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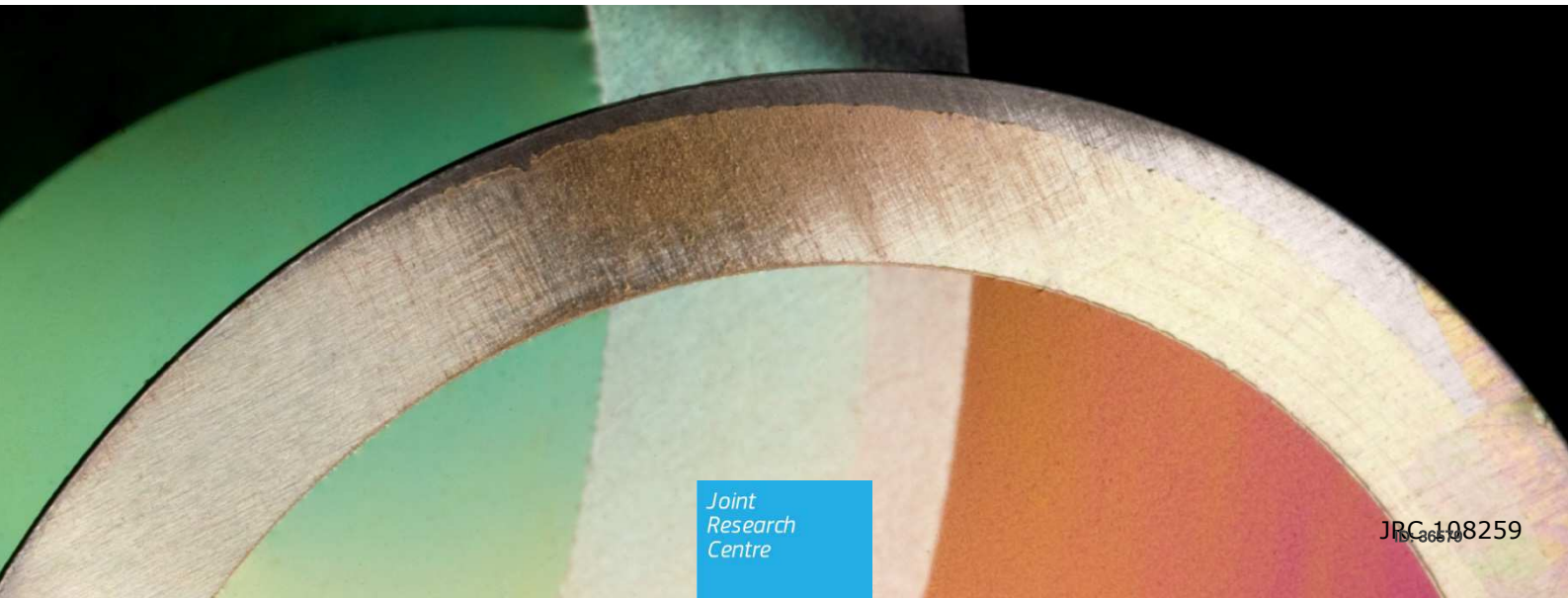
Joint DG SANTÉ and DG JRC workshop

Harmonisation of Approaches for informing EU allergen labelling legislation

Meeting Location:
Geel, Belgium
16-17 June 2016

G. O'connor, M. Haponiuk (DG SANTÉ), F. Ulberth



JRC 108259

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JOINT RESEARCH CENTRE
Directorate F - Health, Consumers & Reference Materials (Geel/Ispra)
Food & Feed Compliance

Joint DG SANTÉ and DG JRC workshop:

Harmonisation of approaches for informing EU allergen labelling legislation.

Meeting location: Geel, Belgium on the 16th & 17th June 2016

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Meeting Summary Report

Introduction

In an effort to protect European consumers Regulation (EU) No 1169/2011, on the provision of food information to consumers (FIC), requires the provision of allergen information on both prepacked and non prepacked foods when allergens are **intentionally** incorporated in foods, namely when they are ingredients. The information of the presence of such allergens-ingredients is not subject to any threshold (except for the sulphur dioxide and sulphites). Even traces of allergens when they are ingredients must be labelled.

