Public consultation on the draft EFSA Scientific Opinion on the evaluation of allergenic foods and food ingredients for labelling purposes

1 – Introduction

The motivations behind the request of the draft opinion were extremely positive as it was thought that it would have helped to assess the exact number of allergy cases in Europe, however, due to the way the opinion is drafted such opportunity is missed . The experts are not using the latest updated data (e.g. the results of the EUROPERAVALL Project on food allergy held within the FP6 framework) and some studies mentioned are very old and outdated. The opinion does not propose anything really new, as EFSA experts are not suggesting to change the list of the existing 14 allergens (by adding new ones and/or deleting others according to recent research) nor establishing thresholds/reference doses. It does not take into account what people with food allergy are requesting, does not focus on the quality of life aspects and does not result in policy change regarding precautionary labelling.

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2 – Classification of adverse reactions to foods and definition of terms

The panel of experts should have proposed clear definitions of:

- different kinds of threshold (individual, population, control, quality management, "free from");
- safe (as in "safe allergen threshold level");
- risk/benefit of unintended ingredients label;
- severity of reactions: people might die from allergy (anaphylaxis, asthma), but food regulators must also take into account quality of life of and long term associated risks for patients with less severe allergies (atopic dermatitis, urticarial) as they represent a heavy burden both at an individual and a collective level (due to the high health costs).

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5 – Management of food allergy

Labelling is a crucial aspect for a good management of food allergy, as it allows allergy patients to be fully aware of the choices they make and, thus, it contributes to a better control of the disease.

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6 – Epidemiology of food allergy

It would have been useful if the experts included estimates of incidence, including data from serious adverse reaction registries to further assess the public health impact of food allergy. In addition, some new data on the prevalence of asthma with rates now around 30% should be mentioned.

The RASFF – the Rapid Alert System for Food and Feed report of 2013 shows 53 cases of food poisoning. One is linked to undeclared ingredient on standard food (1-50 ppm casein, 0,61-2,5 ppm lactalbumine) and another to milk in "free from" chocolate (510 ppm), but more that 10 have been caused by histamine (1000 to 4375 ppm). Out of the 3137 notification, allergens are pointed in 71 cases (0,02%), nearly the same as 76 GMO/novel food. 410 notification come from industry (13%), but for allergen these industry notifications reach 25 (35%). 118 notifications come from consumers complain (3,76%), while for allergen 14 come from consumers (19,7%). More in general, 29% of

notifications come from official controls in the market, but for allergens this share is 42%. Border control and control in non-Member States are much lower for allergens than for other hazards.

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9 – Cross-reactions

Special case of rapeseed protein: in early February we have been informed about the forthcoming authorisation of rapeseed protein as a novel food. The draft Commission Implementing Decision contained a special labelling provision according to which "**any foodstuff containing rapeseed protein shall bear an easily visible and legible statement that the product containing 'rapeseed protein' as a food ingredient may cause allergic reaction to consumers who are allergic to mustard and products thereof**".

The proposal of labelling products containing rapeseed protein in a way that it is made clear that they can provoke cross reaction in people allergic to mustard is NOT acceptable. Either rapeseed protein is considered as an allergen that has to be listed in future Annex II of Regulation on Food Information to Consumers (which will enter into force as for December 2014), and therefore products containing this protein have to follow the same labelling requirements as those containing the other 14 existing allergen, or it is not an allergen. If this is the approach that has been suggested by EFSA (the Agency is responsible for updating the list of allergen in the EU), then products containing rapeseed protein should NOT present any label on the fact that this may provoke cross reaction in people allergic to mustard. Cross reactions happens with other foods too, such as almonds and peach seeds. We do not label green peas, green beans or lentils, even if peanut allergic people might cross-react.

Information about possible cross reaction is best handled as a patient education issue. If people with mustard allergy are at risk, then they should learn to avoid this protein. It should be the task of the dietician or doctor to give the information on possible cross reaction to the person allergic to mustard. Unfortunately, many patients do not get educated on this topic, so better patient education is of course needed, but it is NOT helpful to label products for cross reaction when there are so many different individual reactions.

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11 – Methods for the detection of allergens and allergenic ingredients in food

EFSA should pay attention to the methods and the normalisation process. In particular, the "proprietary methods" will not give all the information for lab users and thus, it might drive to wrong conclusion of the test.

What is more, there is a need to officially specify the relevant method of analysis for detecting each allergen. Currently the use of methods for the detection of allergens varies from actor to actor: authorities responsible for checking allergens might use certain methods, while private labs use the others. Variety of used methods increases the risk of getting different results, thus if methods are clearly defined and processed this risk is avoided and consumers feel more protected. Moreover, this could serve as a real basis for starting future discussions on allergens thresholds.

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12 – Determination of thresholds for allergenic foods/ingredients

Abolishing precautionary labelling is one of the EFA's long-term priorities, as patients believe that "may contain" labels reduce the choices available to consumers, as it is impossible to know if a particular food with a precautionary label contains the allergen and how much of it is potentially inside. It is in many packaging and, as in some cases products with these labels do not contain residues of allergens or very small quantities that are unlikely to cause a clinical reaction; it may therefore lead to unnecessary restrictive diets.

