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Precautionary allergen labeling: Current communication problems and potential for future improvements

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ABSTRACT

While there are EU laws for priority allergenic ingredients information on food product packaging, there is no legislation about Precautionary Allergen Labelling (PAL) for unintended allergen presence (UAP). As a result, PAL is used in different ways by different manufacturers and retailers, which hampers consumers' interpretation of the information in the PAL. Previous research has focused on the forms of PAL that are used and on the way they are interpreted and used by consumers. This study adds the perspective of producers, retailers and branch organizations. Thirteen interviews with QA- and QC-professionals were conducted to find out more about the reasoning behind their PAL-use and to find out how PAL could be optimized. Results show that harmonization is needed, on different levels: in the way information on UAP is shared between parties involved in the food chain; in the way PAL is presented and phrased; and in the rules and regulations on PAL. More research is needed on possible ways to share (updates on) information on UAP with consumers.

1. Introduction

Food allergy is a common health problem. To help consumers choose products that are safe to use for people with a food allergy, EU legislation dictates that the presence of any ingredients existing of or derived from 14 priority allergenic foods must be reported and emphasized on food packaging (Regulation EU No 1169/2011, 2011). For the possible unintended allergen presence (UAP) in food products, manufacturers can provide Precautionary Allergen Labelling (PAL) where appropriate, based on relevant scientific data. If they choose to do so, the information should not be misleading or ambiguous (Article 36 of Regulation EU No 1169/2011). However, since PAL is not mandatory and there are no clear regulations about when PAL should or should not be provided, the absence of PAL on food packaging does not mean that consumers can be sure that there is no risk of UAP. Conversely, the presence of PAL doesn't mean that the allergen mentioned in the PAL will actually or may be present at relevant levels in the product (e.g. Allen & Taylor, 2018; Blom et al., 2018; Giammariolo et al., 2019).

Manufacturers and retailers are free to decide whether or not to apply PAL and to choose the wording as well as the design of the PAL. As a consequence, in some packaging designs, PAL can be easily overlooked (Blom et al., 2021). Variation in the wording of PAL causes consumers to interpret differently phrased PALs as an indication of different risk levels. For instance, allergic and non-allergic consumers attributed a lower risk to a PAL phrased as 'produced in a factory which also processes peanut' than to a PAL stating that a product 'may contain peanut' or traces of that allergen (Holleman et al., 2021), while there are no indications that manufacturers intend to convey different risk levels

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with different wordings, nor can they substantiate those.

As a result of the situation mentioned above, PAL is often perceived as not helpful and many consumers habitually choose to ignore them (e.g. DunnGalvin et al., 2019; De Kock et al., 2020). Barnett et al. (2011) specify four reasons for consumers ignoring PAL. The first reason is pragmatic: some consumers find it impossible to completely eliminate all products with PAL from their diet. The second reason is a lack of trust in PAL: some consumers feel PAL is just a way for manufacturers to avoid liability, rather than useful information for consumers. The third reason is that consumers ignore certain specific PAL wording as they consider the risk level related to this wording to be low. The last reason mentioned by Barnett et al. is that consumers sometimes consider PAL to be implausible, because they feel it's impossible that a certain product would contain that allergen. Another reason for ignoring PAL is that consumers might have consumed the product without adverse reactions in the past (e.g. because there was no PAL information on the packaging at that time) (Hefle et al., 2007).

There seems to be a mismatch between consumers' needs and the information manufacturers and retailers are providing and can provide. Blom et al. (2021) demonstrated serious problems with the design of food labels, impeding allergic consumers to detect and interpret relevant information on allergens. There have been calls from all stakeholders involved for a more standardized and regulated use of PALs, including standardizing the wording and guidance for businesses on the use of PAL (e.g. Allen et al., 2014; DunnGalvin et al., 2015; FSA, 2022; Zurzolo et al., 2016). From the food business perspective the complexity of the global suppliers chain and allergen analytical methods were seen as critical factors for implementing such a robust allergen risk management (DunnGalvin et al., 2015; FSA, 2022; Yeung & Robert, 2018). In addition, PAL statements should be clear, simple and indicate the identified risk levels (DunnGalvin et al., 2015; Zurzolo et al., 2016). But studies conducted are limited in details on the more practical day to day practices in allergen management for food businesses, especially the smaller companies. Improvement of PAL practices could benefit from better understanding of current labelling policies in food companies, the reasoning behind the ways PALs are phrased and designed, and the problems and opportunities the food industry expects to encounter when standardizing information about possible UAP. Much of the research regarding communication aspects for PAL focused on the allergic patient and the PALs that are currently provided, and not on the food business operators and their reasoning behind PAL use. The current study presents the results from interviews with quality control and quality assurance specialists from food manufacturers, retailers and branch organizations in the Netherlands about their current PAL use and their ideas about improvement around the use of PAL.

