FOODDRINK EUROPE

Precautionary Allergen Labelling (PAL)

A risk-based approach including Quantitative Risk Assessment (QRA)

Version 3, October 2024

Executive summary

Allergens as ingredients have been regulated in the EU since 2005. Due to the realities of agricultural and 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 a tool to communicate, and therefore help manage, this risk.

In recent years understanding of the issues associated with PAL has improved, and there has been the development of evidence-based approaches with the aim of assuring appropriate application of PAL across the food industry. Despite much progress, there is evidence that PAL as it is currently applied is still confusing for allergic consumers. This diminishes a valuable and necessary risk management tool and places allergic consumers at risk.

The EU Food Hygiene Regulation (Regulation (EC) No 852/2004) lays down provisions for food allergen management throughout the entire food chain, emphasising the importance of a preventive approach. The Commission Notice (2022/C 355/01) on "The implementation of food safety management systems covering Good Hygiene Practices and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses," provides guidance on best practices applicable to food allergen management across the entire food chain.

The issues associated with PAL can be attributed to several factors, which are covered in detail in this document, particularly the application of a diversity of approaches across food businesses and absence of generally agreed quantitative limits. Furthermore, there is a lack of harmonised requirements, or even conflicting ones, not only across Member States in Europe but also globally. This adds to confusion and could create trade barriers. Harmonising PAL across the EU is a crucial step towards ensuring food safety, protecting consumers with allergies, and promoting fair trade practices.

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. In addition to these advancements, this version of the paper also incorporates recent

Codex and related developments, including the findings of an Ad hoc Joint FAO/WHO Expert Committee, which was tasked with establishing reference doses (RfDs) for priority allergens, and making other recommendations on PAL.

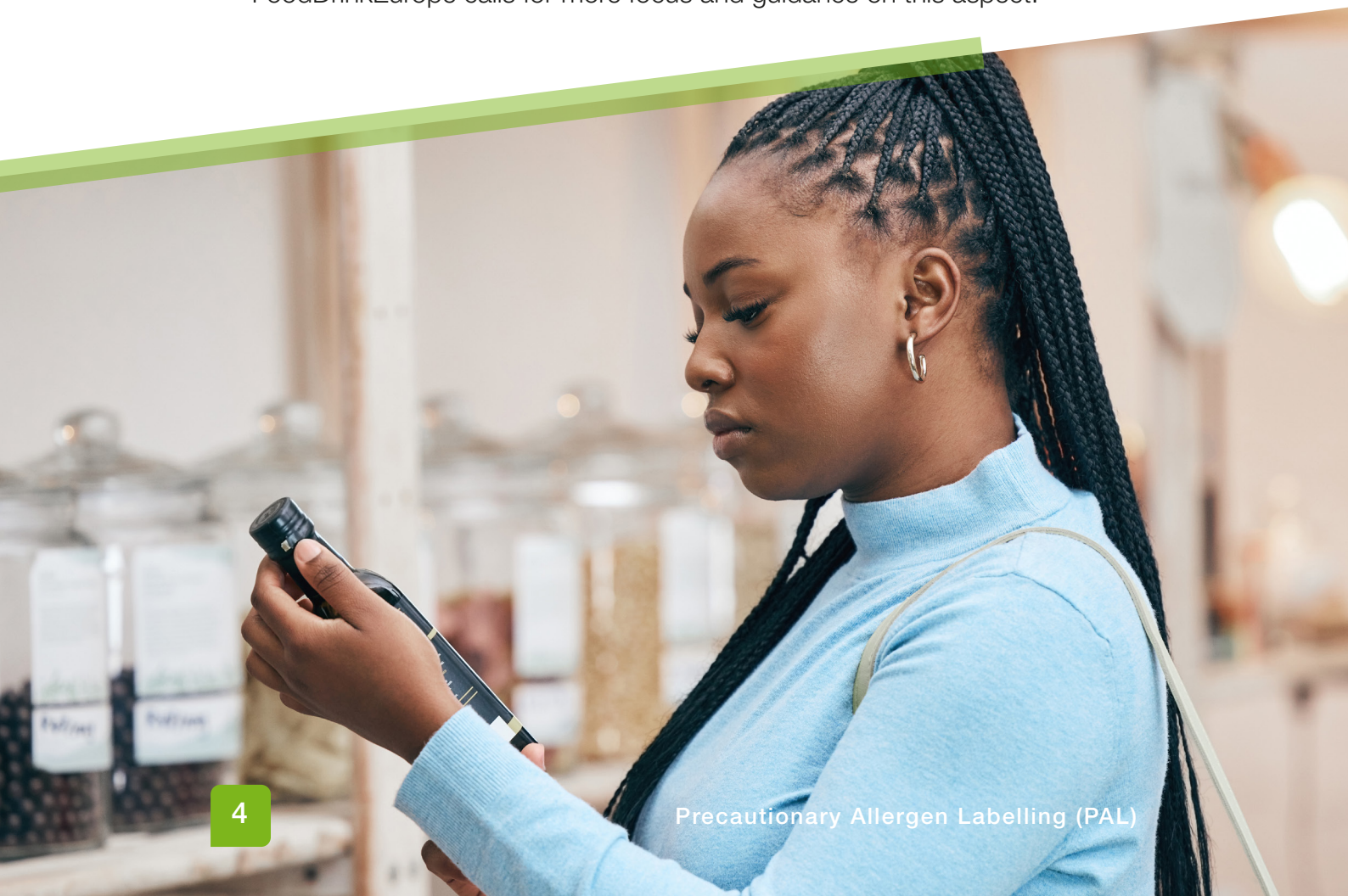
Previous versions of this paper have described how adoption of quantitative limits (based on RfDs) could form part of an EU-wide approach aligned with the principles enunciated in Article 36 of the FIC Regulation, which aligns with the general recommendations of the FAO/WHO Expert Committee on Risk Assessment of Food Allergens. FoodDrinkEurope very much welcomes the fact that these recommendations are now available, on the basis of which a worldwide harmonisation of PAL use can be discussed. However, there are some aspects of the recommendations that FoodDrinkEurope does not fully support in their current form, which require clarification.

