Questions and answers from chat SimplyOK Live event - Reduce allergen recalls 12th November 2021

Overview on international developments in allergen management
Benjamin C. Remington, PhD

1. **Why is only a reference dose for wheat listed, while the priority allergen "gluten containing cereals" also includes rye and barley?**
   Data regarding the prevalence of IgE-mediated allergy to barley or rye is lacking, and there is also a lack data available from oral food challenges in consumers with IgE-mediated food allergies to rye or barley. These foods would be updated in the future if data becomes available, however it does not seem likely due to the rare nature of these allergies and the current lack of data. This situation is not unique to "gluten containing cereals" and shrimp is another example where data was available for a single food within the "crustacea" group.

2. **Is the proposed reference dose of 5 mg for wheat the total of detected wheat proteins (gliadin and glutenin) or total wheat protein?**
   Total wheat protein.

3. **Do we need to take hydrolysed gluten into consideration?**
   Hydrolysed gluten would still need to be considered except when there is a specific, applicable exemption from labelling.

4. **Are oats considered as gluten containing cereals?**
   Pure oats do not technically contain gluten and can be safely eaten by the majority of people with coeliac disease. As such, oats were not recommended to be included in "gluten containing cereals" (in link here). However, a management issue does exist as the presence of "gluten containing cereals" in the oats supply chain and potential cross-contact of "gluten containing cereals" with oats is well-known. In response to this issue, gluten-free oats supply chains have been developed and could be sought out.
   For more details see Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens, 2021. https://cdn.who.int/media/docs/default-source/food-safety/jemra/1st-allergen-summary-report-10may2021.pdf?sfvrsn=c505375a_7

5. **Are the ED05 values used in the recommendations the same as the modelling used for VITAL 3.0 which provided both ED01 and ED05 values?**
   They were the starting point for discussion, but not exactly the final recommendation. As stated in the Summary and Conclusions available for Part 2 of the Ad Hoc meeting, "the Expert Committee discussed potential data sources. They noted that the data reported in the publications of Remington, et al., (2020) and Houben, et al., (2020) were the most comprehensive and best described source available" [Editorial note: they were also used by VITAL Scientific Expert Panel for VITAL 3.0 recommendations] and "the Committee agreed that, for all priority allergens, the safety objective would be met by starting the definition of RfD at the ED05 (as evaluated using the data from Remington, et al. (2020) and Houben, et al. (2020)). To make the application simpler, the Committee further simplified its recommendations by rounding the ED05 values down to one significant figure (with some exceptions for allergens with limited data). Those foods with close ED05 values were then grouped together and a single value derived for the RfD, further rounding down the value, if necessary."
   For more details see: Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens, 2021. https://cdn.who.int/media/docs/default-source/food-safety/jemra/2nd-allergen-summary-report-20aug2021.pdf?sfvrsn=915a8417_8

6. **On what specific data the Reference doses are based? E.g. region of the world, healthy people and or does it take into account the potential for co-factors to change thresholds?**
   Data was collected on a global bases, where available. See the supplemental material in Remington et al., 2020. (https://doi.org/10.1016/j.fct.2020.111259) for more information. Data is collected in oral food challenges, in the absence of co-factors such as exercise, sleep deprivation, and intercurrent infection. To date, the effect of potential co-factors on the change in threshold is debatable and reported decreases of due to co-factors well within the normal, daily intraindividual variation in reaction threshold [in the absence of co-factors]. (Patel et al., 2021. https://doi.org/10.1016/j.jaci.2021.01.025; Turner et al., 2021. https://doi.org/10.1016/j.jaip.2021.08.008) "The difference between allergen and allergy management should be emphasized in this respect. It is recommended to account for individual co-factors as part of the allergy management advice, as discussed between an allergic individual and their physician, not within allergen risk assessment and allergen risk management on a population level" (Remington et al., 2020. https://doi.org/10.1016/j.fct.2020.111259). Still when modelling, the distributions were fit to the data, including accounting for random effects which enter the models through study-to-study heterogeneity (i.e. differing protocols, participant recruitment, dosing schemes, possible regional genetic or environmental differences, etc) (Remington et al., 2020. https://doi.org/10.1016/j.fct.2020.111259).

7. **Does the reference dose for milk only pertain to cow's milk?**
   At this point, data supporting any reference dose for milk is derived from individuals with IgE-mediated allergy to cow's milk.