2. Materials and methods

Semi-structured interviews have been conducted with Quality Assurance (QA) and Quality Control (QC) professionals from food manufacturers, retailers and branch organizations. An interview guide was used, focusing on problems and solutions regarding a number of topics relevant for UAP and PAL. Interviews started with topics about the production process, because challenges and solutions for the prevention and detection of UAP might differ significantly between different producers. Starting with these topics assured that they were discussed in detail. QA en QC professionals can provide detailed information on these topics, often discussing other relevant topics (like rules and regulations, or company ambitions) during their explanation. After the topics on prevention and detection of UAP, the interview guide focused on PAL policies and how the relevant information on UAP is conveyed to consumers. Based on Blom et al. (2021) we believed PAL policies to not always be well-defined, because different PAL phrasings and placements seem to differ between, and sometimes even within, brands. The final topics on the interview guide were knowledge and opinions on the regulatory context of allergen communication and on company ambition for allergen communication and management. We expected these topics to be mentioned regularly while discussing the previous topics, but to make sure all relevant aspects of these topics were discussed, we've added them to the end of the interview guide.

Using semi-structured interviews ensured that all of these topics were discussed in every interview, while interviewees working with different allergens or production processes could provide information that is specific to their situation.

2.1. Participants

Interviewees were selected using purposive sampling: we invited QA and QC professionals from 29 food manufacturers and retailers (supermarket chains) and branch organizations with factories or offices in the Netherlands to take part in this study. Thirteen organizations agreed to participate. The others did not reply or – in just a few cases – replied but declined our request. Reasons to decline our request were for example that there was no time for an interview or that a company was just in the process of reviewing their policy for allergy information and PAL, so they couldn't answer questions about their policy at that time. The thirteen participating organizations were two branch organizations, three supermarket chains selling both private label and brand products, and eight food manufacturers, producing a range of products, both B2B and B2C (appendix 1). The eight manufacturers made or processed baked goods (2), chocolate (2), dairy (1), vegetables (1), meat (1) and spices (1). The researchers visited the company's office or factory for one interview session with one or two QA or QC professionals. After these thirteen interviews, a preliminary analysis indicated that data saturation was reached. No other manufacturers or retailers were contacted for additional interviews.

2.2. Data collection

Interviews were conducted in a meeting room with no non-participants present and lasted between 45 min to an hour. The researchers introduced themselves, gave information on the research topic and goals, and clarified that most questions were about PAL rather than about the ingredient information and allergens as ingredients. Interviewees were asked to describe the organizational structure and the position of the QA- or QC-department within that structure. After that, questions were asked about the topics of allergen communication presented in Appendix 2.

At the end of the interview, interviewees were invited to add relevant topics that hadn't been addressed yet in the interview and any questions they had about the study were answered.

Interviews were recorded (after consent was given) and later non-verbatim transcripts were made by one researcher (removing unnecessary elements such as fillers ('let's see'), and irrelevant sentences (e.g. small talk)). Relevant verbatim quotes were included. A second researcher checked the transcript to make sure it was correct and no relevant parts were omitted. The transcripts were sent to the interviewees for approval.

2.3. Data analysis

A qualitative data analysis was performed. To facilitate analysis, approved transcripts were coded in NVivo 12 (QSR International Pty Ltd, 2020). Using inductive coding, a code system with 22 different codes was created (see Appendix 2 for an overview). Codes were then grouped into seven broader topics, based on the interview guide.

The seven topics were divided into three categories: the first category comprised of all topics that covered communication with suppliers, manufacturers and other parties during the production process. The second category entailed all communication with consumers. The third category contained topics about rules and regulations and communication with authorities and legislators. Codes could be combined, so there

were several routes to retrieve relevant excerpts from the database. The following quote demonstrates this. It is a quote from an interview with a retailer explaining why under their new allergen policy they want analyses according to VITAL®3.0 (https://vital..net/vital-science/Allergenbureau) for all allergens, while under their old policy they always used PALs for peanut, nuts and sesame seeds when these allergens might have been present at a supplier's site, without a VITAL calculation. It was coded for 'PAL policy', 'PAL for liability reasons', 'preventing UAP', 'determining risk levels', 'VITAL' and 'suppliers'.

