenge is therefore to strike the right balance between reference doses that are highly protective of very reactive consumers, while ensuring that they do not result in such proliferation of PAL use that its credibility is undermined, allergic consumers are driven towards risk-taking behaviours, and the overall risk to them is in practice driven up (Figure 1).



**Figure 1: conceptual representation of the relationship between the extent to which PAL is used and how well it is observed.** The blue line shows how the expected number of reactions varies with the reference dose (a lower reference dose protects a higher proportion of the population). The green line shows the extent (%) to which PAL is observed according to the extent of its use. Where a high proportion of products bears a PAL statement, choice for allergic consumers, as well as credibility of PAL is reduced and so is observance.

PAL would therefore serve its optimal risk management purpose, if it were applied based upon reference doses that avoid the occurrence of reactions harmful to health by ensuring its circumspect, transparent and judicious use.

On a population basis, this judicious application of PAL would ultimately be most protective. It cannot avoid the occurrence of every mild reaction, but would be protective against life-threatening reactions, all by re-establishing the credibility of PAL and therefore offering a valuable and trustworthy risk communication tool to producers and consumers. A public health goal for PAL should be to minimise the number of reactions in the susceptible population. This requires

consideration not only of the limits that would be set as a basis for deciding whether or not PAL should be used, but also to socio-cultural factors such as the credibility of PAL, which is critical to its effectiveness and closely linked to the extent of its use, as well as other factors discussed above.

### Why do we need PAL to protect allergic consumers?

Food production operates under a range of technical, scientific, legal and economic constraints which bear upon the need to use PAL.

From a technical perspective, the extreme diversity of food products and equipment, as well as conflicting food safety requirements often impose the need for PAL. Thus, equipment may not be designed to meet evolving food safety or allergen considerations, hence the importance of HACCP and GMPs. Operating it to meet current standards, particularly in the absence of any “official” definition of such standards can therefore be extremely challenging (Stone and Yeung 2010). Effective means of removing allergens, such as wet cleaning are either impractical in some circumstances and could indeed lead to microbiological safety issues (e.g. dry mix operations) (Jackson *et al.* 2008, Röder *et al.* 2010). Effective means of controlling allergen carry-over, such as scheduling are also subject to other limitations, such as taste, colour, etc. Other conflicting requirements include minimisation of waste and more generally environmental impact.

Legal constraints can also impinge on the need to use PAL. For example, grain standards, which are the basis of world trade, allow for the presence of other grains than the one nominally sold (e.g. soy in wheat) in proportions that are potentially significant from an allergen perspective. However, the use of PAL does not exonerate the manufacturer from potential liability, if it is not accompanied by evidence of adherence to good manufacturing practices and an allergen management plan.

Economic constraints and those related to environmental impact also cannot be ignored. It is recognised that dedicated equipment and lines offer an effective solution but are only practicable in a limited number of situations and usually for one or two allergens, rather than all regulated allergens. Cleaning protocols are also limited not only by the resources needed, but by the downtime they impose. The absence of defined standards, applicable to all, may impose a potential competitive disadvantage in favour of less stringent protocols.

### Current situation in the EU (and beyond) - why isn't PAL working?

There is a growing volume of evidence that PAL as currently used in the EU, as well as elsewhere, fails to achieve its goal of protecting vulnerable consumers (Allen, Turner *et al.* 2014, Blom *et al.* 2018, Dunn Galvin *et al.* 2015, Michelsen-Huisman *et al.* 2018). This failure manifests itself in the extent to which it is disregarded by allergic consumers (Barnett *et al.* 2011, Cochrane *et al.* 2013, Soon & Manning 2017), which has the practical result of putting them at risk.

Research among allergic consumers reveals several reasons why PAL is failing, such as:

- proliferation of PAL in certain product categories;
- confusing terminology giving the impression of a risk hierarchy, unsupported by experimental evidence;
- lack of transparency over its use;
- lack of understanding of the framework in which PAL is used (e.g. an assumption that it is mandatory);
- inappropriate use, e.g. on products where it is unexpected;
- lack of agreed standards for application.



Clearly, some of these factors are very closely related to and influence each other and this is covered in detail in Madsen *et al* 2020. All these factors have stimulated a significant proportion of allergic consumers to undertake their own risk assessments, although without a sound evidence base, thereby putting themselves potentially at risk.