In brief, it is still the position of FoodDrinkEurope that a science-based approach to PAL, based on a QRA would greatly strengthen the protection of allergic consumers by making PAL meaningful and transparent. It would also benefit the European food industry by providing an important element of a comprehensive framework ("level playing field"), which would also strengthen the single market. However, it needs to be recognised that PAL should be based on a multipronged approach utilising a range of risk management tools that may, when appropriate, include QRA.

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, and incorporates (but is not limited to) the following elements:

- PAL should be clear: a single statement with a single meaning, easy to translate into EU languages. The statement "may contain [allergen]", as recommended for years by FoodDrinkEurope and also supported by consumer organisations, has proven its worth.
- 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 (QRA).
- A QRA should be applied based on transparent quantitative limits (RfDs) derived using the most up to date, relevant, peer-reviewed and robust scientific data.

- Consumers need to be confident that products have been through a risk assessment and that the presence or absence of PAL is a consequence of that process. However, FoodDrinkEurope does not support the use of a symbol to indicate a risk assessment has been done (as recommended by the Expert Committee). Such a symbol is not required for any other area of food safety, and potentially will increase risk and create confusion amongst consumers.
- FoodDrinkEurope recognises the foundational value of ED05 RfDs for application of PAL as recommended by the Expert Committee, and we support that PAL is prescribed when the unintended allergen presence (UAP) exceeds this value. Nonetheless, FBOs may need to deviate from their use and apply PAL when the UAP is ≤ED05 values, when detailed risk assessments indicate that this is required to meet a consumer safety goal. FoodDrinkEurope therefore supports the use of ED05-based RfDs as recommended by the Expert Committee provided these are described as part of a more flexibly worded Principle.
- As the purpose of PAL is ultimately to communicate risk to consumers, ensuring the public correctly understands the message is critical. FoodDrinkEurope also supports that any new guidance should be accompanied by education / information programs to ensure understanding and appropriate use by consumers, health care providers and FBOs. However, it is not clear how this can be achieved. Therefore, FoodDrinkEurope calls for more focus and guidance on this aspect.