The EU legislation does not contain any specific provisions concerning information on the **possible and unintentional presence** in food of substances or products causing allergies or intolerances. However, the Regulation foresees that the Commission shall adopt implementing acts to ensure that information on the possible and unintentional presence in food of substances or products causing allergies or intolerances does not mislead or confuse consumers (Article 36.3(a)).

In addition, Regulation (EC) No 178/2002 lays down the general principals and requirements of food law. In particular, its Article 14(1) of the Regulation provides that food shall not be placed on the market if it is unsafe. According to Article 14(2) of the same legislation, food shall be deemed to be unsafe if it is considered to be injurious to health or unfit for human consumption. The presence of allergens in food has been defined by the European legislators as subject to safety concerns. This interpretation is also reflected in the Commission document "*Standard operating procedures of the Rapid Alert System for Food and Feed*"[1], which outlines the case of pre-packaged food items in which the presence of an allergenic ingredient, as required by Regulation (EU) No 1169/2011, is not labelled, in cases where Member States have considered that the risk was such as to require rapid action. With regard to foods in which an unintentional presence of allergenic substances has been detected and which are not mentioned on the label, the before-said document lists it under the examples where Member States have considered that the risk was such as to possibly require rapid action (in some cases following an ad hoc risk evaluation).

Many food business operators (FBOs) opt to use precautionary allergen warnings (PAL) to alert allergic consumers on the possibility of, and consequently the risks from, the inadvertent presence of allergenic constituents. PAL is communicated today using a number of different statements. Whilst the intention of such warnings is to help allergenic consumers to make safe choices, the diversity and inconsistent application of the warning messages has left consumers confused. In addition, the lack of a uniform approach adopted at the European level with regard to PAL leads to divergences in the way the warnings are assessed by the competent national authorities.

In this context it was felt necessary to have a meeting with representatives of the competent authorities in the EU Member States, industry and patient groups to discuss how PAL was being applied in different Member States. At the meeting three central issues were first introduced and then discussed in break-out sessions. The results of these sessions were reported back and discussed in a final plenary session. The meeting agenda can be found in Annex I and a list of those in

[1] http://ec.europa.eu/food/safety/docs/rasff_reg-guid_sops_1-5.pdf

attendance is given in Annex II of this document. The meeting aimed to seek guidance on the appropriate use of PAL from an industrial, legislative and affected consumer perspective. The following is a summary of topics for which clarity was requested and the feedback given in response.

Before the meeting, the following were identified as topics for which a consensus view was sought. Where a clear preference was evident, this has been reported back in the meeting summary.

- Wording and conditions of use with regard to precautionary labelling.
- Common reporting unit for all allergens (e.g. mg of offending food per kg, mg of offending food protein per kg, markers).
- Which analytical methods for determining allergens are currently possible to harmonize/standardize.
- For those allergens identified for early adoption of a harmonisation/ standardisation approach, the identification of specific targets and their conversion into the agreed reporting unit.
- What sort of time scale can we expect before threshold levels or minimum required performance limits for methods are available for all allergens?
- Common approach for triggering legal actions:
    - hazard based vs risk based assessment;
    - based on a single method vs use of confirmatory methods.
- Common approach to distinguish between inadvertent presence of traces of an allergen, which could justify PAL, and presence at ingredient level.

Summary and Conclusions

Topic 1: Legislative and Allergy Sufferers Requirements

As regards the exact wording to be used and what message the labelling should convey, most present agreed that uniform wording and more importantly, a uniform approach in the risk assessment performed to enable such a labelling would be beneficial.

"May contain x", where x is the specific allergen contained in the food, was suggested as being the most widely used and understood wording for PAL. More importantly it was suggested that any form of PAL must be associated with an appropriate risk assessment. The harmonisation of this risk assessment process was deemed essential for using any form of PAL. This association between PAL and evidence that a risk assessment had indeed been performed is lacking in the current application.

There was some demand, mainly coming from the representative of the industry, to establish "safe" limits (i.e. a level of protection acceptable to those concerned), below which the unintentional presence of allergens as a result of cross-contamination should not be addressed by PAL. In this context, the use of "may contain" when an analytical measurement result had indicated the presence of an allergen, was discussed. The contradiction between the statement and a confirmed presence by analysis was of concern to some participants.