The efficacy of PAL is thus affected by the circumstances, reasons for and extent of its use, all of which affect consumers' perception of PAL and therefore their trust. Thus, the consequences of using PAL are not limited to what is communicated to the consumer (discussed later). Circumspect and responsible use of PAL is critical to successfully achieving its goal, as illustrated conceptually for the interrelationship between reference dose, the extent of the use of PAL and how well allergic consumers adhere to the warnings in Figure 1 above.

Enforcement authorities' attitudes to the use of PAL in the EU as well as beyond vary across countries. Some authorities consider that the presence of any detectable allergen which is not an ingredient, using any analytical technique, infringes the Food Safety Law (Regulation 178/2000) unless a PAL is applied. This zero-tolerance approach inevitably leads to ever-increasing numbers of products bearing PAL, as the sensitivity of analytical techniques continues to increase.

Other authorities use quantitative risk assessment to determine whether a product warrants a PAL statement, even though allergen might be detectable, in line with their own guidance to industry with regard to the application of PAL. However, there remains a lack of transparency concerning the limits which they use and how they take account of different variables in coming to a decision. It is also unclear whether, when using this approach, authorities have developed a common methodology. The diversity in PAL management decisions from different countries has been summarised in Madsen *et al.* (2020).

### 3. Legislative provisions of relevance for PAL

#### Regulation (EU) 1169/2011 (the FIC Regulation)

In order to enable consumers, particularly those suffering from a food allergy or intolerance, to make informed choices which are safe for them, the FIC Regulation makes it mandatory to provide information on the presence of these substances in foods and drinks (Article 9.1 (c)). Box I provides more details on this.

The FIC Regulation refers to PAL for the very first time and provides a legal basis for adopting EU rules in this respect. More precisely, Article 36(2) clarifies the requirements applying to voluntary food information (and, thus, also to PAL): this must not mislead the consumer, it must not be ambiguous or confusing for the consumer; and it must, where appropriate, be based on the relevant scientific data.

Furthermore, Article 36(3)(a) of Regulation (EU) 1169/2011 provides a legal basis for rules on voluntary information on the possible and unavoidable presence in food, due to cross-contamination, of substances causing allergies or intolerances (PAL). No deadline for adopting this act is set by the Regulation. As mentioned before, there are thus far no formal legal definitions of PAL in the EU.

#### **Box I: Mandatory allergen information**

Article 9.1(c) provides the legal basis for the mandatory provision of allergen information. Substances or products causing allergies or intolerances which are listed in Annex II to the Regulation should be clearly indicated. This list must be systematically re-examined by the Commission.

Article 21 explains the modalities of providing mandatory allergen information. Each ingredient or processing aid originating from a substance or product causing allergies or intolerances, which has been used in the manufacture or preparation of a food and it is still present in the finished product, even if in an altered form, must be:

- Indicated in the list of ingredients with reference to the name of the substance or product as listed in Annex II;
- Emphasized through a typeset that distinguishes it from the rest of the list of ingredients.

If no list of ingredients is provided, the substance or product causing allergies or intolerances must be indicated by means of “contains + [substance(s)/product(s)]”. When the name of the food clearly refers to the substance or product causing allergies or intolerances, it is not necessary to label the concerned substance or product.

Articles 9.1(c), 21, Annex II and 44.1(a) and 44.2 of the FIC Regulation lay down the requirements applicable to mandatory allergen information for both prepacked and non-prepacked foods. Although not directly applicable to PAL, these provisions must be taken into account when considering how to provide information on the possible and unintentional presence in food of substances or products causing allergies or intolerances with the overall aim to ensure clear, meaningful and consistent information to consumers.

## Regulation (EU) 178/2002 (the General Food Law)

The use of PAL has been historically based on the principles laid down in Regulation (EU) 178/2002 (the General Food Law). Article 5 of this Regulation states that food law must pursue, among others, a high level of protection of human life and health and the protection of consumers' interests. In order to achieve this objective, when appropriate, food law shall be based on risk analysis. Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner. Risk management shall take into account the results of risk assessment (Article 6).

