

FOOD SAFETY EXPERTS 

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**7 Important Areas for Allergen
Management to Prevent Recalls**



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Introduction

Imagine the following situation: you are called by your biggest customer and the VP Quality & Regulatory Affairs of that company informs you that due to the presence of undeclared allergens several consumers have been hospitalized and two consumers have already died because of eating your product! Of course this is your worst nightmare. You really feel guilty for those people who have died or are in agony in hospital as well as for their families. You frantically try to think of the root cause for all of this. Your company is fully GFSI certified; how could this ever happen to you and your company?

Is this something you have experienced or do you feel this a realistic scenario in the not too distant future? If yes, you are probably right. From analysis of international alert systems we know



that allergens are the number 1 cause for recalls which are caused by companies themselves. We know that 50% of the recalls are caused by issues handed down the supply chain by your suppliers. The other 50% are caused by the companies themselves – so in total 25% of the annual volume in recalls is based on the presence of undeclared allergens.

Because (international) legislation is still zero tolerant to the presence of allergens in food products, authorities will immediately force you to perform a full blown, most of the time even public, recall of your

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products. Naturally, you want to prevent this from ever happening to you and your company! In this e-book we will share the 7 Must Do's in the area of allergen issue prevention. Make sure you implement all 7 seven aspects which are described as when it comes to allergen management we can clearly stat that the chain is only as strong as its weakest link!

In this book we explain to you the essentials of allergen management that must be in place to prevent recalls for your company. It is of paramount importance that all area's discussed are thoroughly implemented, because a chain is only as strong as its weakest link. Enjoy reading our e-book!

Kitty Appels & Rob Kooijmans



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About us

We are Kitty Appels and Rob Kooijmans, founders and owners of Food Safety Experts, Food Safety University and FoodRecall.nl. Together we have more than 40 years of experience in the international food industry and have worked for and with all the large players in the food industry. We also have a wide experience in working with a vast amount of SME's in all areas of the food industry. Our experience includes fruit & vegetables, nuts & spices, meat, fish, dairy, beverages, baking, bio-technology, infant nutrition, pharmaceuticals and ready to eat.

We believe that everybody should be able to enjoy safe food at all times. We believe that by sharing our knowledge and tools with QA and Food Safety professionals across the globe, together we will make a difference towards improving food safety for everyone. Our vision is a world where safe food is a given for everyone. Our mission is to enable QA and Food Safety professionals to make a difference towards improving food safety. We do this by actively sharing our knowledge and tools and by creating a global community.

Kitty has studied Food Technology at the Van Hall Institute in Bolsward, The Netherlands. From there on she worked for Friesland Domo in Japan, was Technical Sales Manager for Ecolab in The Netherlands, QA manager for Tauw Group, she performed a lot of due diligence investigations and had several interim positions while working for Tauw International and as entrepreneur. Kitty has worked for renowned companies like Heineken, Silliker, Sealed Air and Friesland Campina and has audited many more companies on a global level during her career as part of her due diligence work.

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Rob graduated in Process Control Technology at the Eindhoven University of Technology in the Netherlands. He started his career at Unilever, where he held several positions Quality and Food Safety for both the Home & Personal Care business as the Food business of Unilever, both in operations and in R&D globally. Rob continued his career as QA & Innovation Director for Farm Frites and as QA Director for DSM Food Specialties. Next to this Rob has worked for companies like TNO, Diversey Consulting, BT and PWC. Rob has been involved in several mergers and acquisitions and has a very international experience, having done business in 52 countries. Rob has also audited a wide range of companies around the globe in the food industry over the past 20 years.

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Raw Material Management

All food products start with their raw materials. It is paramount for any company to really understand all the details of the raw materials they use. Make sure you do not only ask your supplier for an allergen statement from their side, indicating those allergens which are present in the material. Also ask your supplier for any allergens which are used in their manufacturing location and take this into equation as well. If there are strongly incompatible allergens present (e.g. nuts / peanut / dairy / egg) and you do not have these in your product formulation, make sure by testing once a year whether your supplier is doing a good job. Of course this needs to be supported by supplier audits where one aspects of the audit should be management of allergens, focussing on all 7 items as discussed in this e-book.

Pay special attention to suppliers that are manufacturing constituted food stuffs of multiple ingredients to see if they in their turn have their act together as well. You really want to make sure that these supplier really understand and execute your requirements when it comes to allergen management. Especially suppliers of herbs and spices and dry powder mixers are good examples of this category. Then need to handle a lot of allergens, hence their allergen management program must adhere to all the elements described in this e-book.

