CODEX COMMITTEE ON FOOD LABELLING

FOOD ALLERGEN LABELLING

ELECTRONIC WORKING GROUP (EWG)

(Chaired by Australia, the United Kingdom and the United States of America)

2nd CONSULTATION PAPER, JUNE 2024

Please respond to the questions in this consultation paper using the response sheet provided (Appendix III) and post on the **online platform** by **19 JULY 2024**

Note: Only one response per Codex Member or Codex Observer is permitted.

Introduction

The EWG Chairs would like to thank EWG members for your comments in response to the 1st consultation round on the proposed draft revisions to the *General Standard for the Labelling of Prepackaged Foods* (CXS 1-1985) (GSLPF) – provisions relevant to allergen labelling and the proposed draft Annex to the GSLPF – Guidelines on the use of Precautionary Allergen Labelling (PAL).

A total of 32 EWG responses were received from 22 members and 10 observers.

Members:
Australia, Belgium, Brazil, Canada, Chile, Colombia, Costa Rica, Ecuador, European Union, Guatemala, Indonesia, Japan, Mauritius, Norway, New Zealand, Kingdom of Saudi Arabia, South Africa, Switzerland, Thailand, United Kingdom, United States of America, Uruguay.

Observers:
Association of European Coeliac Societies (AOECS), European Federation of Allergy and Airways Diseases Patients´ Association (EFA), Food and Drink Europe (FDE), International Confectionary Association (ICA), International Council of Beverages Associations (ICBA), International Council of Grocery Manufacturers Associations (ICGMA), International Dairy Federation (IDF), International Special Dietary Foods Industries (ISDI), Food Industry Asia (FIA), Latin American Alliance of Food and Beverage Industry Associations (ALAIAB)).

This 2nd consultation paper provides a summary of the EWG responses received, and the proposed approach to the draft revision to the GSLPF (Part A) and the revised draft PAL guidelines (Part B). Part A also includes discussion and proposed approach for sections 4.2.1.6 and 4.2.4 of the GSLPF in relation to exemptions.

The proposed draft revisions to the GSLPF and the revised draft PAL guidelines are provided in **Appendix I** and **Appendix II** respectively.

We welcome further EWG feedback on these proposed draft revisions by responding to the questions using the response sheet at **Appendix III** by **19 July 2024**.

APPENDIX I

PROPOSED DRAFT REVISION OF THE *GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS* (CXS 1-1985) PROVISIONS RELEVANT TO ALLERGEN LABELLING FOR eWG COMMENT

(proposed revisions with **bolded** text additions and ~~strikethrough~~ deletions)

2. DEFINITION OF TERMS

"Food allergy" means a reproducible adverse health effect arising from an immunoglobulin class E (IgE) antibody or non-IgE antibody immune-mediated response following oral exposure to a food.

"Food allergen" means a food or ingredient ~~[or substance or~~ **including a food additive or** processing aid~~]~~ ~~used in food~~, usually **containing** a protein or protein derivative**,** that can elicit IgE-mediated or other specific immune-mediated reactions in susceptible individuals.

"Coeliac disease" means a chronic immune-mediated intestinal disease in genetically predisposed individuals induced by exposure to dietary gluten proteins that come from wheat, rye, barley and triticale (a cross between wheat and rye).

4. MANDATORY LABELLING OF PREPACKAGED FOODS

4.2 List of ingredients

4.2.1.3 Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation) constitutes less than 5% of the food, the ingredients need not be declared, except for the foods and ingredients listed in section 4.2.1.4, 4.2.1.7 and where applicable section 4.2.1.5 and food additives which serve a technological function in the finished product.