Article 14 of the General Food Law refers to the general principle that unsafe food cannot be placed on the market. Thus, a legal obligation exists for food business operators to ensure that the food which is offered for sale to consumers is safe. In determining whether any food is unsafe, regard shall be given to the information provided to the consumer on the adverse health effects that the food can have, also taking into account the particular health sensitivities of a specific category of consumers (as they may be allergic or intolerant consumers). PAL is therefore relevant in order to ensure that safe food is offered to consumers and achieve the high level of consumer protection required by the Regulation.

Lastly, Article 16 of the General Food Law and Article 7 of the FIC Regulation provide that food information cannot be misleading for consumers; on the contrary, this must be accurate, clear and easy to understand for consumers.

## 4. The scientific basis for PAL

Why does the application of PAL have to be based on sound science?

PAL aims to convey to a vulnerable subpopulation that a hazard could be present in a food such as to pose a risk to some of that subpopulation. As discussed above, the efficacy and therefore value of PAL relies critically on its credibility and the lack of an agreed sound scientific basis to its current use undermines its value and the protection it can afford allergic consumers. PAL is about risk management and risk communication. Since PAL aims to convey a risk, its application should follow a thorough risk assessment which should be quantitative whenever possible.

The FIC Regulation highlights the importance of sound science as the basis for PAL: Article 36(2)(c) states that *“it shall, where appropriate, be based on the relevant scientific data”*. The last 10-20 years have seen considerable progress in the development of risk assessment approaches for allergens, as well as in the generation of data to do these risk assessments, as recognised in the EFSA Opinion (EFSA 2014) and has been built upon since then. These data and knowledge can thus provide the sound scientific basis for PAL and the means to perform quantitative risk assessments and propose quantitative limits (based on reference doses) for its application (Allen *et al.* 2014, Blom *et al.* 2019, Crevel *et al.* 2014, DunnGalvin *et al.* 2019, Madsen *et al.* 2020, Remington *et al.* 2020, Taylor *et al.* 2014, Westerhout *et al.* 2019, Wheeler *et al.* 2019 ).

### Allergen hazard characterisation and risk assessment

Hazard characterisation is one of the cornerstones of risk assessment and it is useful to review it briefly in the context of allergens.

Hazard characterisation for allergens has advantages compared to characterisation of both chemical and microbiological hazards, as it relies on human data. Animal to man extrapolation of the results of toxicological studies and consideration of various other qualitative and quantitative uncertainties associated with non-human toxicity data are unnecessary.

The need for human data also imposes ethical and practical constraints that limit both the amount and type of data that can be generated. Challenge studies rely on volunteers who can only be tested a limited number of times and may not be fully representative of the whole population allergic to a food. The availability of suitable clinics and trained personnel, as well as the prevalence of allergy to a particular food further limit the numbers that can be tested. All these factors delayed the availability of good quality data in adequate quantities.

Increasing amounts of data of ever better quality continue to become available on the relationship between minimum eliciting dose and frequency of reaction in the population allergic to a number of priority allergens. These data also demonstrate that minimum doses for the elicitation of allergic effects by food allergens exist at an individual level and thus also at a population level. Ideally, everyone at risk of reacting would be protected by setting the

limits above which PAL must be used lower than the lowest Minimum Eliciting Dose (MED) in the population. However, such an approach is currently unfeasible because the lowest MED has not been determined for any allergen, and furthermore, limits derived in such a way would probably be unattainable in most current food production practice. This would result in PAL being used on most products, in circumstances where the risk to the overwhelming majority was negligible. A more practicable solution would be to use an approach such as that proposed by the VITAL Scientific Expert Panel. Using available data and statistical modelling techniques, an international scientific expert panel set up as part of the Australia-New Zealand Voluntary Incidental Trace Allergen Labelling (VITAL) initiative proposed Reference Doses (RDs) for most of the European regulated allergens. VITAL 2.0 RDs were released in 2012 and the science underpinning them published in peer-reviewed journals in 2014 (Allen *et al.* 2014, Crevel *et al.* 2014, Taylor *et al.* 2014). The RDs resulted from a joint effort by TNO (Netherlands) and FARRP (US), facilitated by the VITAL Scientific Expert Panel (VSEP), to model human eliciting dose (ED)\* data for a range of food allergens. Where the data were of sufficient quality and quantity, the ED<sub>01</sub> was used as the basis for the RD. Where the data were insufficient to allow estimation of the ED<sub>01</sub>, the lower 95% confidence interval of ED<sub>05</sub> was used. The authors recognised that a very small minority might still be at risk of more significant reactions, although they would still benefit, and emphasised the need to communicate this clearly.