8. **If soybeans is delisted at Codex and in some regions in the world, would it really be possible to keep regional listing given trade and lack of information with such a widespread commodity?**
   Regional allergen lists already exist and have been worked with in trade or risk assessments for a number of years. Soy would pose some potentially new questions, but I think that it would be possible.

9. **When will the full FAO/ WHO reports be published?**
   I cannot give an exact answer, but the intention is 2022, if all goes smoothly with publishing workflows, necessary translations, etc.

10. **How should a PAL be applied between lots of the same product with different cross-contact?**
    a. Different allergen labelling between lots of the same product is not helpful to consumers with food allergies and their caregivers nor is it feasible for producers. This should not be done.
    b. It would be very confusing and risky for consumers with food allergies and their caregivers to have different labels on different lots of the same product. Consumers would no longer be able to read the label for one product and then put multiple items of that product into their basket. Imagine the added burden this would add during shopping. In addition to the added time spent reading, there is likely a loss in trust of labelling if it differs every time a consumer reads a product. In the end, differing labels on different lots of the same product would lead to added risk taking behaviours, whether they were intentional or not. A consumer could intentionally begin to ignore allergen labelling and increase their risks of a future reaction. Another consumer could be buying what they believe was a safe product and one that looks identical to every other from that brand/flavour combination, but it has different allergen labelling and the end outcome of an unintentional added risk of an allergic reaction. On top of all of that, from a production standpoint, the differing labels on otherwise identical products would lead to a higher risk of the wrong product being produced in incorrect packaging.

Remarks of participants:
Spain requires to highlight allergens in the PAL statement and list individual allergens instead of a group name (hazelnuts instead of nuts).
https://www.aesan.gob.es/AECOSAN/docs/documentos/seguridad_alimentaria/gestion_riesgos/Etiquetado_Precautorio_alergenos.pdf The Australian legislation has changed just this year to require allergens to be bolded in the ingredient lists (and for tree nuts they need to be called out individually). They have also mandated the contains statement. Allergen Bureau has recommended industry best practice is to also call out the allergens individually in the PAL statement.

Allergen recalls- analysis, insight and simple steps to reduction.
Rob Kooijmans

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Impact of SimplyOK certification – differences with GSFI recognised schemes and next level in food safety. Jisvi Schreuder

SimplyOK certification

11. **Are there retailers that demand the SimplyOK certification?**
    The five basics of SimplyOK and the VITAL approach are used by several Dutch retailers for their private label suppliers. At this moment Jumbo requires a SimplyOK certification in case of lactose-free products and allergen related recalls.

12. **What are the advantages to be SimplyOK certified?**
    SimplyOK is a specific standard focussing completely on allergen management, so the customer knows that the organization has been audited by a trained auditor with focus and enough time to assess the complete allergen management system. Not all basics of allergen management and underpinning of a PAL by VITAL are covered in GFSI endorsed standards. SimplyOK helps to reduce allergen incidents and improving "trust".

13. **What is the difference between the SimplyOK certification and the VITAL scheme?**
    SimplyOK applies a management system approach. VITAL is a risk assessment tool and an element of the requirements of SimplyOK.

14. **Are audit calculations for an SimplyOK audit, likewise GFSI based on standard tables and calculations, e.g. amount of lines, FTE, m2 factory?**
    Yes, a minimum time is calculated based on FTE (in scope) and product groups/complexity. This is discussed during the stage 1 audit and agreed on between auditor and organization that applies for certification.

Labelling and SimplyOK certification

15. **How do you deal with PAL requirements when there is no harmonised wording in the world?**
    The concept of risk assessment and the use of PAL as a risk communication is a general approach. It can be used without harmonised wording, although this is preferred.

16. **Can a "gluten-free" claim be made if a gluten-free ingredient <10 ppm) is sourced from a supplier where also wheat is handled and cross-contamination risk is managed by measurements in place?**
    Gluten-free production is not excluded when gluten containing ingredients are processed in a same area. However, rigid measures should be taken to prevent cross-contact and evidence (eg. by analysis) should be provided gluten contamination does not occur.

17. **Is there a SimplyOK logo for the labelling of consumer products that have passed a SimplyOK audit during their manufacture?**
    SimplyOK is a management system audit. No product certification is performed. So no logo's on products are applied.