> *'[We want to change this policy] because a warning for [peanuts, nuts and sesame seeds] was often given for liability reasons, while we actually want our suppliers to do everything they can to prevent cross contacts. Every risk that is left after that, we want to substantiate with a VITAL calculation. If that calculation shows there is a risk, we'll mention it on the packaging. '*

By assigning multiple codes to this quote, it can be linked to what other interviewees have said about any of these topics. For each code, answers could be compared to find patterns in the answers and differences between organizations or product groups. In the next section, results for each of the three main categories ((1) communication between suppliers, manufacturers and other parties during the production process, (2) communication with consumers, and (3) rules and regulations) are presented.

3. Results

3.1. Communication between suppliers, manufacturers and other parties during the production process

Production begins with raw materials and it is important for all personnel and parties involved to be aware of any possible risks of UAP in the production, storage and transport of these raw materials. That is why suppliers of raw material and ingredients should provide information on possible UAP of their products/material to companies. The interviews show that this information is shared through several links in the production chain. The use of different information systems to share this information between links complicates the communication between parties. Errors are made or information is lost between links in the chain.

3.1.1. Information from suppliers not always available or reliable

Several interviewees reported that suppliers of ingredients and raw materials are often unable to provide reliable and useful information on allergen risks. Interviewees felt that many suppliers are not informed well enough regarding the relevant information on UAP and consider it difficult to provide accurate information (see Box 1). In other cases the rules appear to be unclear for interviewees as well, which could lead to expectations that suppliers cannot fulfill. When working with VITAL, a calculation is applied on the final consumer product. The food producer will combine possible UAP of each of the ingredients into a final concentration for the allergenic food. Information on the concentration UAP for each ingredient should be provided by suppliers, but they do not have to do VITAL calculations (Remington et al., 2022b), but in some cases producers expect them to be able to do these calculations anyway (see Box 1).

Interviewee 7 (meat, snacks and meat substitutes) explained that some suppliers in the past used to fill in a question mark for some allergens on the specification forms. Only after repeated requests by the producer they would change it to that allergen being either present or absent.

3.1.2. Lack of uniformity in communication systems increases the risk of errors

In several interviews, manufacturers and retailers said they felt hindered by the lack of a common system for communication about allergens with suppliers. There are many different forms and systems in use for informing other parties about the specification of ingredients and possible UAP. Because of these different systems and databases, information can't be copied from one form or system to the other. Doing this by hand means that errors can be made, resulting in incorrect specifications that are passed on to the next link in the production chain (see Box 2).

Errors are not only caused by features of the system but also by characteristics of its users. One of the branch organizations mentioned that some food manufacturers have outsourced the allergen data entry to low-wage countries where workers with little or no knowledge on allergens and of the language used by the system have to fill in the allergen information.

3.1.3. Diversity in allergen lists results in incompleteness and errors

A third source of errors is the fact that different lists of allergens are used by different companies both nationally and internationally. This means that suppliers and manufacturers have to work with different lists of allergens for different clients. Some companies, for example, still work with a set of 24 allergens that was the standard in the Netherlands until 2017 (the LeDa-list), while others work with the fourteen allergens that have been included in current EU ingredient labeling regulations. This leads to relevant fields in the forms being skipped and information being entered in incorrect fields.

3.2. Communication with consumers

Manufacturers and retailers want to inform consumers in the most useful way about the possible unintended presence of allergens in their products. This means they have to decide in what cases they want to provide a PAL and how to phrase PAL. In addition to decisions that have to be made about PAL on food packaging, manufacturers and retailers have to decide how and when to provide online information. Detailed allergen information based on the specifications that manufacturers share with each other is becoming increasingly available to consumers online via retailer websites and mobile applications. In some cases customers can search for (the absence of) specific allergens on a website.

3.2.1. Difficulties in providing PAL

DunnGalvin et al. (2015) state that consumers may consider the use of PAL as a way to protect the food manufacturer or and avoid liability.

Box 1

A company producing chocolate products for both consumers and businesses indicated that suppliers sometimes report all allergens they work with in their factories as possible allergens, even if there is no chance of cross contact because the allergens are only used on another line. 'But still they are listed as *traces* on the specification. Because it's easier that way.' […]

'[Suppliers] should do VITAL calculations as well, to inform us. […] But companies that don't make consumer products have never heard of VITAL. So we have to explain to them what it is. They find it very complicated and hard.' (Chocolate products).