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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 manage this risk, when control measures are not able to mitigate it.

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 (QRA) 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, to restore its value and maximise consumer protection, an urgent need exists for the adoption of a comprehensive and consistent EU approach to 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 QRA, guided by the principles set out in the EU Regulation[1]. 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.

1 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 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 PAL 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 FoodDrinkEurope, ILSI[2] and the UK Food Standards Agency (UK FSA).

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

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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.

PAL 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 RfDs 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 RfDs 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).

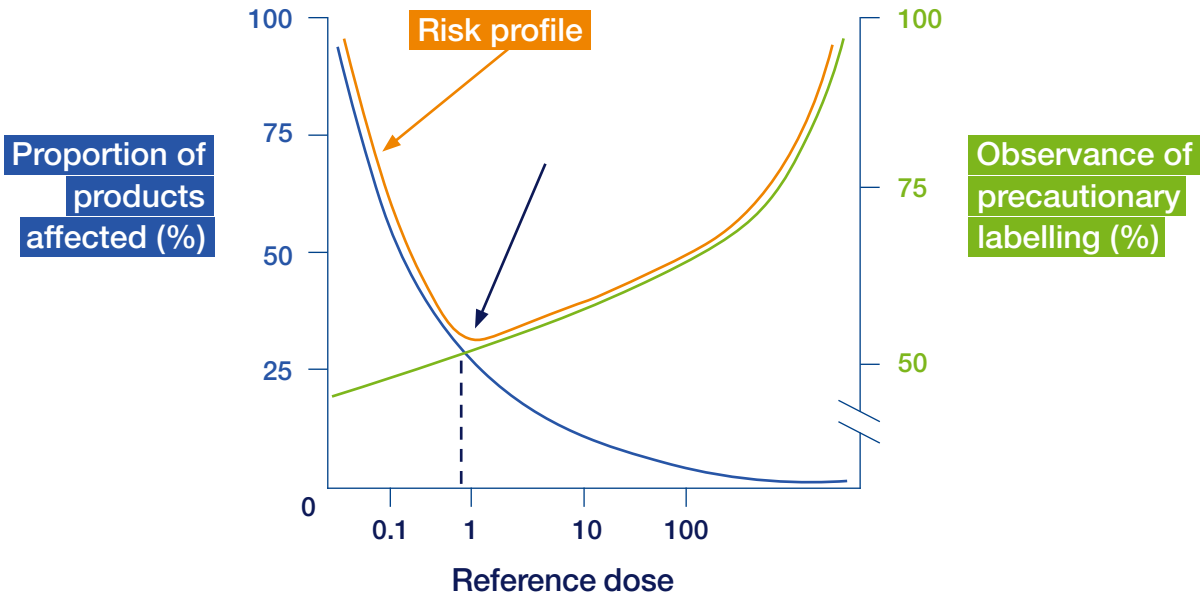

Figure 1: conceptual representation of the relationship between the extent to which PAL is used and how well it is observed.

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 RfDs 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 the need to meet all safety standards, often leads to the application of 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 management 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) – what is missing?

There is evidence that PAL, as 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).

Research among allergic consumers revealed several reasons for this, such as:

- proliferation of PAL in certain product categories;
- confusing terminology giving the spurious impression of a risk hierarchy;
- 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 disregard PAL (Barnett et al. 2011, Cochrane et al. 2013, Soon & Manning 2017), and 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.