4.2.1.4 The following foods and ingredients are known to trigger food allergy or coeliac disease and shall always be declared using the specified name in addition to or as part of the ingredient name[1]:

FOODS AND INGREDIENTS	SPECIFIED NAME
Cereals containing gluten[2] − wheat and other *Triticum* species − rye and other *Secale* species − barley and other *Hordeum* species and products thereof	 'wheat' 'rye' 'barley'
Crustacea and products thereof	'crustacea'
Eggs and products thereof	'egg'
Fish and products thereof	'fish'
Peanuts and products thereof	'peanut'
Milk and products thereof	'milk'
Sesame and products thereof	'sesame'
Specific tree nuts − Almond (*Prunus amygdalus)* − Cashew (*Anacardium occidentale)* − Hazelnut (*Corylus ~~avellana~~ spp.*) − Pecan (*Carya illinoinensis*)	 'almond' 'cashew' 'hazelnut' 'pecan'

[1] In accordance with Section 4.1.1 of the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985), the ingredient declaration should specify the true nature of the food and be specific and not generic.

[2] Includes spelt, Khorasan, and other specific cereals containing gluten that are species or hybridized strains under the genus names of *Triticum*, *Secale* and *Hordeum*. Specified names are to be used according to the associated genus. Hybridized strains are to use specified names in conjunction from all of the parent genera (e.g. 'wheat' and 'rye' for triticale).

− pistachio (*Pistacia vera*) − walnut (*Juglans spp. ~~regia, Juglans nigra~~*) and products thereof	‘pistachio’ ‘walnut’

4.2.1.5 In addition to the foods and ingredients listed in section 4.2.1.4, the declaration of any other foods and ingredients, including those listed below may also be required[3] using a specified name in addition to or as part of the ingredient name[4]. This shall be based on available risk assessment data for the respective population(s)[5] taking into account risk management considerations.

FOODS AND INGREDIENTS	**SPECIFIED NAME**
Buckwheat and products thereof	‘buckwheat’
Celery and products thereof	‘celery’
Oats and other *Avena* species (and their hybridized strains) and products thereof [6]	‘oats’
Lupin and products thereof	‘lupin’
Mustard and products thereof	‘mustard’
Soybean and products thereof	‘soy’
Specific tree nuts − Brazil nut (*Bertholletia excelsa*) − macadamia (*Macadamia integrifolia, Macadamia tetraphylla*) − pine nut (*Pinus* spp.) and products thereof	‘Brazil nut’ ‘macadamia’ ‘pine nut’

~~[~~4.2.1.6 Subject to evaluation using established criteria[7], national authorities may exempt other ingredients derived from foods listed in section 4.2.1.4, and where applicable section 4.2.1.5, from being declared.~~]~~

4.2.1.7 In addition to the foods and ingredients listed in section 4.2.1.4, ~~When~~ sulphite ~~is present in a **[**ready-to-eat**]** food **[**or products as reconstituted according to the instructions of the manufacturer**]**~~, ~~at a total~~ **in** concentration**s** of 10 mg/kg or **more** ~~above~~[8], ~~it~~ shall always be declared using the specified name ‘sulphite’ **or ‘sulfite’ in addition to or as part of the ingredient name**.

RENUMBER existing sections 4.2.1.5 and 4.2.1.6 to 4.2.1.8 and 4.2.1.9 respectively.

[3] These foods and ingredients are not included in 4.2.1.4 but have been recommended to be considered for risk management at the regional or national level (see FAO and WHO Risk assessment of food allergens: Part 1: Review and validation of Codex Alimentarius priority allergen list through risk assessment https://doi.org/10.4060/cb9070en.).

[4] In accordance with Section 4.1.1 of the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1- 1985), the ingredient declaration should specify the true nature of the food and be specific and not generic.

[5] The assessment of risk in the respective population(s) to be based on the evidence criteria of prevalence, potency and severity of immune mediated adverse reactions to the food or ingredient as established by FAO and WHO Risk assessment of food allergens: Part 1: Review and validation of Codex Alimentarius priority allergen list through risk assessment. https://doi.org/10.4060/cb9070en

[6] Oats can be tolerated by most but not all people who are intolerant to gluten. Therefore, the allowance of oats that are not contaminated with wheat, rye or barley in foods covered by this standard may be determined at the national level.

[7] FAO and WHO (2024). Risk assessment of food allergens: Part 4: Establishing exemptions from mandatory declaration for priority food allergens https://doi.org/10.4060/cc9554en

[8] Sulphite measured as the total concentration of sulphur dioxide (SO2) and sulphur dioxide equivalents.