Box 2

A spice company indicates that it would help if all companies involved would use the same system for their specifications. If a chain has six steps, which isn't exceptional in the case of spices, specification forms have to be filled in six times. '*Many things can go wrong, and it takes a lot of time and effort. It would help to have just one system, in which the first supplier enters their information and in which everyone can add their information. That way, you would end up with a complete overview of what has happened to each ingredient, where it has been, and where cross contact might have occurred.*'

Indeed, in the end, the brand or private label owner is responsible for the allergen information and may be confronted with claims. One of the retailers reported that some manufacturers of their private label products are too cautious and want to mention allergens that aren't relevant or present below a level at which an allergic reaction could be expected. If the retailer refuses a PAL on the label, some manufacturers may make the retailer sign a statement to explicitly accept responsibility for allergen information on the food label. When discussing the use of PALs on packaging however, most interviewees stressed that they want to provide information that is useful for allergic consumers, rather than just use PALs for liability reasons (see Box 3).

Problems with PAL may arise when recipes change. Several manufacturers and retailers mention the problem of updating information, both for online information and for information on the packaging. If recipes (and ingredients) or possible UAP change, manufacturers and retailers don't just want to put the updated information on the packaging in order to fulfill their legal obligation. In such cases they discuss the importance of allergic consumers actually checking the new information and ways to stimulate them to pay attention to relevant changes (see Box 4).

One strategy manufacturers mentioned in case of recipe changes is to keep the list of allergens as short as possible, by keeping allergens in their factories to a minimum, and working with suppliers that don't use too many allergens. This strategy is relevant as well when adding new products to their brand, which sometimes leads to discussions with research and development departments (see Box 5). Adding new products, could mean a change in allergens present at manufacturing sites and distribution centers, and a possible change in UAP. Even without a change in recipe, this could mean that the PAL should be changed too.

All interviewees state they want to base warnings on the packaging on adequate risk assessments. Several manufacturers and retailers explicitly state they use the VITAL system. One retailer even started training their suppliers on ingredient specifications and how they are used for VITAL-calculations. Other manufacturers and retailers would like to work with VITAL, but feel it's not feasible yet, for several reasons (e.g. lack of accurate information from suppliers or too complex or dynamic processes to do reliable calculations). The trade associations agree that VITAL is useful but they notice as well that it's not the only system to decide whether to include PAL that is being used by their members. Some interviewees report using PAL, irrespective of a risk calculation, for every allergen that is present on site during the production and transportation process, especially when UAP-prevention options are limited (see Box 6).

Some respondents indicated that they feel some allergens cause more serious allergic reactions than others and that the expected seriousness of allergic reactions is taken into consideration when deciding whether or not to provide PAL. One of the trade associations was against PALs on the label, but used to make an exception for peanuts and nuts, because they felt these allergens can result in the most serious reactions. This idea is shared by more manufacturers and retailers: seven interviewees specifically mention peanuts and nuts as the allergen they are most careful with. Some refuse to allow their suppliers to work with peanuts and nuts stating that allergic reactions to peanuts and nuts can be more serious than reactions to other allergens and others treat peanuts differently than other allergens when deciding on when to include PAL (see Box 7).

3.2.2. PAL phrasing is highly variable

When a company decides to include PAL on their packaging, there are different ways to phrase that PAL. Not all interviewees were aware of the PAL-phrasing that is (most frequently) used by their company, or of the reasoning behind it. In some cases this is the case because packaging design is left to other parties than the QA- or QC-department. Sometimes the marketing department is involved in the phrasing of warnings on packaging and when products are produced for different brands or private labels the owner of the brand or label decides where the PAL is placed and how it is phrased. One example based on marketing ideas was that the company producing baked goods used to use the phrasing 'made in a bakery where [allergens] are processed as well.' The idea behind this was that using the word 'bakery' helped present their company as artisanal. They have changed the phrasing of their PAL however, because they found out that consumers understand this warning differently than 'may contain traces', the phrasing they currently use.

Another interviewee (retailer) reports a similar switch of phrasing for their private label products. They used the phrasing 'made in a factory that also processes … ' and changed it to 'may contain traces of … '. They based this decision on their own research about what works for consumers. These two examples show companies using 'may contain traces' based on research or consumer information. However, there is no broad consensus among companies on this phrasing. We found quite diverse preferences and reasonings, as demonstrated in Box 8.