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Question 4: Fill in the details of all GFSI certification you have for your site:

Certification	Scope	Date last audit	Valid Until	# Majors / Minors during last audit
BRC		/ /	/ /	/
IFS		/ /	/ /	/
FSSC 22000		/ /	/ /	/
SQF		/ /	/ /	/
China HACCP		/ /	/ /	/

If you have at least one entry in the above table you can continue with question 25 on page 13.

Figure 1: Example of supplier questionnaire potentially skipping a lot of important information

The following questions you should ask your supplier at all times for the product(s) you buy from them:

- A. Provide a list of all raw materials for the product.
- B. What allergens are present in the product?
- C. What other allergens are present in your production location where the product is produced?
- D. What other allergens are present in the sites of your suppliers of raw materials that you have not yet listed under the previous question?
- E. Do you have a validated cleaning process in relation to allergen management? If so, please provide the details of the validation.
- F. Please describe your allergen management performance, including the following aspects: production planning, segregation of materials, use of dedicated equipment.
- G. Do you use visual management to ensure your allergen management procedures are executed properly?
- H. Do you perform tests on the raw materials supplier to you to test for the presence of undeclared allergens? What is the frequency of these tests?

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- I. How often do you audit your suppliers on their allergen management approach?
- J. How do you impose a full supply chain allergen management approach to your suppliers?

If the answers in one or more areas are negative, you really need to pay strong attention to this supplier as there might be a substantial risk involved for your company!

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Segregation during Transport, Storage and Handling

Cross contamination is one of the key principles when it comes to allergen management. This is especially true during transport, storage and handling of all materials, so not just those raw materials, intermediates or finished products containing allergens. You must always be cautious during all stages of transport, storage and handling of raw materials for potential cross contamination. The only exemption to this is when there is really no allergen involved in any of your raw materials and in the preceding production processes of these raw materials.

The first item we will look at is storage (as this is the first step performed by the supplier before transporting the raw material). In a warehouse it is important to physically segregate materials containing allergens from those not containing allergens. The best solution for this is to have separate warehouses or at least two separate storage locations in one warehouse. The second important item when it comes to storage is to always make sure allergens are stored on the floor only. The reason for this is that despite all the packaging materials around the product (bags / boxes / pallet foil) still some product might be present on the packaging and might be blown off due to air movements and end up on top of the packaging material of a product with an incompatible allergen profile (i.e. not containing that specific allergen). If you really need to store products containing allergens at higher levels than the floor, do take the effect of air movements into consideration and leave

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sufficient room (e.g. 3 pallet rows) in between products with incompatible allergen profiles.



Transportation even more that storage can be a time when cross contamination might occur. Try to arrange transport in such a way that products with incompatible allergen profiles

are transported separately. If this is not possible, consider adding an additional layer of protection by inserting a pallet cover (i.e. big plastic bag used to cover the entire pallet) to reduce the risk of cross contamination. Of course this is the place where you really want to make sure the transport vehicle is really clean from the inside. A vehicle inspection scheme should really make sure there is no dust or liquid lying on the floor of the vehicle, nor on the supports on the walls.

When it comes to handling of materials containing allergens you want to keep check of the following rules:

- A. Never use latex gloves as latex can attract and therefore proliferate allergens in your factory.

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- B. Use as much as possible dedicated equipment to handle allergens (see the section on separate tools for minors dosing as well) e.g. separate silos for materials containing allergens.
- C. Be aware of dust migration during handling and especially manual dosing of materials. Also air extraction systems which are connected to the same extraction system might pose a risk as well due to reverse flow due to air pressure differences.
- D. Make sure people are aware that they are handling allergens by implementing visual management structures and labelling. Of course adherence to the rules taking additional care is paramount as well.
- E. If necessary, required your production staff to re-gown after handling allergens or have separate over-clothes to be worn during the handling of allergens.
- F. Keep the presence of materials containing allergens on the production floor to an absolute minimum. When goods containing allergens are to be returned to the warehouse do so promptly after use.

By applying the above ways of working you will minimize the risk of cross contamination during storage, transport and handling of your raw materials, intermediates and finished products.

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Management of Recipes, Labels and Product Information

The single biggest root cause of recalls in the area of allergens is a misrepresentation of information either by not having the correct information in the recipe (and have the incorrect information displayed on the label and product information) or by applying the wrong label to the product. In both cases the customer (and consumer) receives the wrong information on the allergen profile of the product, which in its turn is a potential severe health risk.