4.2.2 The presence in any food or food ingredients obtained through biotechnology of a~~n~~ **food** allergen transferred from any of the foods and ingredients listed in sections 4.2.1.4 and where applicable 4.2.1.5 shall be declared.

When it is not possible to provide adequate information on the presence of these **food** allergens through labelling, the food containing the **food** allergen should not be marketed.

4.2.3 Except for those foods and ingredients as listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 that must be declared using the specified name in addition to or as part of the ingredient name, ingredients in the list of ingredients shall be declared in accordance with the provisions set out in Section 4.1 (Name of the Food) except that:

4.2.3.1 Unless a general class name would be more informative, the following class names may be used. ~~In all cases, the food and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared using the specified names listed in those sections.~~ ***When a class name is used, those foods and ingredients as listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 must be declared using the specified name in addition to or as part of the class name.***

4.2.4 Processing aids and carry-over of food additives.

4.2.4.2 A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. The exemption does not apply to food additives and processing aids that contain the foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5.

6. EXEMPTIONS FROM MANDATORY LABELLING REQUIREMENTS

With the exception of spices and herbs, small units, where the largest surface area is less than 10 cm², may be exempted from the requirements of paragraphs 4.2 and 4.6 to 4.8. This exemption does not apply to the declaration of foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5.

8. PRESENTATION OF MANDATORY INFORMATION

8.3 Declaration of certain foods and ingredients

8.3.1 **The specified name for** ~~T~~**t**he foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared so as to contrast distinctly from the surrounding text ~~[whenever possible]~~, such as through the use of font type, style or colour.

~~[~~8.3.2 The specified name for the ~~F~~foods and ingredients in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared in the list of ingredients or in a separate statement ~~which shall be~~ **~~[~~**~~placed directly under~~ **~~or in close proximity to]~~** ~~the list of ingredients~~ or in both **as determined** ~~The most appropriate manner to declare these foods and ingredients shall be decided~~ by national competent authorities.

8.3.2.1 The **separate** statement shall commence with the word ‘Contains’ (or equivalent word) and **be ~~[~~placed directly under or in close proximity to~~]~~ the list of ingredients. The statement** must declare **the specified names of** all the foods and ingredients which are declared in the list of ingredients as applicable in accordance with section 8.3.1.~~]~~

8.3.3 Where a food is exempt from declaring a list of ingredients, the foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared, such as in a statement made in accordance with section 8.3.2.1.

8.3.4 For single ingredient foods, section 8.3.3 does not apply where foods and ingredients listed in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 are declared as part of, or in conjunction with, the name of the food.

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APPENDIX II

PROPOSED DRAFT ANNEX TO THE GSLPF:

GUIDELINES ON THE USE OF PRECAUTIONARY ALLERGEN LABELLING

FOR eWG COMMENT

(proposed revisions with **bolded** text additions and ~~strikethrough~~ deletions)

1. PURPOSE

To facilitate a consistent and harmonized approach to the effective use of precautionary allergen labelling (PAL) for communicating to consumers with food allergy**[1]** about the risk from the unintended presence of allergens in food due to cross-contact.

2. SCOPE

These guidelines apply to PAL when used to indicate the risk from the unintended presence of a food allergen(s) caused by cross-contact in prepackaged[1] foods.

3. DEFINITIONS

For the purpose of these guidelines:

> ***"Precautionary allergen labelling"*** *is a statement made in the labelling of prepackaged**[1]** foods to indicate a risk from the unintended presence of a food allergen(s) due to cross-contact**[2]** that has been identified by a risk assessment..*

4. GENERAL PRINCIPLES

4.1 Effective allergen management practices including controls to prevent or minimize the unintended presence of food allergens caused by cross-contact shall be implemented **in accordance with** ~~as outlined in~~ the Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020). The use of PAL shall be restricted to those situations in which the unintended presence of a food allergen(s) cannot be prevented or controlled using these allergen management practices and may result in an exposure above a reference dose.

4.2 The decision to use PAL ~~should~~ **shall** be based on the findings of ~~an appropriate~~ **a** risk assessment**[3]** ~~which shall include, but is not limited to, quantitative risk assessment~~ of unintended allergen presence to ~~indicate~~ **determine** exposure above a reference dose.