There are however some aspects that most interviewees agree on. Many interviewees mentioned the fact that the phrasings in general and specifically the word 'traces' are vague and abstract for consumers and don't help them to assess risk levels. That's why all but two interviewees

Box 3

'*It's not about legal protection for ourselves, we want to provide a substantiated advice to the allergic consumer*' (Retail).

'*We don't have the policy to label 'may contain' just for legal reasons. […] We use it for real risks, based on measurements and calculations, or risks in the supply chain that can't be controlled. […] We feel that allergic consumers aren't helped with long lists [of allergens].*' (Dairy producer).

Box 4

One retailer mentioned that recipe changes are indicated on the packaging for three months. A sticker stating 'renewed recipe' alerts consumers to possible new allergens in the ingredients. There is no such policy however for announcing possible new UAP because of changes in suppliers, production or transportation.

A producer of baked goods explained that it would be useful for the food industry to learn more about how and when allergic consumers read labels when shopping: *'It's interesting to know whether consumers check every packaging for each purchase, or whether they just trust that if it has always been safe to eat they can just buy it.'*

Box 5

'*Sometimes [a colleague] will approach us and say "wouldn't this be a great product to make?" "Sure, we agree, but did you say satay? That's peanut, so no."*'

This producer (vegetables and legumes) reported limiting the allergens that they use to just two (sulphite and milk). They decided to limit their work for private labels a couple of years ago, to make sure they have more say in products and processes.

Box 6

'We include all five allergens [that are present in our factories in our PALs] because most products are made on the same line. […] There are more lines, but we switch products between lines if needed because of our production capacity. […] Since we can't use water to clean because we work with chocolate, we can't guarantee that there are no traces of allergens left.' (chocolate producer).

Box 7

'*For particulate allergens such as nuts and sesame seed, we always say that "may contain" should be on the packaging. Just one single dose, one single contamination can be so strong that it triggers an allergic reaction. […] Retailers however tend to overrule us on sesame seeds. But when peanuts are concerned they'll say things like "we always warn for peanuts" […] In the end the product owner is responsible. The producer does have a responsibility as well. […] It is not like we think "this retailer includes PALs, so we can just use allergens when we like. We'll always have the same measures to prevent cross contact, that we think are effective and sufficient.*' (Sweet baked goods).

Box 8

Preference for 'may contain' over 'may contain traces': *'The term traces isn't always accurate, because cross contact can lead to high levels of UAP.'* (Interview with a branch organization).

Preference for 'may contain traces' over 'made in a factory': *'Made in a factory sounds like, we're not quite sure, let's just put it on there. Like "we have some peanuts stored somewhere" or something like that.'* (Interview with producer of spices and spice mixes).

Preference for 'made in a factory' over 'may contain traces': *'I feel it's a more factual statement than may contain traces'* (Interview with producer of dairy products).

Preference depends on situation: "Made in a factory" is a statement that can be made without further research on possible cross contact, while "may contain traces" suggests that some research had to be done to figure out where cross contact is possible or even likely. (Interview with a branch organization).

Box 9

'It's impossible to distinguish between risk levels. Customers wouldn't understand. It is difficult enough as it is to control for cross contact, let alone if you would have to indicate gradations of risk levels.' (retailer).

'A customer can't do anything with it. We can't even assess the exact risk. Customers would definitely not be able to do it.' (Sweet baked goods).

felt that using just one statement for all products would be best and that different phrasings shouldn't be used to convey different risk levels (see Box 9).

Only one (chocolate) company uses different phrasings to indicate different risk levels: for most of their products they use 'may contain traces', but for one specific location there is a line where they use different allergens during the day, because different products are made on that line. For products made on that line, with a higher risk of cross contact, they use the phrasing 'made on a line on which [allergens] are used'.

Several interviewees feel that using icons might also help consumers in interpreting PAL, if one set of icons for the allergens was used by the entire food industry. That system would have to be clear for consumers to use and the use of it would have to be regulated. If too many icons and systems of icons are used, there is a risk of misinterpretation by the customers (Box 10).

Interviewees agreed that more information about how consumers understand PAL (both using icons and phrasings as mentioned before) would be useful for the food industry.

3.2.3. Is allergy information online a good alternative?

Several interviewees mention online availability of allergen information as an option to make the information on what allergens are or could be present in a product more flexible. On a website or in a mobile application the information could be updated if needed because of changes in recipe or in the allergens that might unintentionally be present. Interviewees also mention some complications when updating information online, specifically when different versions of a product might be available at the same time. It would be important to find out how consumers interpret and use the information that is available to them online (Box 11).