The first step in the proper management of information in relation to allergens is to manage your recipe information in a flawless manner. This start with getting the right information of your suppliers (see the first section of this e-book), but next to this it is paramount to automate as much as possible toe recipe information. You can make use of dedicated software to do this. Many ERP systems already have this functionality built in or you can buy it as an additional option. Usually it includes automatic generation of aspects like the ingredient list, nutritional information and of course the list of allergens.

If you do not have access to these tools, you can still build these easily all by yourself in Excel. Based on the dosing quantities of raw materials in your recipe, you will be able to calculate the material order, nutritional values and the list of ingredients in an automated fashion. Similar for allergens you can just “add-up” all the allergens present in your raw materials to come to the correct allergen information for your labels and product information.

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Before we elaborate more on the management of labels we want to discuss product information first. For most business to business (B2B) customers you will need to provide product information including a correct list of allergens present in the product and more and more also a list of allergens present on site. Most ERP systems do not have a good solution for the latter. Hence you might need to make an extract of your ERP system each time you change a raw material or add (or delete) one to ensure your list of potential allergens is still correct. Next to this you want to make sure that you update your ERP and Excel based information at each change of raw materials and inform your customers accordingly.



INGREDIENTS: WATER (75%), **SUGARS (12%)** (GLUCOSE (48%), FRUCTOSE (40%), SUCROSE (2%), MALTOSE (<1%)), STARCH (5%), **FIBRE E460 (3%)**, **AMINO ACIDS** (GLUTAMIC ACID (19%), ASPARTIC ACID (16%), HISTIDINE (11%), LEUCINE (7%), LYSINE (5%), PHENYLALANINE (4%), ARGININE (4%), VALINE (4%), ALANINE (4%), SERINE (4%), GLYCINE (3%), THREONINE (3%), ISOLEUCINE (3%), PROLINE (3%), TRYPTOPHAN (1%), CYSTINE

Now let's focus on the labels. In essence, there are two kinds of mistakes to be made here:

- Providing the wrong information on the label.
- Attaching the wrong label to the product.

Getting the right information on the label is very often a difficult task, unless the printing of the label is a fully automated task from your ERP system or Excel file (which is the best solution as you will always work with the current set of information of course). When labels are printed off-line, you really want to be sure that the information printed on the

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labels is correct. This is best done by printing the required information from the system and comparing it to the information on the label. Have two people independently perform this task: check the information on the label versus the information printed from the system in two directions, to ensure all information is correct and complete. This way you will have the highest likelihood of finding any misspelled, incorrect and incomplete information.

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Physical Label Management

As indicated in the previous section, applying the wrong label is one of the single highest causes of recalls related to allergens. Managing the labels physically is as important as managing the information on the labels. There are some golden rules you can implement to minimize the risk misplacing labels and attaching the wrong label to your products:



- A. Use a barcode system in your warehouse to manage the stocks and picking of labels to be used in the production process.
- B. In your warehouse set-up try to ensure that similar labels are placed as distant from each other as possible. Alternatively, you should use fully randomized material numbers for your labels, thus forcing the warehouse staff to really picking the right materials.
- C. If you use two or more labels at the same time on one product (e.g. front and back label or promotional and standard labels) you do want to store these in the same location, this reduces the risk of mixing the labels with the wrong combination in production.

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- D. Only have one set of labels present at the production line at a time (and make sure it is the correct set).
- E. Have two operators cross check whether they are using the right label before the production run starts.
- F. You can also assign the task of cross checking each new set of labels to a staff department, by asking an operator to show the new label of a new production run first to the planning department or the shift leader.
- G. Use an in-line barcode scanner to verify the correct label is on each primary / secondary product packaging, preferably configuring the barcode reader directly from the MES or alternatively again by two independent operators in connection to the previous point.
- H. Periodically (every 30 minutes) check the correct label is applied against the production information. This should again be done by two operators cross checking each other.
- I. If you have a high complexity in labels, use colour coding on the label (small coloured blocks on the side of the label) You might even want to use the same colour coding for the storage locations of the labels and include it in the product information as well.
- J. A true best practice is to insert your labels into plastic boxes and have these boxes labelled with a random number for picking in the warehouse. If you then insert the related product number inside the lid of the boxes (so it can only be read once opened in production), you can use this product code as a verification tool to prove that the right labels are present at the production line.



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Of course only one set of labels can still be present at one time otherwise you might mix the labels inside the boxes.