4.3 PAL shall only be used if ~~the~~ unintended allergen presence cannot be mitigated to a level at or below the action level[4] for a food allergen based on the reference dose in the table at 4.3.1.

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[1] As defined in the *General Standard for the Labelling of Prepackaged Foods (CXS 1-1985)*.

[2] *Allergen cross-contact* as defined in *Code of Code of Practice on Allergen Management for Food Business Operators (CXC 80-2020).*

[3] ~~*FAO and WHO (2022). Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens: Part 2: Review and establish threshold levels in foods of the priority allergens. https://doi.org/10.4060/cc2946en.*~~
FAO and WHO (2023). Risk assessment of food allergens – Part 3: Review and establish precautionary labelling in foods of the priority allergens (Sections 3.3.1 to 3.3.6). https://doi.org/10.4060/cc6081en

[4] Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg). The amount of food should be established based ~~on the 50th percentile or population mean for~~ a single eating occasion intake of the food **preferably using the 50th percentile or mean of consumption data for the respective population(s) where available**.

4.3.1 References doses

	Reference dose (RfD) **(mg total protein from the allergen)**
Almond	1.0
Brazil nut	1.0
Cashew (and Pistachio)	1.0
Macadamia	1.0
Pine nut	1.0
Walnut (and Pecan)	1.0
Celery	1.0
Mustard	1.0
Peanut	2.0
Egg	2.0
Milk	2.0
Sesame	2.0
Hazelnut	3.0
Wheat	5.0
Fish	5.0
Buckwheat	10
Lupin	10
Soy	10
Crustacea	200

4.3.2 Where a reference dose is not established for a particular **food** allergen by 4.3.1 above, national authorities can establish a reference dose consistent with recognized principles[5] for the purposes of determining an action level.

4.4 PAL should be accompanied by education/information programs to ensure understanding and appropriate use of PAL by consumers, health care providers and food business operators.

5. PRESENTATION OF PAL

5.1 Section 8.1.1, 8.1.2 and 8.1.3 and 8.2 of the General Standard for the Labelling of Prepackaged Foods (GSLPF) (CXS 1-1985) apply to PAL labelling.

5.2 PAL should appear as a separate statement in the same field of vision as the ingredient list (when present).

5.2.1 A PAL statement shall commence with the words ‘May contain’ (or equivalent words) and include the identified allergens using the specified names as listed in sections 4.2.1.4 and where applicable 4.2.1.5 of the GSLPF.

5.2.2 A PAL statement shall contrast distinctly from surrounding text such as through the same font type, style or colour used for declarations made in accordance with section 8.3.1 of the GSLPF.

[5] FAO and WHO (2022). Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens: Part 2: Review and establish threshold levels in foods of the priority allergens. https://doi.org/10.4060/cc2946en.

APPENDIX III

RESPONSE FORM

Codex Committee on Food Labelling
Electronic Working Group on Allergen Labelling

2nd Consultation Paper

Please provide a response using this form and post on the Codex eWG Allergen Labelling online-forum by **19 July 2024**.

Name of Member Country/Observer:
European Federation of Allergy and Airways Diseases Patients' Associations (EFA), with special to the members of our Food Allergy Working Group for their valuable contributions.

Part A

Question 1: Do you support the proposed revision to the definition of 'food allergen'?	
Yes **X**	No ☐
Please provide reasons for your answer: EFA agrees with the revised text proposal.	

Question 2: Do you support the proposed revision to section 4.2.1.7?	
Yes **X**	No ☐
Please provide reasons for your answer: EFA agrees with the revised text proposal.	

Question 3: Do you support the proposed revision to section 4.2.3.1?	
Yes **X**	No ☐
Please provide reasons for your answer: EFA agrees with the revised text proposal.	