3.3. Rules and regulations

Both during the production process and in dealing with consumers, manufacturers and retailers have to consider rules and regulations for allergy information and information on possible UAP. These rules and regulations aren't always interpreted in the same way by different manufacturers and retailers. Sometimes manufacturers feel limited by rules and regulations, while in other instances interviewees felt that new rules would be needed to make PAL-information as useful as possible for consumers.

3.3.1. Interpretation of and limitation by rules

The status of PAL-information isn't always clear. While manufacturers might think they've sufficiently warned consumers by including PAL-information, this doesn't mean there can't be an imposed obligation recall when an allergen mentioned in the PAL-information is actually present. Another difficult topic is the use of 'free from'-claims. Rules for the use of 'free from'-claims are clear to manufacturers, but they feel that consumers (and marketing departments) have a different understanding of this subject. Box 12 demonstrates some of the different interpretations of PAL-rules and regulations.

A limitation by the current rules is the fact that allergens which might be present as a result of cross contact, but that aren't present as an ingredient cannot be mentioned in the allergen box on the packaging. Eight interviewees feel that including PAL-information in the allergen box would help allergic consumers find all relevant information but European laws make very clear that it is not allowed to include UAP in the allergen box (Box 13).

3.3.2. Need for harmonized rules on PAL

One might think that manufacturers, retailers and branch organizations feel that less rules and regulations would make their task easier. However, there were some clear statements about the need to regulate PAL-information stronger. Almost all interviewees would prefer to work with VITAL or a VITAL-like system. At this point, for the Netherlands (and Europe as a whole) there is no system that is commonly used. Interviewees mentioned three different systems (although more exist): VITAL thresholds differ from thresholds used in other systems like the Netherlands Food and Consumer Product Safety Authority NVWA (Nederlandse Voedsel-en Warenautoriteit), and Belgian Federal agency for food chain safety (Federaal Agentschap voor de Veiligheid van de Voedselketen FAVV).

Interviewees would prefer a harmonized system and thresholds. This would lead to more useful information for consumers and less discussion between suppliers, manufacturers and retailers. The interviewee from the spice mix producer stated that changing laws will take time, but that in the meantime branch organizations could play a part in aligning PAL-use.

Two interviewees mentioned that the fact that including PAL-information is not mandatory at this point, leads to unfair situations where they invest time and money to inform consumers while other companies aren't stimulated to present PAL-information at all. Products without PAL aren't necessarily safer for allergic consumers, but might appear to be safer, which adds to the frustration of manufacturers who do strongly invest in allergen risk assessment and management and optimal application of PAL.

4. Discussion and conclusions

The goal of this study was to find out how manufacturers, retailers

Box 10

'*What does an icon mean? Does it mean that the allergen is present? Because there are icons stating that a product is free from a specific allergen as well. That is complicated'* (dairy products).

Box 11

The interviewee for the sweet baked goods producers thinks taking up less space on the packaging for something that is only relevant for a small group of people is a good thing. For this small group, there is another advantage of online information: *'If you want to provide detailed information, which is very important for allergic consumers, you shouldn't communicate on the label. If you provide the information online it can be updated as often as needed.'* (sweet baked goods).

A retailer predicts problems for products with a long shelf life when information changes and products with old and new possible allergens are in stores at the same time: '*Of course we can link the correct information to the barcode, because that changes as well. But the consumer is not going to check what barcode is on [the product they want to buy]. We can't fix that completely. So the consumer has to keep checking the label.'*

A interviewee from a branch organization feels that consumers might interpret the fact that an allergen isn't marked as being present as that product being 'free from' that allergen. On the actual packaging however the producer wouldn't claim the product is 'free from' that allergen, because the allergen might be possibly present but below the threshold level, which wouldn't warrant a 'free from'-claim.

Box 12

One producer (meat, snacks and meat substitutes) includes all possible UAP in the list of ingredients '*Something is either in there or not in there. It's on us to prove that. […] What do we tell our customers, when we say "may contain"? We tell them: "It could be in there." Well, then you have to say that it is in there. So that's what we do*.'

Other producers state that even if this would be a way to prevent recalls, this is not the way to go because if something is mentioned as an ingredient, it should be present in every portion of a product and this usually isn't the case with UAP.