Whilst the VITAL approach and VITAL 2.0 RDs have been well received by stakeholders, and many food companies and authorities (ANSES, FSA) have endorsed their use for risk management purposes or considered them for more general enforcement purposes (Germany - Waiblinger & Schulze, 2018; Belgium - SciCom 2017), there has been a continued lack of consensus regarding regulation of PAL by authorities. Therefore, to further support and develop the use of RDs, further research has been undertaken that has generated additional data and new methodologies, including a stacked modelling averaging approach, resulting in the publication of updated population minimum eliciting dose distributions for use in risk assessment and release of VITAL 3.0 RDs (Allergen Bureau 2019, Houben *et al.* 2020, Remington *et al.* 2020, Westerhout *et al.* 2019, Wheeler *et al.* 2019, 2020).

From a scientific perspective, the current use of PAL reflects uncertainty about both the extent and nature of the risk posed by allergens, which can result in a hazard-based approach to risk management (i.e. if there is a possibility that allergen may be present, PAL is always used). However, the extent of the risk, in terms of the populations at risk and the distribution of MEDs (individual minimum eliciting doses) in those populations is now well understood, as discussed above. The nature of the risk, in terms of the type of reaction provoked by a defined dose of allergen has been more uncertain, although evidence indicated lower doses were associated with a lower probability of severe reactions (Rolinck-Werninghaus *et al.* 2012, Crevel *et al.* 2014). Research into the nature of reactions at different doses is emerging to support this. For example, in the Peanut Allergen Threshold Study (PATS) only 8/375 (2.1%) of subjects had a convincing objective reaction to the VITAL 2.0 ED<sub>05</sub> for peanut and all were considered to be mild (Hourihane *et al.* (2017). Additionally, the TRACE (Threshold Reactivity Clinical Evaluation) study has provided information on how individual minimum eliciting doses in peanut allergic adults are altered by co-factors (sleep deprivation and exercise) indicating that the proposed VITAL RD would not need adapting to account for this (Dua *et al.*, 2019).

Madsen *et al.* 2020 have reviewed and summarised the scientific progress in this area concluding that sufficient knowledge exists to implement a proposed framework for reaching consensus on a defined level of protection for allergic consumers, such that PAL can be

\*The Eliciting Dose (ED), where ED<sub>p</sub> refers to the dose of total allergen protein predicted to produce a response in p% of the allergic population, represents the dose of an allergen (ED<sub>p</sub>) at which a proportion of the allergic population would be likely to react to but, importantly, does not identify a dose below which no allergic individual would react. Thus, the ED<sub>01</sub> and ED<sub>05</sub> are the doses at which only 1% and 5%, respectively, of the allergic population would react with objective symptoms.



applied on the basis of transparent quantitative limits (based on reference doses). Madsen *et al.* hoped to trigger cross-stakeholder engagement and collaboration to define appropriate levels of protection for food-allergic consumers, calling upon Competent Authorities to champion and lead the activity, which FoodDrinkEurope also support.

\*The Eliciting Dose (ED), where ED<sub>p</sub> refers to the dose of total allergen protein predicted to produce a response in p% of the allergic population, represents the dose of an allergen (ED<sub>p</sub>) at which a proportion of the allergic population would be likely to react to but, importantly, does not identify a dose below which no allergic individual would react. Thus, the ED<sub>01</sub> and ED<sub>05</sub> are the doses at which only 1% and 5%, respectively, of the allergic population would react with objective symptoms.

Where food consumption data are available, additional assessments based on probabilistic modelling techniques can be used, which take account of the uncertainty and variability associated with each input variable. Because their output is a range of values generated from probabilistic distribution functions, they also negate the need to apply, often arbitrary, uncertainty factors to the risk assessment output (e.g. Rimbaud *et al.* 2010).