Although it has been stressed that establishing a threshold for allergens could be beneficial for the risk assessors and managers based both in industry and regulatory authorities, it was also felt that there is not enough accessible data which would achieve it for all allergens. In this context, some

participants proposed to progress on the topic progressively using "small steps". As a priority, there is a need to frame the wording of PAL and its condition of use on the basis of Article 36(1)(a) of the FIC Regulation. In parallel, it could be envisaged to start the work on the threshold for allergens on which there is sufficient knowledge and science based data (e.g. on peanuts, egg or milk).

Although it was requested that consideration be given to the two separate types of contamination, sporadic and continuous very low level, in terms of how they are labelled, no consensus was reached on this during the discussions.

Conclusions/agreement

- **Wording** of PAL should be harmonised, in a way that it is simple, not misleading and provides for meaningful information. The term "may contain" was the one favoured by the participants.
- **General conditions of use of PAL** should be established. In particular, PAL should only be used when an associated risk assessment has been performed. The conditions of use should be general ones and leave the room for guidelines (at EU, national or sector level).

- Finally, any new provisions/approach with regard to PAL should be accompanied by appropriate **consumer information and education**.

Topic 2: Risk based approaches to allergen management

The role of appropriate risk assessment was acknowledged as an integral part of any PAL. It was felt by most that the link between the risk assessment and PAL was currently missing and that this link should be evident and mandatory in future. Questions were raised about who would provide and how it should be endorsed the risk assessment procedure. Input from EFSA was seen as essential as regards the setting of reference doses by allergen and this may help expedite its use by industry. It was also felt that establishing "industry best practice" could possibly help the process.

Approaches currently being used by industry to aid in the risk assessment process and when to appropriately use PAL were discussed. The Australian & New Zealand Allergen Bureau's VITAL (voluntary incidental trace allergen labelling) risk assessment tool and a tier based risk assessment being developed as part of the iFAAM (integrated approaches to food allergen and allergy risk management) project were specifically mentioned. For these the reference dose is given as the mg amount of allergen food protein observed to trigger a response in 1% of affected individuals (ED_{01}). Reference doses have been published for 11 common foods known to cause allergies representing 10 of the 14 products listed in Annex II of the FIC. The level of risk, serving size and reference doses currently used in these were suggested as being a good starting point but continuous review of reference doses was considered necessary.

Conclusions

- Guidance on a harmonised risk assessment procedure or approach for PAL is necessary.
- Framework on risk assessment should be feasible for all, including SME's.

- Sectorial guidance which would take into account specific characteristics of different FBO's would be beneficial.
- Existing risk assessment tools such as the iFAAM tiered risk assessment or VITAL 2.0 are good starting points.

Topic 3: The role of analysis in enforcing legislation

A number of issues were identified when discussing the impact of the measurements used when enforcing legislation. The lack of comparable measurement results, even when using the same measurement procedures, was seen as hampering progress in the area. It was suggested that efforts should be made to improve this situation, via developing reference measurement procedures, reference materials, etc. However, measurements performed to identify the presence of different priority substances are at different stages of maturity. Therefore a single approach that would have an immediate effect on all allergens was thought unlikely.

The most effective markers to use for PAL were discussed. It was thought measurements were most beneficial when they indicated the likely amount of the allergen present. This impacts on two particular aspects that, as of yet, have not been harmonised. The selection of appropriate analytical targets and the most appropriate unit to express results. After discussion it was suggested that the measurement of the allergenic proteins would be most beneficial. However, current gaps in knowledge concerning both the exact allergenic protein sequences and the robustness of these protein markers to food processing currently hamper this global approach for all priority food allergens. The use of genetic markers, while not considered ideal by some, were proposed as the only currently available option for arriving at standardised detection methods for certain foods. Therefore it is likely that whilst protein methods may be the most appropriate in conveying the likely allergenicity of a product DNA based methods may still be used for screening purposes.

When it came to the issue of universally agreed units in which to express measurement results most agreed that the mg of total allergen containing food protein per kg of total food was the most appropriate. The reasons given for this were that the measurement results were likely only to be useful to those performing risk assessments or for legislative reasons. Currently most risk assessment tools required input in terms of mg of allergenic food protein. Therefore expressing results in this unit is most appropriate.