- In a study from 10 European countries of over 500 types of biscuits and chocolate, "**may contain" labelling for nuts is included on the packaging of 26% of biscuits and 80% of chocolate – regardless of the label [1]**
  It is likely that **90% of products with "precautionary labelling" do not contain residues of peanuts' proteins or very small quantities unlikely to cause a clinical reaction** – starts an **unnecessary restrictive diet [2]**

As a consequence, often people with allergy feel frustrated and they have risk-taking behaviours due to:

- **Variety of the wording**: 80% of parents with children who are allergic to nuts would not let them eat products with "not suitable for" or "may contain" labelling, only 50% would do so with "cannot guarantee nut free," "may contain traces of" labelling
- **Distrustfulness of the message sources**: food business operators are deemed to use it to **discharge any possible liability** in case of adverse reactions following the ingestion of their products
- **Implausibility of the labelling**: either when it is **located on products that legitimately contain the allergen** (e.g.: nuts in a packet of peanuts) or on **others where it is considered impossible that they actually contain it** (e.g.: nuts in a bottle of lemonade)
- **Previous experience** and **personal preferences [3]**

However, serious reactions, and even deaths, have been caused by foods with "may contain" labelling (8% of people with accidental reactions may attribute it to having ignored a "precautionary labelling").

If there is enough data for some of the allergen, EFSA could start by identifying possible thresholds and leave the others unregulated. Risk assessment methods would require the involvement of healthcare professionals and patients as they are the ones taking the risks and they should be involved in the decisions influencing their health. Legislation regulating precautionary labelling already exists in some countries. After thresholds set in Japan in 2001, reported allergic reactions were mostly caused by illegal labelling and they were mainly associated with mild symptoms. Unfortunately, in Switzerland, there are not enough studies and patients' data on this topic to evaluate the legislation on the labelling and advertising of food products to show a decrease in anaphylaxis cases after the entry into force of the law regulating precautionary labelling.

In a short-term, precautionary labelling could possibly be used only as an ultimate solution after the implementation of best-practices to avoid cross-contamination (e.g.: allergen management as part of hygiene/safety manual, responsibility of food business operators at each step of the distribution chain). The establishment of thresholds should not undermine patients' safety. If EFSA cannot find the right scientific evidence for establishing thresholds, then it is the responsibility of food business operators to guarantee that cross-contamination is avoided and thus "may contain" is not used. The new food information to consumers' regulation still requires the Commission to adopt an

implementing act (there is no deadline for this) on different ways Member States adopt precautionary labels. The opinion could have helped the Commission doing this.

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Analytical methods thresholds must be added too. We must obtain some clear "typology" of thresholds regarding not only "how much" but also "how" and "why". Individual sensibilities are used to determinate population ones. EFSA concludes (line 2516) that there is not enough scientific evidences to give them and it doesn't provide any definition of "severe", "mild" reaction neither. Those might be used by political bodies to fix "official" threshold once they'll decide the % of person that can reasonably be protected by consuming "standard" foods (regarding a reasonable daily intake of various foods).

We must also imagine thresholds to protect consumers of "free from" products (that might be more expensive of course for consumers).

Now we must "translate" those thresholds on food content. Those thresholds will be used on the quality management system of food producers all through the food chain. First to test a new line, a new recipe before production and second during production to verify.

Thresholds must, of course, also be used in laboratory: the food producer lab or its analytical supplier must realise analyses (quantitative or qualitative) and conclude if yes or no there is this ingredient on the product and how much. However, analytical methods usually dose only a part of the ingredient (for example only cor8 protein for hazelnut).

After all that decision must be taken: take a decision of labelling or there is no obligatory link between internal quality management and label. That is indeed the case for chemical (pesticides content) or bacteriological (salmonella or listeria *monocytogenes*) or even physical (for example piece of glasses) contaminants.

In the mind of several stakeholders, it seems to be taken for granted that thresholds are dedicated to label decision. In HACCP method, they must be used as quality management decision (that means whether the product is conformed or not, if not it should not be sold) that are not systematically translated in label (would we accept "may contain bacteria" as a warning sticker?). It is thus possible to define thresholds which must be used in HACCP and not appear on label. It is exactly the case in animal feed for example.

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Coeliac disease

EFA supports European Coeliac society which is aimed to work for the best possible safety, availability and labelling of gluten-free food advantageous for all stakeholders involved (celiac disease patients, food sector industry and caterers).Currently there are many products where stickers "gluten free", "may contain gluten" and "non-suitable for coeliac person" are used simultaneously. We also see more and more "gluten free" stickers on products that are not containing naturally gluten and, thus, have no right to say that. We can imagine that in the future, we will find more and more products saying free from but with no regulation. What is more, "gluten free" mode is often driven not by celiac disease awareness but is used as a market opportunity for food production based on threshold and analytical official method.

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