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Minors Dosing



In most companies the dosing of minor ingredients is a totally manual process. We know that manual processes are more prone to errors than (semi) automated ones. For the proper management of allergens it is important to use separate tools (e.g. scoops, buckets) and cleaning utensils for handling different classes of allergens. The best way to achieve this is to use a dedicated scoop (bucket etc.) for each single raw material. A good way to manage this is to place each raw material in a separate drum and place the scoop to dose / weight the ingredient inside this drum.

When weighing minor ingredients always use separate, clean bags to weigh the raw material into. This way you will prevent cross contamination via to balance tray. Ensure to properly close each bag before placing it next to other bags intended for the same production run. In order to prevent mixing up of bags of minor ingredients always work on one batch or one single product at one time when pre-weighing the minor ingredients.

Another aspect to take into consideration is the use of barcode lot code for all raw materials in the minor dosing area. This is a good method to minimize the risk of picking the wrong ingredient in the first place. Of course this will only work if just before dosing the minor ingredient, the

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barcode is checked, preferably connected to an automated recipe management system. The ultimate solution will be to even integrate the weighing scale into the recipe management system in order to verify the correct amount of raw material is dosed.

If automated systems like barcode systems and integrated recipe management systems are not feasible you might want to consider the use of cameras to register the dosing process. Of course this only provides a good means of verifying afterwards the right material was used, but if you have an member of a staff department review the video before using the pre-weight ingredients in production you still have a four-eye check on what has been dosed. The use of a Google Glass or similar device is very useful for this purpose.

Another way of creating more certainty that the right ingredients have been used is to perform a mass balance of all the minor ingredients on a regular basis (best is daily). You can best do this by checking to consumption of each ingredient versus the theoretical consumption based on the recipe information. Of course this method and the previous one are only checks afterwards and if mistakes are found, you still need to take the appropriate corrective measures.

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Production Segregation and Sequencing

If you have products with different allergen classes (e.g. nuts vs other allergens or products containing allergens vs products which are totally allergen free) it is of course the best solution to have dedicated production equipment for these products. However, for a lot (if not most) of the food production sites this is not an economically viable solution. Hence other principles must be applied.

Good allergen management starts of course with the planning department. The best way to reduce the risk of cross contamination of allergens in the production area is to start after a full deep cleaning with products containing no allergens. The next step up would be to introduce products with one or a few (mild) allergens, not containing severe allergens (i.e. nuts, eggs and dairy). Following this principle you will work your way up to products containing more and more allergens and finally you end up with products containing the most severe allergens. But be aware! Still you need to be aware if incompatibilities between products (e.g. you don't want to use eggs in a product formulation before producing a product containing no eggs at all, but which has only nuts as allergens). The best solution to achieve this is to incorporate the allergen profiles of all recipes and / or raw materials used in the production scheduling tool of the planning department. If this is not possible or not even existing on your site, you want to create a cheat sheet indicating classes of products and the mandatory sequence of production including making sure you insert the appropriate cleaning step (also see next section of this e-book) in between each production run with incompatible allergen profiles.

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Next to sequencing the products and cleaning cycles you want to make sure you have a physical segregation at some production lines as well. If you have the option to produce multiple products at the same time, you want to make sure that physical cross contamination



through air movement, use of shared tools and most importantly people is not possible. In this case you need to look at and potentially invest in segregation was around production lines, separate sets of tools (preferably with different colours) and ways to prevent staff to easily walk from on production line to another without re-gowning and hand washing. Of course this might drive up cost, this is the reason why planning and scheduling should always be the starting point! If through planning you can achieve that at all times only comparable products are being produced, you can avoid these additional costs. But be aware, this only holds true if you are able to solve it through scheduling at all times!

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Cleaning and Cleaning Validation

Finally cleaning and cleaning validation is of utmost importance when it comes to a sound approach to allergen management in your factory. As discussed in the previous section of this e-book you need to plan proper cleaning steps in between production runs with an incompatible allergen profile (i.e. the first product containing allergen A and the second product not containing allergen A, but a different set of allergens or even being totally free of allergens). As the regulatory landscape is still zero tolerant to the presence of allergens, you need to make sure your cleaning steps are really getting rid of all the allergens still present in your production equipment after the production run. The reason for this is that some people are even allergic to the parts per billion (ppb) level of allergens in products.



This is the main reason why cleaning validation is such an important topic. The easiest and best way to prove that your cleaning, either with Cleaning In Place (CIP) or manual cleaning is truly effective is to take samples of your final rinse water and have this analysed for the presence of the relevant allergens by means of ELISA testing

(Enzyme-Linked Immuno Sorbent Assay test). Of course you want to test for several allergen classes if you have multiple allergens present in your

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products. One allergen might stick stronger to a certain surface than another and also the combination of cleaning chemical used will make a difference in the effectiveness at which you are able to clean your production lines.