Allergen management is an integral part of food safety management by FBOs, and as understanding of the issues associated with PAL has improved, so have the approaches used for its application across the industry. This is also reflected in the publication of the guidance on food allergen management (version 2), such as the one developed by FoodDrinkEurope, and publication of earlier versions of this document. This means that an increasing number of FBOs across the EU have been implementing a risk-based approach to PAL for several years, applying QRA where possible and utilising RfDs. Due to both varying levels of understanding and capability among FBOs, as well as the ongoing evolution of scientific

knowledge that leads to changes in recommended RfDs, different approaches are used across the industry.

In addition, the acceptability by enforcement authorities' to the use of PAL in the EU, as well as beyond, vary across countries (although the risk-based approach is nowadays widely accepted in Europe). However, some authorities still consider that the presence of any detectable allergen which is not an ingredient, using any analytical technique, infringes the Food Safety Law (Regulation 178/2002) 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 QRA 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).

Most recently, steps have taken by the Codex Alimentarius Commission in this space, and these and other related developments are detailed in Sections 4 and 5.

3. EU legislative provisions of relevance for PAL

Food Hygiene Regulation (Reg. EC No 852/2004) and Commission Notice (2022/C 355/01) on "The implementation of food safety management systems covering Good Hygiene Practices and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses"

The Food Hygiene Regulation (Reg. EC No 852/2004) lays down provisions on food allergen management in primary production and subsequent stages, highlighting the need for a comprehensive preventive approach along the whole food chain.

The Commission Notice (2022/C 355/01) on food safety management systems also states that food allergens must be considered as part of the food safety management system. Both the Food Hygiene Regulation and the Commission Notice highlight that good hygiene practices are needed to prevent or reduce the unintentional presence of substances causing food allergies or intolerances due to cross-contamination.

Regarding Precautionary Allergen Labelling (PAL), the Notice explains that according to Regulation (EU) No 1169/2011, information on the possible and unintentional presence in food of substances or products causing allergies or intolerances may be provided on a voluntary basis, while ensuring the food is safe in accordance with provisions laid down in Regulation (EC) 178/2002. Such voluntary information must not be misleading or confusing to consumers and must be based on relevant scientific data.

Furthermore, it is stated that: Precautionary allergen labelling (PAL) should only be used where a preventive strategy cannot be efficiently implemented and the product may present a risk to allergic consumers. PAL is a separate statement next to the list of ingredients and should be based on the findings of an appropriate risk assessment, conducted by the food manufacturer, to evaluate the possible and unintended presence of allergens. Allergens (potentially) present in the product via cross-contamination should not be included in the list of ingredients as they are not intentionally added and are no part of the formula of the product. Such labelling should never be used as an alternative to preventive measures.

FoodDrinkEurope is aligned with the expectations in the Notice related to allergen management. PAL shall only be applied where a defined, appreciable risk has been identified, including (where it is relevant and possible) through a QRA to evaluate the possible and unintended presence of allergens.

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
- Emphasised 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, Houben et al. 2020, 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 not be measurable by available analytical methods and would be unattainable in most current food production practices. This would result in PAL being used on most products wherein there was feasibility of cross-contact, 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 RfDs for most of the European regulated allergens. VITAL 2.0 RfDs 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 RfDs 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_{01} was used as the basis for the RfD. Where the data were insufficient to allow estimation of the ED_{01}, the lower 95% confidence interval of ED_{05} 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 RfDs were well received by some stakeholders, and many food companies and some authorities (ANSES, FSA) 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 RfDs,

