1. Checklist for:
Product Developers

Purpose: To help product developers improve the safety of food handling from an allergy perspective.

To help consumers with allergies and food intolerances.

Requirements: To be aware that consumers expect and demand that all food handlers have the knowledge and insight required to supply safe foods of high quality. Consumers can not be responsible for mistakes and errors at the production and distribution stage.

To read and understand the Food Sector Guidelines and have insight on what "allergy and intolerance" involves! It is important to be aware of the level of sensitivity, reactions and consequences.

In this document, *allergens* refers to allergens and other food intolerance-causing substances. The substances and products thereof listed below are those that most often cause allergic and adverse reactions. These are also the foods and ingredients for which special requirements regarding labelling and food information to consumers apply (Regulation (EU) No. 1169/2011 and Swedish National Food Agency regulation LIVSFS 2014:4).

1. Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut or their hybridized strains, and products thereof, except: a) wheat based glucose syrups including dextrose[1]; b) wheat based maltodextrins[1]; c) glucose syrups based on barley; d) cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin.	2. Crustaceans and products thereof. 3. Eggs and products thereof. 4. Fish and products thereof, except: a) fish gelatine used as carrier for vitamin or carotenoid preparations; b) fish gelatine or Isinglass used as fining agent in beer and wine. 5. Peanuts and products thereof.

6. Soybeans and products thereof, except: a) fully refined soybean oil and fat[1]; b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources; c) vegetable oil derived phytosterols and phytosterol esters from soybean sources; d) plant stanol ester produced from vegetable oil sterols from soybean sources. 7. Milk and products thereof (including lactose), except: a) whey used for making alcoholic distillates including ethyl alcohol of agricultural origin; b) lactitol.	8. Nuts, namely: almonds (*Amygdalus communis* L.), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoinensis* [Wangenh.] K. Koch), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia or Queensland nuts (*Macadamia ternifolia*), and products thereof, except for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin. 9. Celery and products thereof. 10. Mustard and products thereof. 11. Sesame seeds and products thereof. 12. Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO_2 which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers. 13. Lupin and products thereof. 14. Molluscs and products thereof.

[1] And the products thereof in so far as the process that they have undergone is not likely to increase the level of allergenicity assessed by the authority for the relevant product from which they originated.

If changes involving allergens are made to a product or production process, the following control procedures should be reviewed to ensure that mistakes do not occur.

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
1. Hazard analysis – Risk assessment Is a HACCP-based assessment of allergy risks carried out in the product development work? .	New allergens introduced in a factory without the risk for contamination of other products having been evaluated. New allergens added to products where the consumer does not expect them.			
2. Coordination - Cooperation Do product developers, production staff, purchasers, raw materials suppliers, etc., work together during product development to ensure that allergy risks are considered at every step of the production process – from purchasing and receiving, to handling and storage of raw materials and the finished product?	A risk assessment must always be conducted during trial runs of new products in order to avoid introducing new allergens to the production line and contaminating other products.			
3. Training Do the company's product developers receive ongoing training in allergy issues?	Employees must understand the risks of allergens in order to minimize contamination of the product by allergens.			
4. Documentation of raw materials Are there procedures to ensure that only well-documented raw materials are used?	The supplier has inadequate knowledge about allergies and food intolerance issues, and does not provide complete specifications for raw materials. Note that an allergen can sometimes be present as a sub-component of a raw material, additive, etc., e.g. in the form of a carrier in a seasoning mix or a processing aid.			

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
5. Raw material specifications Are there raw material specifications for all ingredients in the product as well as other allergy information as required by EU labelling rules?	Carry-over additives, processing aids, etc., stemming from allergenic raw materials.			
6. Raw material suppliers Are there procedures in place to ensure that raw material suppliers are not able to change a recipe without prior approval from the company using the raw material?	The manufacturer does not find out that the supplier has modified a recipe until after the change has been made.			
7. Alternate suppliers Are there procedures in place to ensure that another supplier can not be substituted for a raw material supplier without prior approval?	A new raw material is introduced that involves a change in the ingredient list.			
8. Measures for suspected contamination Are employees encouraged to take immediate action in the case of suspected contamination, incorrect labelling, etc., and are there procedures for how this information should be passed on? Inform appropriate authority if there is reason to believe that a food product that has entered the market may be harmful to human health, and inform of the measures taken.	An employee does not understand the risks and does not know that such cases must be reported immediately.			

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
9. New allergens When developing products, the addition of new allergens to recipes of existing products should be avoided. If this can not be avoided, are there procedures for recipe changes?	Wrong raw material is used in a product. The risk of this can be reduced, e.g. by changing the product numbers of the raw material, intermediate product or finished product. Rules for GTIN barcodes must be followed.			
10. Consumer information for new allergens If a new allergen is introduced to a recipe of an existing product, are there procedures for how to communicate this to consumers?	When recipes are changed, "new recipe" or similar wording should be stated on the package. When selling unpackaged foods, this information may be provided in other ways, e.g. by posting the information at the sales counter or point of sale.			
11. Contracted manufacturing When a product is made by another company, are there procedures to ensure that the ingredient list is correct and that allergen contamination is minimized?	The contractor has not been informed of the recipient's rules and requirements.			
12. Allergen management systems Are there quality systems in place for the products included, e.g. in an official allergen list, to ensure that the risk of contamination is minimized?	The allergen lists provided do not match the actual production situation.			

Control Point	Example of problem	Yes	No	Note current routines and areas for improvement
13. Procedures for "may contain", "free" labelling Are there procedures to ensure that package labelling follows existing regulations, e.g. regarding the use of "may contain" and "free from", etc.?	The product developer is not aware of Food Sector Guidelines and requirements for using "may contain" on labels. The use of "free from" labelling is also regulated.			

Date: ……

Name of person who completed checklist: ……

Company name and address: ……

Review your work practices with the help of the checklist regularly. Take and document corrective actions. Save completed checklists!

Handling procedures for product alerts

Control Point	Comments	Notes
A. General points A.1 Are there procedures for handling product alerts? A.2 Are the procedures used and followed?	The company's internal procedures should always be followed first. People involved in product alerts are usually those who work with consumer contact, purchasing, and marketing and distribution managers.	
B. Gather information B.1 Is the consumer still sick? B.2 Which product did the consumer eat? B.3 What else did the consumer eat? B.4 Does the consumer have a known allergy or intolerance – to what? B.5 Tell the person you will get back to him/her.	If the consumer is sick – suggest that he/she seek medical attention. Note the product name, size, "use by" date, date of purchase, where the product was purchased, batch number and GTIN code. If possible: save the product in question and try to obtain an unopened package from the same batch for testing. *(Add your own comments to the checklist!)*	
C. Evaluate C.1 Contact your supervisor or person in charge of handling urgent consumer complaints – evaluate together. C.2 If necessary, gather more information. Contact supplier? Perform analyses? Seek the assistance of the control agency!	*(Add your own comments to the checklist!)*	

Control Point	Comments	Notes
D. Take action D.1 Protect other consumers – Consider whether sales should be stopped! D.2 Inform supplier and regulatory agency? D.3 Investigate whether the product should be recalled? D.4 Investigate, in cooperation with authorities, whether a press statement should be issued? D.5 Inform the affected consumer. D.6 Request an investigation and follow-up by supplier.	*(Add your own comments to the checklist!)*	
E. Follow up – Improve E.1 Once the case is resolved, follow up the outcome and discuss how your procedures can be improved! E.2 Ensure that the responsible product developer is informed of the situation.		

Date: ……

Name of person who completed product alert checklist: ……

Company name and address: ……

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