A good place to send samples to is the Food Allergens Research & Resource Program group (FARRP) at the University of Nebraska, USA. This is the world leading institute when it comes to allergens. They also have great on-line resources you can tap into. You typically want to validate your cleaning program this way on annual basis and of course after every change to your production process, cleaning process or after introducing new recipes (certainly when these contain new allergens to your site). So even when changing the dilution factor of your cleaning agents or the rinse time or speed of your booster pump of the CIP system you want to go through a full validation once more, as all these factors might have a crucial impact on the overall cleaning performance efficiency and give rise to issues with allergens.

Also be aware at times of replacing equipment which has been broken. Sometimes different spare parts are being used, which might be more difficult to clean. The best approach when it comes to equipment is to ensure it is as easy to clean as possible. A good place to start here is with EHEDG (European Hygienic Engineering and Design Group) certified equipment. By applying the EHEDG principles your equipment will be easy to clean and minimize the risk of remaining allergens after cleaning (as well as a lot of microbiological related issues).

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Summary

In this e-book we have given you several good tools and tips to address the essential areas in allergen management in order to prevent recalls. Below you will find a brief summary of each of the subjects.

Raw Material Management

As all products start with your raw materials, you need to make sure your raw materials are 100% free of undeclared allergens. This can only be achieved by really knowing your supplier and raw material related supply chain. Audits are a helpful tool in this respect in order for you to really see the allergen management practices of your suppliers and understand the potential risks for your business.

Segregation during Transport, Storage and Handling

At all stages of transport, storage and handling cross-contamination can take place, whether it is inside your factory, the supplier's factory or in the distribution centre of your logistics service provider. It is really important to keep primary (and preferably secondary) packaging closed at all times. And when you need to open the packaging to handle the materials you really want to make sure no other in-compatible materials in terms of allergens are nearby. You must also be aware that allergens can fall down like dust, hence products containing (incompatible) allergens must always be stored on the floor and not up in the racks of your warehouse.

Management of Recipes, Labels and Product Information

One of the biggest mistakes when it comes to allergen management is displaying the wrong information on a product label. All information starts again at the source – hence getting the right and correct

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information of your suppliers on the allergen content and potential risks for cross-contamination is where you need to start. It is best practice to enter all the information into an automated recipe management system which automatically calculates the right ingredient declaration and allergen list for your finished products. As an alternative you might consider automating this yourself in Excel.

Minors Dosing

The dosing of minor ingredients is very often a manual process. Hence it is also one of the high risk steps in the entire production process when it comes to prevention of cross-contamination with allergens. The best way to operate is to have a separate drum or box for each of the minor ingredients, including a dedicated scoop for each of the raw materials. Combining this approach with pre-weighing into clean, single use plastic bags at all times will significantly reduce the risk of cross-contamination in this part of your production process.

Production Segregation and Sequencing

If you have different classes of allergens (or even allergen free vs. products containing allergens) on your production site and in your products the best solution to prevent cross-contamination is to have dedicated production lines for each of these products. If this is not possible you will need to consider sequencing your production runs in such a way that you will always start with products containing no or the least allergens after a cleaning cycle. After that you can produce products containing more allergens, bearing in mind that cleaning still needs to take place if you switch from one product to another product which has an incompatible allergen list with the previous product.

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Cleaning and Cleaning Validation

When it comes to preventing cross-contamination proper cleaning and hence cleaning validation is of utmost importance. It is always best to automate cleaning as much as possible (CIP), because this ensures the cleaning is executed in the same manner time and time again. Each time you make a change to your cleaning cycle, you must validate that the cleaning is still effective. The easiest way to do this is to produce the worst case product in terms of allergen content (i.e. the product containing the allergens which are most difficult to clean). After that you run a cleaning cycle and collect the final (clean) rinse water from all the drainage points in your production line. You have an external lab perform an ELISA test on the presence of the specific allergen(s) present in the product you last produced. If the level is below detection you are sure your cleaning cycle is performing well. If not, please consult an expert of the cleaning agent supplier to help optimise your system.

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Do you want to have more useful and easy to implement tools and knowledge?

Do you want to stop searching the internet for hours in order to find only half-useful information?

You don't want to participate in course that take a lot of your time (an money) and only give your academic information which is difficult to apply in real life?

YES? Then this is your chance!!

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