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 RfDs (Allergen Bureau 2019, Houben *et al* 2020, Remington *et al* 2020, Westerhout et al 2019, Wheeler *et al* 2019, 2020). These updated reference doses were discussed in a BfR opinion (Bundesinstitut für Risikobewertung, 2020). Other groups have proposed alternative approaches to standardise the application of PAL, such as the proposal from Zuberbier et al (2021),that 0.5 mg of protein/100 g of processed food could be a threshold for voluntary declaration of food allergen traces, in conjunction with a quality label. This proposed approach was supported by several medical professionals but reservations were also raised within the allergen expert community (Turner et al. 2022b) regarding the proposal. Also to note is that Switzerland requires any regulated allergen, whether ingredient or not, present at concentrations above 1000 ppm to be declared. Japan has also defined a threshold (10 µg per g of food (10 ppm)) above which all regulated allergens (whether deliberately added or not) must be declared in the ingredient list. Whilst the presence of allergens below 10 ppm does not require labelling in Japan, alternative PAL statements may be used (Madsen et al 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 there is evidence for some allergens, indicating lower doses are associated with a lower probability of severe reactions (Rolinck-Werninghaus *et al* 2012, Crevel *et al* 2014). Research aiming to validate estimated ED values and providing insights into the nature of reactions at different doses has also emerged. For example, in the Peanut Allergen Threshold Study (PATS) only 8/375 (2.1%, so less than the predicted 5%) of subjects had a convincing objective reaction to the VITAL 2.0 ED05 for peanut and all were considered to be mild (Hourihane *et al* (2017). For cow's milk a single-dose challenge study generated data that supports an estimated ED05 of 0.5 mg protein (7% of the patients ((5% CI 3.7–11.9%) experienced objective symptoms at 0.5mg) , which was lower than the estimated ED05 of 2.4mg (95% CI 1.3-5.0) reported by Remington et al 2020 and Houben et al 2020 (Turner et al (2021). Additionally, the TRACE (Threshold Reactivity Clinical Evaluation) study has provided information on how individual minimum eliciting doses in peanut allergic adults are altered by two co-factors (sleep deprivation and exercise) indicating that the proposed VITAL RfD would not need adapting to account for this (Dua *et al*., 2019). Data on the impact of co-factors is however still limited, only

available for adults and for a few allergens, and either self-reported questionnaire data (Versluis et al 2016 and 2019) or an investigation of a single co-factor (sleep deprivation or exercise) at a time in a clinical setting (Dua et al 2019) when Versluis et al (2016 and 2019) indicate that in almost half of reported reactions more than one co-factor can be involved.

The quantity and quality of MED and severity of reaction data varies across allergens, and recognising this it has been suggested that peanut, the allergen for which there is the largest dataset available, could be used as a reference allergen for hazard characterisation (Turner et al 2022).

Madsen *et al.* 2020 reviewed and summarised the scientific progress in this area available at that time, 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 applied on the basis of transparent quantitative limits (based on RfDs). 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 undertake the activity together with the stakeholder community, which FoodDrinkEurope also support. As mentioned, most recently, steps have taken by the Codex Alimentarius Commission in this space, and these and other related developments are detailed later in this section and section 5.

Operational use of RfDs requires their conversion to action levels (mg of total protein from the allergenic source per kg of food), based on data on food consumption/ intake per eating occasion. Whilst a deterministic approach can be applied drawing on available data on product serving sizes and food intake, additional assessments based on probabilistic modelling techniques can also 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 (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 risk that is above a defined level. 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 the metric used to understand individual and population sensitivity. More fundamentally, a zero-tolerance approach presents ever-changing standards, and therefore works against transparency and the establishment of generally agreed common and safe standards, which are critical to restoring the credibility of PAL.

Latest global developments

In 2021 the Codex Committee on Food Labelling (CCFL) started a review of provisions relevant to allergen labelling, including developing guidance on the use of PAL, and the FAO/WHO initiated an Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens in response to Codex requesting scientific advice to support this.

For the consultation, an Expert Committee was established to provide specific scientific advice on the following 5 task areas:

1. Review, validate and, if necessary, update the list of global priority allergens in section 4.2.1.4 of the General Standard for the Labelling of Packaged Foods (GSLPF)
2. Establish threshold levels in foods of the priority allergens
3. Review and evaluate the evidence in support of precautionary labelling
4. Develop a process for the consideration of future exemptions of highly refined foods and ingredients derived from or containing a priority allergen food
5. Review and establish threshold levels for specific tree nuts (Brazil nut, macadamia nut or Queensland nut, pine nut), soy, celery, lupin, mustard, buckwheat and oats.