The alternative of mg of total allergenic food per kg of food was also discussed. This was thought to be more appropriate for some end users and more meaningful to consumers. As the major wish was to link PAL with an appropriate risk assessment it was thought most beneficial if results were expressed in the units that can be used directly by risk assessors (mg of allergen food protein).

On discussing the challenges associated in providing measurements to support labelling provisions for all allergens it was suggested that gaps still exist in terms of the knowledge required for certain allergenic foods. The choice of robust quantitative markers, the natural variation of these markers and/or the ratio of these markers to the total protein content of the allergenic food need to be agreed to enable such an approach to be practical. The fact that methods to detect the presence of the fourteen different priority substances causing allergies are at very different stages of maturity

suggests a staggered approach may be more practical. Therefore continuous communication will be necessary to ensure a harmonised approach in the future.

Conclusions

- Possible agreement on analytical marker(s) and their conversion to a common reporting unity should be encouraged.
- The most appropriate reporting unit for reporting analytical results is mg total allergenic ingredient protein per kg food.
- Establishing an expert group to facilitate the progression of all allergenic foods to report in this manner was thought beneficial. This group should be considerate of work done by CEN and other standardisation bodies in the area.

Annex I

Meeting agenda

Harmonisation of approaches for informing EU allergen labelling legislation

Joint DG JRC and DG SANTÉ workshop
JRC-IRMM, Geel - 16th & 17th June 2016

Participants: Delegates from Member States' competent authorities and delegates representing relevant stakeholders (e.g. Food and Drink Europe and the European Federation of Allergy and Airways Disease Patients Association).

Background: The workshop is organised in the context of Regulation (EU) 1169 /2011 on the provision of food information to consumers and the observed proliferation of precautionary allergen labelling by food producers. The workshop aims to identify the sequence of steps required for framing the current use of precautionary allergen information and its enforcement across the EU. This is expected to include an agreement on the specific reporting units and the required infrastructure for enabling the comparison of allergen measurement results

Thursday 16 June 2016

12:30-14:00	*Arrival, registration, sandwiches*
14:00 - 14:10	Welcome and introduction (Elke Anklam/ Franz Ulberth)
14:10 - 16:00	**SESSION 1: Legislative and Allergy Suffers Requirements**
14:10 – 14:35	Talk 1: Current legislative requirements (Magdalena Haponiuk, DG SANTÉ)
14:35 - 15:00	Talk 2: Perspective of the patient (Roberta Savli, EFA representative)
15:00 - 16:00	Discussion
16:00 - 16:15	*Coffee Break*
16:15 - 18:00	**SESSION 2: Risk Based Approaches to Allergen Management**
16:15 - 16:40	Talk 3: Industrial perspective on allergen risk management (René Crevel, FDE representative)
16:40 - 17:00	Talk 4: Report on the outcome of the recent ILSI/iFAAM workshop on the application of food allergen management tools (Clare Mills, iFAAM representative)
17:00 – 18:00	Discussion
18:05	Bus to the hotel
19:00	*Dinner*

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Friday 17 June 2016

09:00 - 10:45	**SESSION 3: The Role of Analysis in Enforcing Legislation**
09:00 – 09:30	Talk 5: Comparability of analytical measurements for allergens (Gavin O'Connor DG JRC-IRMM)
09:30 – 09:45	Nordic co-operation report on "undeclared allergens in food: Food control, analysis and risk assessment" Ylva Sjögren Bolin, Sweeden
09:45 - 10:45	Discussion
10:45 - 11:00	Coffee Break
11:00 - 12:30	**SESSION 4: Conclusions from Discussion Topics**
11:00 - 11:20	Topic 1: Legislative perspective of precautionary labelling, its current wording and conditions of use.
11:20 - 11:40	Topic 2: Risk based approaches.
11:40 - 12:00	Topic 3: Comparing results from analytical measurements.
12:00 - 12:30	Wrap up and farewell.
12:30 - 13:00	Laboratory tours or allergen lab and reference material production hall
13:00 - 14:00	Sandwiches and departure