### The need for harmonised quantitative limits (zero tolerance is not zero risk)

When PAL was first introduced quantitative data on minimum eliciting doses, as well as on the size of the at-risk population hardly existed. Risk assessment was therefore extremely challenging in the face of this high degree of uncertainty. Not surprisingly, as there was little basis other than analytical limits of detection to base quantitative limits, those were often adopted by authorities as well as risk managers in industry in an approach designated “zero tolerance”. However, “zero tolerance” obviously cannot be equated with zero risk.

An even more serious consequence of the high level of uncertainty and lack of quantitative standards was that application of PAL lacked consistency across industry, with decisions effectively based on each risk manager’s understanding and perception of the risk. Therefore, every food manufacturer’s PAL statement potentially referred to a different level of risk/level of protection, limiting the capacity of PAL to communicate effectively risk to consumers, with the consequences already described earlier.

A prerequisite to restoring the credibility and value of PAL is therefore to assure consistency of its application, such that a PAL statement indicates a defined level of risk. Quantitative limits are a critical element in defining such levels of risk at a population level. The data and techniques have already been developed and indeed deployed in initiatives such as the VITAL Program. Clearly, a zero-tolerance approach cannot provide this assurance because of the variability in the capacity of assays to detect and quantify allergens of interest, particularly given the extreme diversity of food matrices. Furthermore, it is based on detection limits rather than dose, which is acknowledged to be the appropriate metric. More fundamentally, a zero-tolerance approach presents ever-changing standards, and therefore works against transparency and the establishment of generally agreed common standards, which are critical to restoring the credibility of PAL.

### The role and limitations of analytical methodologies

A necessary prerequisite of the practical application of PAL for all stakeholders, particularly producers and authorities, is the availability of reliable and practical analytical methods. Producers need to validate analytically and subsequently verify their allergen management measures. Authorities rely on analysis to verify whether products conform to provisions on food safety and information regarding allergens.

Currently, the most commonly used analytical technologies are based on antibody recognition (ELISA – Enzyme-Linked Immunosorbent Assay) and DNA sequencing (PCR –

Polymerase chain reaction. Both these technologies have limitations with regard to sensitivity, accuracy and specificity, which makes their deployment challenging. Analytical results can vary significantly, depending on the methods, equipment and/or test-kits used, the product matrices as well as the laboratories operating the analysis. The lower the values analysed, the greater the possible error rates.

The scientific analytical community recognised these issues as attested by publications such as Johnson *et al.* (2014) from the EuroPrevall consortium. EFSA also acknowledged these issues in its 2014 Opinion. While these issues affect both zero tolerance and risk-based approaches, to verification and enforcement, they are particularly pertinent to quantitative approaches. One particular aspect, but by no means the only one, noted by both the EuroPrevall consortium and EFSA was the lack of certified reference material and methods for the effective quantification of all allergens as listed in Annex II of EU Reg 1169/2011. In response there has been significant work undertaken and progress made in addressing these issues, though challenges do still remain (Holzhauser *et al.* 2020).

Effective implementation of quantitative limits (based on reference doses) will require development and implementation of methods and protocols capable of reliably and accurately detecting allergens at relevant concentrations

#### Further considerations in the application of PAL

Protection of allergic individuals is a shared responsibility among all stakeholders, which necessitates a clear communication about what the use of PAL implies. In particular, it needs to be clear that its application is aimed at foods for normal consumption, with the implication that there may be a very small number who cannot be protected totally against reactions given current knowledge and practice. Risk assessment must therefore also take account of stakeholder understanding of PAL and behaviours in relation to it.

#### Consumer and health care professionals (HCP) perspectives on PAL and relevance to risk

Stakeholder perspectives on PAL, including those of allergic consumers and HCPs, were described as part of the iFAAM project. For consumers, the use of PAL is seen as inconsistent and lacking transparency, not helped by misunderstanding about its legal status (voluntary vs mandatory). This perception is not helped by a poor understanding of PAL statements by many consumers and some healthcare professionals (HCPs) who advise them. Consumers with food allergies respond by being very selective in their food purchases, which gives rise to extra costs, anxiety, and impaired quality of life. The proliferation of PAL, together with its appearance on unexpected products, has led to a loss of credibility (Barnett *et al.* 2011, DunnGalvin *et al.* 2015, 2019a, 2019b, Soon & Manning 2017) and reduced observance by consumers. There is a clear relationship between the extent to which PAL is used and the extent to which it is observed by consumers. In December 2019 the European Federation of Allergy and Airways Diseases Patients' Associations (EFA) published the final report of the Food DETECTives project focusing on the quality of life of people with food allergies in Europe. Within this report a key recommendation for regulators is to establish RDs and a harmonized quantitative risk-based approach to applying PAL.