All reports have been published (FAO and WHO 2022a, 2022b, 2023a, 2024 and 2023b respectively) and a consultation process is underway to incorporate findings into Codex guidance.

In brief, based on a review of the available scientific data (including that detailed earlier in this section) the Expert Committee recommended that "for all priority allergens, the safety objective[3] would be met by starting the definition of RfD at the ED05[4]….". Furthermore, the Expert Committee made it very clear that the recommended RfDs were not appropriate, nor intended to be used to define 'free-from' labelling.

Aligned with these activities, some regulatory bodies have also taken steps to review the recommendations and their provisions for PAL.

3 The Expert Committee agreed on a safety objective from a public health perspective, which was "to minimise the probability of any clinically relevant objective allergic response, (as defined by dose-distribution modelling of minimum eliciting doses [MEDs]) to a point where further refinement does not meaningfully reduce public health impact."

4 The ED05 is the eliciting dose at which it is estimated no more than 5% of the allergic population would have an objective reaction.

For example, in August 2022, The Scientific Committee of the Belgian Federal Agency for the Safety of the Food Chain (FASFC) issued an opinion (based only on the summary document), recommending use of the reference doses (RfDs) recommended by the FAO/WHO.

Then in 2023, the UK FSA, as part of a full roadmap of activities on PAL, requested peer review of the Expert Committee report on thresholds. The review by a UK Committee on Toxicity (COT) subgroup (published September 2023) concluded that there were uncertainties associated with the data upon which EDs are based and that there was "insufficient evidence to demonstrate that using RfDs based on ED05, as opposed to ED01 values would not significantly impact on public health".

In 2024 the Dutch authority (NVWA) working together with the national food industry association (FNLI) issued guidance on cross-contact of allergens to support a Regulation that would come into force on 1 Jan 2026 linking the presence of PAL on food labels to the RfDs derived by the FAO/WHO Expert Consultation.

Additionally, the German authorities published updated assessment values for the evaluation of analysis results for undeclared allergens for official food control laboratories in March 2024. The updated assessment values are also based on the Expert Committee recommendations.

Some academic papers have also been published commenting upon the Expert Committee recommendations. For example, in a paper covering various aspects of PAL La Vieille et al (2023) also discussed perspectives for a better use of PAL on the basis of the FAO/WHO recommendations, stating that "it is expected that their (allergic individuals) food choices could increase". At the same time it is noted in the publication that "With the approach suggested by the FAO/WHO WG , concerns still remain for the 5% of allergic individuals who are very low dose reactors (i.e. below ED_{05}). Their QoL might not be improved because the absence of PAL on a product could mean either an absence of allergen or an amount of allergen that would still be sufficient to trigger allergic reactions". The authors do recognise severe anaphylaxis would likely be a rare event but do raise the question of what options there would be for these individuals, including discussion of the lack of regulation of 'allergen-free' claims and potential role of immunotherapy. These questions, amongst others, are also being explored by the World Allergy Organisation (WAO) under the Act Up! initiative at the time of writing, with the aim of producing a consensus paper.

Most recently the Allergen Bureau announced VITAL 4.0. After discussion with stakeholders including industry, clinicians and consumer advocacy groups, the VITAL Program will adopt ED05-based RfDs and Risk Management Values, as recommended by the FAO/ WHO Expert Committee, as the default setting from August 2024. The Allergen Bureau also recognises that there may be occasions

when it may be suitable or necessary to consider the labelling outcome if an ED01-based value is used and therefore, in the Action Level Grid Report functionality of the online tool, ED01-based outcomes are available for comparison purposes.

The Expert Committee also drew conclusions and made recommendations in relation to analytical methods and application of PAL, which are covered in the following sections of this document.

The role and limitations of analytical methodologies

A prerequisite of the practical application of PAL for all stakeholders, particularly producers and authorities, is the availability of reliable and practical analytical methods. Analytical data is one of the tools that producers use to validate and subsequently verify their allergen management measures. Furthermore, authorities rely on analysis to verify whether products conform to provisions on food safety and information regarding allergens.