Question 4: Do you support the proposed revision to sections 8.3.1, 8.3.2 and 8.3.2.1?	
Yes **X** to 8.3.1 and 8.3.2.1 (with comments)	No **X** to 8.3.2
Please provide reasons for your answer: **8.3.1:** EFA agrees with the proposed revision in 8.3.1 as for food allergy patients it is of paramount importance that the presence of allergens in the ingredient list is easily identifiable at all times. Therefore, we consider that deleting 'whenever possible' offers greater clarity to the provision. **8.3.2.1:** EFA agrees with the spirit of the revised 8.3.2.1, with two comments:	

- We strongly suggest to remove '(or equivalent word)' after 'Contains', as the use of different wording in different national settings might trigger confusion and leave room for alternative interpretations. We consider that the **harmonised use of a single word** such as 'Contains' provides for safety and equal implementation.
- We insist that the separate statement should be placed 'directly under' to the list of ingredients, and therefore the text 'in close proximity to' must be removed from the revised version. We consider that 'in close proximity' is too vague and might prove difficult in cases of big packaging.

8.3.2: Like in previous rounds of consultation on this aspect, EFA insists that **separate allergen statements must be mandatory**, and placed **directly under** to the ingredient lists. Again, this assessment is based on testimonies from the European food allergy patient community, showing that these statements can be very helpful for consumers, combining convenience, exhaustiveness and standardisation. You can find EFA's response to the previous consultation on allergen labelling here.
For EFA, this is an overarching principle that would benefit consumers horizontally, regardless their country. Therefore, at EFA we do not see value in leaving this issue at the discretion of national competent authorities, as this would certainly lead to imbalanced implementation and confusion among consumers.

In this regard, EFA reiterates its call for the establishment of a unified **'allergy statement'** that would gather in one place not only information from the ingredient list but also Precautionary Allergen Labelling (where applicable) and other allergen-related information of the food product (e.g. Precautionary allergen statements for Novel Food such as Insects or rapeseed protein or - maybe in the future - products from precision fermentation such as animal free milk protein, that contain the allergen but do not fall under mandatory allergen labelling, because the milk protein is not produced from milk).
EFA has also made specific proposals for the operationalisation of this statement, offering relevant templates/examples that could be used, both with and without PAL for unintended allergen presence. You can find them below:

"Allergy statement with PAL"

“Allergy statement” when PAL for unintended allergen presence is not needed:

*‘May contain: -‘: (as indicator that a risk assessment has been conducted and there is no unintended allergen presence).

In this light, EFA propose that the text changes as follows:
*‘The specified name for the foods and ingredients in sections 4.2.1.4, 4.2.1.7 and where applicable 4.2.1.5 shall be declared in the list of ingredients ~~or~~ **and** in a separate statement**.** ~~which shall be [placed directly under or in close proximity to] the list of ingredients or in both as determined The most appropriate manner to declare these foods and ingredients shall be decided by national competent authorities~~.’*

Question 5: Do you support the removal of the square brackets from Section 4.2.1.6 and the update to the associated footnote?	
Yes **X**	No ☐
Please provide reasons for your answer: EFA agrees with the removal of the square brackets from section 4.2.1.6 and the updated associated footnote.	

Question 6: Do you support including a list of exemptions in the GSLPF based on the ‘current accepted exemptions’ in Annex 1 from the Expert Committee’s Part 4 report? If Yes which of the ‘current accepted exemptions’ from Annex 1 do you consider suitable for inclusion on a list of exemptions?	
Yes **X**	No ☐
Please provide reasons for your answer: EFA supports all current accepted exemptions of Annex 1 provided in the European Union. EFA also largely agrees with the exemptions provided beyond the EU, with one exception: beer (provided in Australia and New Zealand). This is because beer contains high levels of wheat, barley and gluten. For example, wheat-based-beer is known to elicit allergic reactions in patients with wheat allergy.	

Moreover, we would like to note that there are at least two current exemptions that are not listed in this table:

- Lactitol (exempted in EU, Argentina)
- Refined oils (exempted in the US), including refined fish oil e.g. DHA and other oils (except cold pressed oils).

We invite the Chairs to consider including in the table of Annex 1 these exemptions too, as well as other accepted exemptions currently in place worldwide.