The attitudes of HCPs have not been as extensively studied as those of consumers with food allergies. Nevertheless, they often mirror those of allergic consumers in terms of their interpretation of PAL statements as a hierarchy of risk. Less than 60% HCPs recommended total avoidance of products with PAL, a message at variance with the intent of industry risk managers (Turner *et al.* 2014). Those working as allergy specialists were even less likely to recommend stringent avoidance, possibly because of their awareness of the impact of limited choices on their patients' lives or because of lack of knowledge of voluntary industry systems such as status of PAL (Turner *et al.* 2015). Avoidance advice was differentiated according to medical history, with more stringent avoidance advised for those with co-existent asthma, prior anaphylaxis or previous reaction to a tiny amount of allergen.

### The twin roles of PAL: risk communication and risk management

PAL has two closely linked roles: risk communication and risk management. The communication element is to inform at-risk consumers that the product in question could precipitate a reaction. It is critical that those consumers understand the meaning of the warning, rather attempt to do their own risk assessment, for which they do not have the right information. It therefore also is incumbent on manufacturers and suppliers of products to understand how consumers interpret such warnings, as well as to be clear about how they want their message to be interpreted. The message should thus be clear and indicate that the food producer's considered judgement, based on a risk assessment, is that the product is not suitable for people with the relevant allergies. The basis of that judgement should also be clear, hence the need for agreed, consistent limits, as discussed in the preceding paragraph.

While clarity and transparency are critical to PAL, they are also required for the converse situation, i.e. when PAL is not used, as already discussed. Thus currently where no PAL statement is present, this may mean one of two things: (1) the manufacturer has performed a risk assessment and deemed the product not to require PAL because the risk is negligible (because the allergen content per portion is below the reference dose) or (2) the manufacturer has not done a risk assessment, e.g. owing to lack of understanding, knowledge or awareness of unintended allergens. Under current circumstances, where there is no common standard for the application of PAL, the risk associated with the absence of PAL (as well as with the use of PAL) can therefore vary considerably. The nature and magnitude of the risk where no PAL is used (scenario 1) still need to be accurately and clearly communicated so that allergic consumers can make an informed decision. This requires the use of multiple channels of communication, such as websites, carelines, etc., not just the label. However, as PAL is currently voluntary, a product without PAL could also be one for which no risk assessment has been performed (scenario 2). Such a product would carry an unquantifiable risk to allergic consumers, rather than one to which an upper limit has been set.

Risk management, i.e. the minimisation of allergic reactions, is the second role of PAL and it will be obvious from the foregoing discussion that it can only be discharged successfully if communication of the PAL message is successful. A pre-condition to success is that the PAL is observed by (ideally) all at-risk consumers, but this cannot be achieved solely by setting limits without regard to the implications for the proportion of products that would be affected. The right balance needs to be struck between the extent to which PAL is used and any quantitative limits which are set, as already discussed. This is likely to be an iterative process, and of course, will be influenced by the efficacy of allergen management

procedures. Ward et al. (2010) defined what those levels of protection could mean in practice. Foods not bearing PAL as a result of risk assessment exercise, although not specifically designed for people with allergies, would not provoke adverse reactions in the vast majority of allergic individuals. Allergen management of cross-contact control would be well-managed. The allergen may be analytically detectable, but the amount is below the action level (based on reference dose).

## 5. Implementation of PAL: towards more consistent allergen risk communication

As mentioned in the previous section, PAL has two closely linked roles: risk management and risk communication. Allergens should be managed to avoid their unintentional presence in products. As discussed above, FoodDrinkEurope has developed [Guidance on Food Allergen Management for Food Manufacturers](#) in order to minimize the unintentional presence of allergens in products and manage the risk deriving from this presence. Following completion of the risk assessment and elimination or reduction of the risks where possible through risk management, a decision on whether or not PAL is appropriate then needs to be made.