Currently, the most 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 regarding 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, when such calculations use analytical data as an input. 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 remain, especially the discrepancy in the analytical method result reporting units (such as mg food/kg or number of DNA copies/sample) that needs to be compared to RfDs expressed as mg food protein (Cubero Leon et al 2023, Holcombe et al 2024 and Holzhauser *et al.* 2020).

The FAO/WHO Expert Committee also made several related recommendations such as standardising analytical results (expressing results in milligrams of protein per kilogram of food product), developing clear criteria for analytical methodologies, ensuring consistency and reliability, making extensive reference materials available for priority allergens, enhancing understanding of assay performance in different food matrices for accurate allergen detection, increasing transparency regarding assay-specific reagents, and establishing clear procedures for obtaining and curating samples for analysis by third-party laboratories. The AOAC are in the final stages of publishing 'Guidance on Food Allergen Immunoassay Validation' which aims to address some of these problems (AOAC, 2023).[5]

Therefore, whilst good advances have been made, effective implementation of quantitative limits (based on RfDs) still requires further development and implementation of methods and protocols capable of reliably and accurately detecting all regulated allergens at relevant concentrations. This is especially important for QRA approaches that rely on analytical data for occurrence and concentration information of an allergen within a food, as opposed to QRA approaches which rely on input data which is calculated based on knowledge of the cross-contact scenario under assessment. As part of the CCFL consultation process the CCMAS is requested to recommend suitable analytical methods and guidance on the validation and applications for determining allergenic proteins in foods.

5 https://www.aoac.org/news/call-for-consensus-draft-guidance-on-food-allergen-immunoassay-validation/

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 stakeholders' 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 RfDs and a harmonised 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 (absence of PAL should not communicate the message 'allergen free'). 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 and quantity consumed).

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 and/ or undeclared presence in products. As discussed above, FoodDrinkEurope has developed Guidance on Food Allergen Management for Food Manufacturers in order to minimise 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 unintentionally 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 are used to checking 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.

FoodDrinkEurope commentary on the FAO/WHO Expert Committee PAL Recommendations and incorporation into Codex Guidance

FoodDrinkEurope welcomes the work that the FAO/WHO Expert Committee and many others have done to make progress towards a global harmonised risk-based approach to PAL, and agree that effective allergen management practices (including controls to prevent or minimise UAP), should be implemented. Furthermore, the use of PAL should be restricted to situations where UAP cannot be prevented or sufficiently controlled using these practices and may result in exposure above a reference dose.

FoodDrinkEurope also recognises that there needs to be a defined point at which PAL is applied for it to be meaningful, and that at Codex level pragmatism is required to aid implementation across a variety of economies with differing capabilities.

However, whilst noting that consultation on development of guidance on PAL in the General Standard for the Labelling of Prepackaged Foods (GSLPF) is ongoing, FoodDrinkEurope also calls for recognition that the application of QRA needs to be set within the wider context of the challenges of allergen management within complex supply chains. This includes taking into account variability in data availability and quality for multiple variables including the change of occurrence of cross contact, the form, distribution, frequency, and concentration of cross contact resulting from the specific cross contact scenario in question.

Additionally, analytical data is not always adequate when deciding on the use of PAL. As an example: Almond flakes in a waffle mix. After a production of “almond cake mix” the line is wet-cleaned. As observed during periodic maintenance where the line is being dismantled it became apparent that some areas of the production-line cannot be completely cleaned from pieces of almonds due to its design and almond flakes have the tendency to stick to surfaces. A waffle-product (not containing almonds) is produced after the cleaning of the line. The waffle product is sent to be analysed for traces of almonds and always comes back “not detected”. Based on such analytical results the product does not need PAL. However, from the qualitative observations during maintenance, there is still a risk of a piece of almond ending up in a bag of waffle-mix, such a piece would have almond protein in a quantity above the RfD and therefore the use of PAL should be considered.