VITAL calculations

18. **Is there a tool for calculating possible allergen concentrations in a product due to cross-contact?**
    Based on the VITAL approach many calculation tools are available, ranging from integrated product specification software tools to standalone tools such as VITAL Online https://vital.allergenbureau.net/ .

19. **How do you calculate the allergen protein of an allergenic ingredient?**
    For single ingredients the total protein from the nutritional table can be used as being the allergenic protein (eg. wheat flour with 11% protein). For multiple ingredients, consisting of more protein sources, the composition of the product and its individual ingredients should be taken into account.

20. **Is there any example regarding calculations ? I think, this is very complex. An estimated calculation can be done, nevertheless testing is must**
    Examples of VITAL calculations and practising skills in the use of the calculator can be obtained from endorsed VITAL Trainers: https://vital.allergenbureau.net/vital-training/ .

21. **Can a calculation be performed on ingredients (B2B) as well?**
    Yes. But to decide if a PAL should be used on an end product as presented to consumers, the amount of cross-contact should be compared to the action level. A consumption size is needed to calculate the action level. In most cases consumption sizes of end products of customers are not known for bulk products. In that case only the calculated concentration of cross-contact is provided to the next step in the food chain.

22. **What do you advice on selecting product groups for doing the calculations for worst case recipes? Is a whole department with approx. 70 recipes too big?**
    In a VITAL calculation the total cross-contact of ingredients (due to cross-contact in the supply chain) and due to processes are totalised. For cross-contact in a process products with similar process steps can be grouped and calculated from a worst-case approach.

Analysis

23. **What about the analyses used to investigate whether allergens are present or not within the product?**
    Analysis is not the starting point of a VITAL calculation, but analytical testing can be used to confirm the allergen status of an incoming ingredient or can be useful for validating a VITAL risk assessment, including assumptions made.

24. **How do we do it quantitative calculations, as we not have Elisa methods for all allergens.**
    Analysis is not always needed (see 23). Also other quantitative methods are available than only ELISA. A VITAL calculation can always be performed based on total protein from an allergenic source.

25. **Is there an overview of now existing allergen analyses tests per allergen including their detection limit?**
    Analysis of allergens is very complex. If analytical allergen testing is conducted, consult a skilled analyst to ensure that the correct methodologies are used and that the units of measure are appropriate to use with the VITAL Action Levels. Be aware of cross-reactivity, influence of matrix or processes, target proteins and applicable conversion factors.

Allergen management

26. **Does alcohol/disinfection denature allergens? Case: employee forgets to wash his hands after eating gluten, but does disinfect his hands. Is this a risk for cross contamination?**
    Allergens should be completely removed, i.e. by washing. Alcohol does not 'destroy' allergens.

Remarks of participants:

Good supplier information is generally considered as a challenge. SimplyOK provides a template to streamline information in the supply chain: https://tinyurl.com/allergentemplate.

Developments in SimplyOK allergen management certification: an innovative modular approach. Jules Rojer

27. **What is an AMC?**
    AMC is an abbreviation of Allergen Management Complexity. Based on the characteristics of an organization an AMC profile is defined. The AMC profile does not give a judgement on functioning of the allergen management system, but only indicates the degree of complexity. Therefore an AMC profile does not reflects a risk or level of control of an organization's allergen management system. Complexity is determined, among others by the number of allergens, allocation of recipes over production lines, free-from claims, product change-overs, type of cleaning and data management.

28. **Can you change your AMC profile?**
    In first instance your AMC start profile will be determined by an online tool. Using the set of guided questions your AMC profile will be determined. This start profile is the minimum on which the first assessment will be performed. The start profile will be validated, confirmed or adjusted by the certification body during the assessment.

29. **What is the time-planning of the AMC pilot?**
    Currently we are in the process of defining the pilot and planning. The focus is the conduct the pilot in the Q1/Q2 of 2022 in association with a retailer.

30. **When can I be assessed according to the new modulair approach?**
    The system is not ready yet for assessing organizations against the new modular approach. During the SimplyOK live event the new approach was shared with the community. As explained, we first will have to validate the new system by the pilot. Also, the SimplyOK Code of Practice shall be updated to support the new modular approach. Considering the amount of work involved we estimate that the first organizations could be assessed against the new modular approach in early 2023.

Remarks of participants:
If you are interested to extend the pilot into other regions we can facilitate in South Africa.