Effective and clear risk communication is crucial to ensure that PAL fully plays its role in protecting allergic consumers. As said before, the inconsistent and, in some cases, unclear use of PAL, has reduced consumers' trust and confidence in these warnings and weakened its role in informing allergic and intolerant consumers. PAL should be communicated to consumers in a clear, meaningful, consistent way, in order to enable them to correctly understand the risk and make informed choices when purchasing foods for them and their families.

This section covers some aspects that, in FoodDrinkEurope's view, can help moving towards more consistent risk communication.

### Which substances and products should be covered by PAL?

It is important that the scope of PAL is clarified in order to ensure consistent information to consumers across the EU. In this respect, it is the industry's understanding that **PAL should cover any substance or product causing allergies or intolerances which is listed in Annex II to the FIC Regulation.**

### Should PAL be clearly distinguished from the allergen information given in the list of ingredients?

As explained, the FIC Regulation requires substances or products causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form, to be indicated in the list of ingredients. It follows that **labelling should clearly distinguish between the allergen information provided in the list of ingredients and precautionary allergen labelling for those allergens which may be present.**

### Expression and presentation of PAL

A consistent approach to the expression and presentation of PAL would facilitate consumers' understanding and thus ensure the protection of allergic and intolerant consumers.

#### i) Wording for precautionary allergen statement

There is no legally prescribed wording for PAL. However, the FIC Regulation requires food information to be given in such a way as not to be misleading, ambiguous or confusing for

the consumer. On the contrary, food information must be accurate, clear and easy to understand for the consumer.

FoodDrinkEurope considers that the statement used for PAL should take into account these general requirements and also be brief, simple, and easily translatable into the different EU languages.

The preferred single harmonised statement for precautionary allergen labelling recommended by FoodDrinkEurope is: “may contain [allergen]”. “May contain [allergen]” is a well-known indication for consumers as it has been widely used for many years now. In order to allow operators to progressively adapt their labels to this single statement, a sufficiently long transition period is a prerequisite.

#### ii) Location of wording

With the entry into force of the FIC Regulation, consumers will get used to check the list of ingredients to see whether the food contains substances or products causing allergies or intolerances. Therefore, **when feasible, the PAL statement should be placed in close proximity to the ingredient list** and be followed by a list of the products or substances for which an appreciable risk of cross-contamination exists based on quantitative risk assessment.

In the absence of a list of ingredients, the FIC Regulation states that the indication of the allergens shall comprise the word “contains” followed by the name of the substance or product listed in Annex II. In such a case, it is recommended to place the PAL statement in close proximity to the “contains” statement.

The Regulation foresees a derogation from the obligation to provide information on allergens, when the name of the food clearly refers to the substance or product concerned (e.g. milk, butter). In such a case, if an appreciable risk of allergenic cross-contamination exists, PAL is still recommended. It is up to the operator to decide where to place the PAL statement on pack, provided that this is clearly legible and visible for consumers.

The above considerations should also be valid in cases where foods are marketed by means of distance selling.

#### iii) Other legibility aspects

Other legibility aspects could also be addressed in order to enhance the effectiveness of PAL:

- General principles: in line with the general requirements applying to mandatory food information, **precautionary allergen information should be easily visible, clearly legible and, where appropriate, indelible**. It shall not in any way be hidden, obscured, detracted from or interrupted by any other written or pictorial matter or any other intervening material.
- Font size: The FIC Regulation requires a minimum font size for mandatory allergen information. However, the use of a minimum font-size is not obligatory for PAL. Notwithstanding this, **the rules applying to mandatory food information with regard to the minimum font size should also be followed for PAL statements**.

The use of a font size bigger than the one chosen for the list of ingredients is not recommended, as this may induce allergic/intolerant consumers to focus more on the PAL statement (which informs about the possible presence of allergens) than on the list of ingredients (which informs about the certain presence of allergens).

- ***Emphasis:*** in case of mandatory allergen information, the FIC Regulation requires the name of the substance or product causing allergies or intolerances to be emphasised in the list of ingredients, for example by means of the font, style or background colour. However, there is no legal obligation to emphasise the substances or products within a PAL statement (which, as mentioned above, should be clearly distinguished from the list of ingredients). Nevertheless, **operators can voluntarily choose to emphasise the substances or products causing allergies or intolerances to underline that there is a risk that these are present in the food** (e.g. ‘may contain: **milk**’).