Therefore, while FoodDrinkEurope agrees that the decision to use PAL should be based on the findings of an appropriate risk assessment, which can include but is not limited to QRA, and should be applied if UAP cannot be mitigated to a level at or below an appropriate action level based on the Expert Committee recommended RfDs and risk management values, FoodDrinkEurope also recognises that FBOs may need to deviate from these in some situations. FBOs may apply RfDs based on lower ED values when detailed risk assessments (considering factors such as data variability, the frequency of occurrence, and the sensitivity of specific consumer groups) indicate that this is required to meet consumer safety goals.

FoodDrinkEurope therefore supports the use of ED05-based RfDs as recommended by the Expert Committee, provided these are described as part of a more flexibly worded Principle incorporating clear language to this affect.

As the purpose of PAL is ultimately to communicate risk to consumers, ensuring the public correctly understands the message is critical. FoodDrinkEurope also support that any new guidance should be accompanied by education and information programs to ensure understanding and appropriate use by consumers, healthcare providers and FBOs. However, it is not clear how this can be achieved. Therefore, FoodDrinkEurope calls for more focus and guidance on this aspect.

Regarding presentation of PAL, FoodDrinkEurope supports the implementation of a single clear statement ('may contain'), which should appear following the ingredient list and contrast distinctly from adjacent label text.

However, FoodDrinkEurope does not support the use of a symbol to indicate a risk assessment has been done (as recommended by the Expert Committee). Such a symbol is not required for any other area of food safety, and potentially will mislead consumers.

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. This framework should recognise that PAL should be based on a multipronged approach utilising a range of risk management tools, including quantitative risk assessment (QRA). Such a framework should incorporate (but not be limited to) the following elements:

- Clarity in communication to consumers: 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 QRA.
- A QRA should be applied based on transparent quantitative limits (RfDs) derived using the most up to date, relevant, peer-reviewed, and robust scientific data.
- When QRA relies on analytical data, it should be noted that sampling procedures and analytical methods have varying limitations regarding sensitivity, specificity, and accuracy. The applicability of analytical data as an input into QRA requires harmonisation.
- In addition, consumers need to be confident that products have been through a risk assessment and that the presence or absence of PAL is a consequence of that process. However, FoodDrinkEurope does not support the use of a symbol to indicate a risk assessment has been done (as recommended by the Expert Committee). Such a symbol is not required for any other area of food safety, and it potentially will confuse consumers.
- FoodDrinkEurope recognises the foundational value of ED05 RfDs for application of PAL as recommended by the Expert Committee, and we support that PAL is prescribed when the unintended allergen presence (UAP) exceeds this value. Nonetheless, FBOs may need to deviate from their use and apply PAL when the UAP is ≤ED05 values, when detailed risk assessments indicate that this is required to meet a consumer safety goal. FoodDrinkEurope therefore supports the use of ED05-based RfDs as recommended by the Expert Committee provided these are described as part of a more flexibly worded Principle.
- As the purpose of PAL is ultimately to communicate risk to consumers, ensuring the public correctly understands the message is critical. FoodDrinkEurope also supports that any new guidance should be accompanied by education / information programs to ensure understanding and appropriate use by consumers, health care providers and FBOs. However, it is not clear how this can be achieved. Therefore, FoodDrinkEurope calls for more focus and guidance on this aspect.

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Annex I

FoodDrinkEurope Statement on Precautionary Allergen Labelling[6]

- 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 but as a result of manufacturing and other operations (and which are therefore not labelled as ingredient) 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 decision- making on when PAL may be needed, including the application of quantitative risk assessment, has led to divergent standards applied by different manufacturers, as well as divergent approaches by enforcement authorities across Europe.
- 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 recognise that following a risk-based approach may cause reactions in a very small proportion of susceptible individuals, this approach will minimise risk to consumers with food allergies, while maximising 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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