Part B

Question 7: Do you support the revised text for Principle 4.2 in the draft PAL guidelines?	
Yes **X** (with comment)	No **X**
Please provide reasons for your answer: As in the previous consultation, EFA recognises that both quantitative and qualitative approaches can be used for the assessment of risks from unintended allergen presence. However, we firmly believe that quantitative risk assessments are the most effective method in determining whether a PAL statement should be used or not, and that this should be reflected in the text. Therefore, we strongly encourage the Chairs to reinstate the reference to *quantitative* risk assessment in the text suggest as follows: '…which shall include, **where possible**, **quantitative** risk assessment', or at least retain the previous text: '…which shall include, **but is not limited to, quantitative** risk assessment'	

Question 8: Do you support the revised text for Principle 4.3 in the draft PAL guidelines?	
Yes **X** (with comments)	No ☐
Please provide reasons for your answer: EFA overall agrees with the proposed text version, as we have consistently called for a balanced PAL approach that protects allergic consumers' health from exposure to unintended allergens in foods; while also safeguarding their food choice by avoiding proliferation of PAL in food products. Moreover, we would like to reiterate **EFA's support to the use of ED05-based methodology for deriving reference doses (RfDs)** for the priority allergens and the one that can best ensure the balance described above. With regards to calculating single eating occasions, at EFA we fully acknowledge the potential gaps in knowledge and data collection capacity. However, allowing the use of alternatives to consumption data (e.g. using a serving (or portion) to determine single eating occasions, would offer excessive flexibility to food business operators (FBOs) to define portion sizes that are not necessarily based on realistic consumption scenarios. This is likely to lead to large variations and heterogeneity in the use of PAL, which is the exact	

opposite from the harmonisation that food allergy consumers need and would not solve any of the current shortcomings of PAL.

Therefore, EFA reiterates that, instead of using data from food consumption surveys as a starting point, the FBO's knowledge of the product and its use should be considered.

To avoid an imbalanced use of PAL, the above flexibility should be explicitly limited to those cases where neither data from food consumption surveys nor FBO knowledge of how consumers use their product are available.

Footnote 3: Action level (mg total protein from the allergen / kg food) = Reference dose (mg total protein from the allergen) / Amount of the food (kg). The amount of food shall be established based on the 50th percentile or population mean for a single eating occasion intake of the food ***preferably using the 50th percentile or mean of consumption data for the respective population(s) where available.***

Question 9:

Do you have any further comments on the proposed draft annex to GSLPF: Guidelines on the Use of Precautionary Allergen Labelling in Appendix II which the EWG Chairs propose to take forward for discussion at CCFL48?

Yes **X** (with comments)	No ☐

Please provide reasons for your answer:
4.3.1 and 4.3.2: EFA is in full alignment with the principles as they are presented.

4.4: We encourage the Chair to make explicit reference to the need for *mandatory* education/information programs, ensuring the appropriate use and interpretation of PAL by all stakeholders. To the same goal, we stress the need to develop a communication guideline addressed to consumers who react to very low doses of the priority allergens (below ED05); explaining the context and the key principles to them in an accessible way; and fighting common misconceptions around PAL, including explaining the different health implications at the population level of using one or another quantification method as the basis to use PAL.

5.2: We strongly recommend to replace 'in the same field of vision as the ingredient list' with 'directly under the ingredient list' or 'immediately following'.

5.2.1: As noted in the previous consultation, EFA insists that there shall be one harmonized wording for PAL. In this respect, we would remove the text *'or equivalent words'* as it can be easily misunderstood and even possibly lead to a variety of statements.

Use of a risk assessment indicator
In line with our response in the previous consultation, EFA insists that, in the event that PAL remains voluntary, as it is now, **the risk assessment indicator is absolutely critical and should be included in the Guidelines**, as it would be a key factor reassuring consumers that a risk assessment has been performed, based on which PAL has been used.

In case of PAL becoming mandatory, as we strongly believe should be, information on risk assessment would be incorporated into PAL so an indicator would be redundant. Especially in combination with a mandatory 'allergen statement' based on the principles outlined above (Question 4), this scenario would appear as 'May contain: -', indicating that a risk assessment has been conducted and there is no unintended allergen presence.