The above considerations on legibility should also be valid in cases where foods are marketed by means of distance selling.

#### [PAL for non-prepacked foods](#)

The FIC Regulation requires information on substances or products causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form, to be given also for non-prepacked foods.

Member States may adopt national measures concerning the means through which mandatory allergen information is to be made available for non-prepacked foods.

Many Member States have already adopted such rules, often allowing for mandatory allergen information to be given orally provided that certain conditions – which vary depending on the country – are fulfilled.

Regard should be taken to these national rules, which might also refer to PAL.

It should be noted that PAL for non-prepacked foods would in most cases require consideration of other factors (handling environment, etc.) which would require development of further guidance.

## Summary Recommendations on PAL

FoodDrinkEurope would like to see a defined framework for the application of PAL which meets the requirements of Article 36(2) of the FIC Regulation, namely:

- Clear: a single statement with a single meaning, easy to translate into EU languages, i.e. “may contain [allergen]”
- PAL should not be misleading: it should only be applied where a defined, appreciable risk has been identified, including (where it is relevant and possible) through a quantitative risk assessment.
- PAL should be applied based on transparent quantitative limits derived using the most up to date, relevant, peer-reviewed, and robust scientific data.
- When Quantitative Risk Assessment (QRA) relies on analytical data, it should be noted that sampling procedures and analytical methods have limitations regarding sensitivity, specificity, and accuracy. The applicability of analytical data as an input into QRA requires harmonization.
- In addition, consumers need to know that products have been through a risk assessment and that the presence or absence of PAL is a consequence of that process.

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## Annex I

### **FoodDrinkEurope Statement on Precautionary Allergen Labelling<sup>2</sup>**

- Allergens are common constituents of consumer products with valuable functional and/or nutritional attributes which can cause adverse, even life-threatening, reactions in susceptible individuals. The unintended presence of small amounts of certain allergens which are not part of a product's formulation as a result of manufacturing and other operations (and which are therefore not labelled) can pose a risk to allergic consumers.
- Progressively over the last decades, the food industry has made significant efforts in reducing the unintended exposure of allergic consumers to major allergens. In particular, FoodDrinkEurope has developed and published comprehensive Guidance on Allergen Management for Foods for practical use by operators, which encourages a shift from the current hazard-based approach to a risk-based approach.
- While current practices in the management of major allergens have increased the safety of food products for allergic consumers, the lack of an agreed approach to quantitative risk assessment has led to divergent standards applied by different manufacturers, as well as divergent approaches by enforcement authorities across Europe. The subsequent increase in precautionary allergen labelling, in turn, has resulted in reduced amounts of foods that allergic/intolerant consumers can choose from.
- FoodDrinkEurope considers that precautionary labelling has an important role to play in protecting allergic consumers, but in order to fulfill that role, it needs to be applied consistently, in a circumspect manner and in accordance with defined and agreed principles. FoodDrinkEurope therefore supports a risk-based approach to major allergen management and the application of precautionary 'may contain' labelling.
- Precautionary labelling should only be used where a thorough risk assessment demonstrates that there is a real risk of a significant but unavoidable amount of allergen in the consumed product due to cross-contact within the ingredient supply chain or from manufacturing operations. Although we recognize that following a risk-based approach may cause reactions in a very small proportion of susceptible individuals, this approach will minimize risk to consumers with food allergies, while maximizing their food choices.
- To clarify when precautionary allergen labelling applies and to further facilitate its optimal use for consumers, FoodDrinkEurope supports the development of EU-wide harmonised approach with transparent and applicable limits based on latest scientific evidence and guidance on appropriate forms of wording for labelling statements. This will allow industry to consistently apply precautionary labelling and clearly communicate the allergen status of a food.
- Given the globalisation of the food chain FoodDrinkEurope recognises that the development of a harmonised global risk-based approach would be optimal and also supports activities aiming to achieve this.

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<sup>2</sup> For ease of reference, precautionary allergen labelling referred to in this statement refers to the labelling of substances and/or products causing allergies or intolerances in accordance with Regulation (EU) 1169/2011 on the provision of food information to consumers.