One interviewee for a branch organization indicates the problems they encounter because of the unclear status of PAL-information: '*You can put a PAL on the packaging, but the consumer doesn't have to read it. If [the allergen] is actually in there, a recall can be ordered. Even if it's on there, it isn't regulated by law, and if someone gets sick, you've got a recall. […] It's unfair that consumers aren't expected to read the label. The problem is that it isn't an ingredient but a cross contact. It is like a grey area in the law.'*

Interviewees see a 'free from'-icon as possibly helpful for consumers, but there are only rules for gluten and sulphites (and in some countries for lactose) based on thresholds for using a 'free from'-claim. For all other allergens 'free from' means that the allergen is not present at all. One of the branch organizations demonstrates discussions this could lead to: '*You've made a calculation and have found that [presence of a certain allergen is] below the level that would warrant a PAL. The supermarket might say "well, that's great news, that means we can put 'free from' on it".'* The branch organization always advised against this incorrect use of 'free from', but this leads to discussions about the rules with marketing departments.

Box 13

An interviewee from a branch organization states: *'An allergen box is easier, especially for people who don't have an allergy themselves, but who shop for someone with an allergy. […] I would prefer to have it both: allergens highlighted in the ingredient list and an allergen box with both allergens in ingredients and cross contacts. But that's not allowed.*

The interviewee for the spice mix producer agrees: '*I would say that an allergen box is very clear. I can imagine that if you are allergic, that with an allergen box you know where the information can be found. So you'll always know where to look.*

and branch organizations in the Netherlands communicate with each other and with consumers about unintended allergen presence (UAP) and how manufacturers or brand owners decide when and how to apply PAL. It is clear that the interviewees in this study call for more uniformity in the use of PAL and that they feel the rules for PAL use have to be adjusted to reach this goal. However, it will take time to change the laws and regulations, especially in an increasingly international market.

4.1. Limitations of the study

Since food business is in most cases an international business, communication on UAP often has an international dimension. This means international cooperation is necessary. The interviews were only performed in a national (Dutch) setting. Although all manufacturers work in an international context, the data might not disclose the broad perspective of all possible international practices.

We also expect differences in companies' attitudes towards PAL within the Netherlands. Unfortunately, self-selection couldn't be prevented in this study. It is very likely that manufacturers and retailers with less clear policies on PAL-use or with no interest in the use of PAL didn't respond to our interview request and their opinions might differ from the ideas presented in this study. Based on our interviews, we can't estimate the extent of the variation. However, we did obtain an in-depth understanding of policies and barriers regarding PAL use of companies motivated to spend time on good allergy information.

4.2. Conclusions and recommendations

In Table 1, the main obstacles in the use of PAL discussed by our interviewees are summarized.

Table 1
Summarizing top issues in PAL indicated by food business interviewees.

Communication supply chain
- Lack of knowledge on UAP
- Unclear how to provide information
- Lack of a common system to register possible UAP
- Different lists of allergens to be warned for used by different parties
Communication to consumers
- Reasoning for PAL-phrasing often unknown as responsibility is with others (marketing, product owner, retail)
- PAL-phrasing based on intuition
- Preference for one statement, but unclear what consumers prefer and understand best
- Unclear how to deal effectively with changing UAP
Rules and Regulations
- The fact that PAL is not mandatory leads to differences in PAL use
- Interpretation of local regulations differs between stakeholders
- Lack of harmonization between rules and regulations for different countries in an international market

Based on the interviews, it has become clear that the manufacturers deal with parties with different knowledge levels on UAP and with different ideas on how to provide information on possible UAP during the production process and what this information means. Similar findings on supply chain regulatory complexity and different levels of expertise were noted by a recent ILSI Expert Group focusing on consensus on the methodologies needed for allergen quantitative risk assessments by food business operators, and their implementation (Remington et al., 2022a). The ILSI Expert group developed a practical guidance that provides tools and approaches to help harmonize the data gathering process for food allergen risk assessments and therefore aid with their implementation, including communication across the supply chain (Remington et al., 2022b).

Another important suggestion mentioned by QA- and QC-professionals is that there should be more agreement on communication with consumers about UAP and more harmonized rules and regulations are needed for how and when information on UAP should or should not be provided. There have been some important and promising developments on these topics. During three joint FAO/WHO expert consultations research based guidelines on allergens, threshold levels and PAL-use has been formulated. A list of eight priority allergenic foods has been proposed, with additional allergens that could be considered as priority allergens for specific countries (FAO/WHO, 2021a). Threshold levels and appropriate analytical methods for testing were determined (FAO/WHO, 2021b) and FAO/WHO (2021c) recommends the use of a (preferably regulatory) framework for when and how PAL should be provided. The preferred phrasing should be one that unambiguously conveys the message than a food product carrying a PAL is 'not suitable' for consumers with an allergy to the allergenic food warned for (FAO/WHO, 2021c).