Annex II

List of participants

First Name	Last Name	Nationality	Organisation
Minna	ANTHONI	FIN	the Finnish Food Safety Authority
Daniela	BARTSCH	DEU	Chemical and Veterinary Analytical Institute
Martina	BEVARDI	HRV	Teaching Institute of Public Health:Dr. A. Stampar
Anne	BUESO	NOR	The Norwegian Food Safety Authority
Emmanuelle	BUFFET	FRA	ANIA
Chun-Han	CHAN	GBR	UK Food Standards Agency
René	CREVEL	GBR	Unilever Safety & Environmental Assurance Centre
Marc	DE LOOSE	BEL	ILVO
Geert	DE ROOIJ	NLD	FNLI
Sophie	DUSSOURS	FRA	DGCCRF
Jan	ELIËNS	NLD	the Netherlands Food and Consumer Product Safety Authority
Roberto	FANNI	ITA	Olam Europe B.V.
Nathalie	GILLARD	BEL	CER Groupe
Caterina	GUBBIOTTI	ITA	FoodDrinkEurope
Zoltán	HANNIG	HUN	National Food Chain Safety Office (Hungary)
Patrick	HAU	LUX	Direction de la santé
Herodotos	HERODOTOU	CYP	Ministry of Health - Medical and Public Health Services - Helath Services
Geert	HOUBEN	NLD	TNO
Tanja	IVEKOVIĆ	HRV	Ministry of Agriculture
Dirk	JACOBS	NLD	FoodDrinkEurope
Mira	KOS SKUBIC	SVN	The Administration of the Republic of Slovenia for Food safety- veterinary sector and plant protection
Pavla	KUNDRIKOVA	CZE	CAFIA - Czech Agriculture and Food Inspection Authority
Annie	LOCH	FRA	Food Drink Europe
Peter	LOOSEN	DEU	BLL e.V. German Federation for Food Law
Charlotte	MADSEN	DNK	Technical University of Denmark
LUZ MARIA	MARTINEZ	ESP	MINISTRY OF HEALTH-SPANISH AGENCY FOR CONSUMER AFFAIRS- FOOD SAFETY AND CONSUMPTION
Clare	MILLS	GBR	The University of Manchester
Bruna	MORINO	ITA	Ferrero S.p.A.
Angelika	MROHS	DEU	Bund für Lebensmittelrecht und Lebensmittelkunde e.V. (BLL)
Lisbet	NORDLY	DNK	The Danish Veterinary and Food Administration
Giannella	PISANI	MLT	MCCAA - Malta Competition and Consumer Affairs Authority
Katarzyna	POSKOCZYM	POL	CHIEF SANITARY INSPECTORATE
Jean	POTTIER	BEL	Federal Public Service Health- Food Chain Safety and Environment
Michael	PREAN	AUT	Agentur für Gesundheit und Ernährungssicherheit (AGES)

First Name	Last Name	Nationality	Organisation
Antje	PREUSSKER	DEU	BLL e. V.
Stefan	RONSMANS	BEL	Coca - Cola Services
Roberta	SAVLI	ITA	EFANET
Sabine	SCHNADT	DEU	Deutscher Allergie- und Asthmabund
Jürgen	SCHLÖSSER	DEU	Dr. August Oetker Nahrungsmittel KG
Ylva	SJÖGREN BOLIN	SWE	Livsmedelsverket
Hilke	THORDSEN-BÖHM	DEU	Federal Ministry of Food and Agriculture
Christof	VAN POUCKE	BEL	Institute for agricultural and fisheries research (ILVO)
Angeliki	VLACHOU	GRC	FoodDrinkEurope
Mojca	ŽEFRAN	SVN	National laboratory for health- environment and food
Magdalena	HAPONIUK		European Commission - Directorate General Health and Food Safety
Sabine	PELSSER		European Commission - Directorate General Health and Food Safety
Elke	ANKLAM		European Commission - Directorate General Joint Research Center
Franz	ULBERTH		European Commission - Directorate General Joint Research Center
Gavin	O'CONNOR		European Commission - Directorate General Joint Research Center
Chiara	NITRIDE		European Commission - Directorate General Joint Research Center
Jurgen	NORGAARD		European Commission - Directorate General Joint Research Center
Maria José	MARTINEZ ESTESO		European Commission - Directorate General Joint Research Center

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