These guidelines would solve part of the problems mentioned by the participants in this interview study. Especially when these research based guidelines lead to international rules for PAL-use, and different stakeholder groups are involved in the formulation of these rules, great progress could be made. Based on the interviews in the present study, we can formulate a number of recommendations for new guidelines and practices:

4.2.1. Training for food business operators

Training on QRA and (thresholds for) priority allergenic foods is needed to make sure all chains in the production process follow the guidelines and know how to put these guidelines into practice. Training should cover the effect of PAL wording and information needed for (VITAL) calculations. It should also clear up misunderstandings about differences in risks for different allergens (peanuts were mentioned in several interviews as being higher risk, while other allergens frequently lead to anaphylaxis as well (Baseggio Conrado, Patel, & Turner, 2021). When standardized guidelines for QRA are established, education on these guidelines (and on priority allergenic foods and thresholds) could be more efficiently organized.

4.2.2. A harmonized (software) system to register possible UAP

Even if Food Business Operators use the same list of allergens and the same guidelines for QRA, they could still use different software systems to inform each other about the possible presence of allergens. With the guidelines and priority allergens list harmonized, it would be more feasible to use one software system to share UAP information (or several software systems that are mutually compatible) among manufacturers, leading to less errors while entering data and a more efficient exchange of information.

4.2.3. More research on sharing information on UAP with consumers online

Even if rules and regulations on PAL are harmonized and common guidelines are followed, making PAL more reliable and useful, that does not guarantee that consumers will use the information provided to them correctly. Especially when possible UAP changes, because of a change in recipe or a new supplier, consumers need to be aware of these deviations. More research is needed into how and when groups of (allergic) consumers use online product information and how this information could be shared online most effectively.

While these interviews made clear that on several levels improvement is needed, it is very promising to hear that the food industry is willing to work together in order to provide information about UAP in the most useful way for consumers.

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CRediT authorship contribution statement

Yvette F.M. Linders: Methodology, Validation, Formal analysis, Investigation, Data curation, Writing – original draft. **Leo R. Lentz:** Methodology, Conceptualization, Validation, Writing – original draft. **W. Marty Blom:** Conceptualization, Methodology, Resources, Writing – review & editing. **Anouska Michelsen-Huisman:** Methodology, Investigation. **Jelle Strikwerda:** Investigation, Resources, Data curation, Writing – review & editing. **Liselotte M. van Dijk:** Resources. **André C. Knulst:** Methodology, Writing – review & editing. **Geert F. Houben:** Methodology, Writing – review & editing. **Harmieke van Os-Medendorp:** Conceptualization, Writing – review & editing, Funding acquisition. **Bregje C. Holleman:** Conceptualization, Methodology, Resources, Writing – review & editing, Supervision, Project administration, Funding acquisition.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available on request.

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Appendix 1. Participating organizations in the interviews

Organization	Category	Main products
1	Producer	Baked goods
2		Sweet baked goods
3		Chocolate
4		Chocolate products
5		Dairy products
6		Vegetables and legumes
7		Meats, snacks and meat substitutes
8		Spices, spice mixes
9	Retail	Supermarket
10		Supermarket
11		Supermarket
12		Food retailers
13	Branch organization	Sweets and baked goods

Appendix 2. Code system for the analysis of the interviews

Category	Topic	Codes
I. Communication supplier-producer during production process	1) Minimizing, determining and communicating risk of UAP	1) Suppliers
		2) Checks
		3) Preventing UAP
		4) Determining UAP
		5) Specifications
		6) Determining risk levels
		7) VITAL
II. Communication with consumers	2) PAL policy	1) PAL policy
		2) PAL for liability reasons
		3) New allergens in existing products
	3) PAL positioning and phrasing	1) Allergen box
		2) PAL phrasing
		3) Packaging design
		4) Icons
		5) Ingredients
	4) Past problems	1) Recall
		2) Technical errors
	5) Ambitions	1) Ambitions
III. Rules and regulations	6) Rules and regulations and requirements for innovation	1) Rules and regulations
		2) Requirements
		3) International market
	7) Research needed	1) Follow up questions

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