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# Easy-to-use risk management matrix for (SME[1]) manufacturers to reduce unintended allergen presence in food products.

## 1. Introduction

Allergens can be in food products as a result of cross-contact and pose a risk for the food allergic consumer. They may remain undeclared on the label. During the production of foodstuffs in factories, allergen cross-contact may occur at different stages in food production, especially at preparation, processing and packing (see also figure 1). UAP will mainly occur in products from factories where multiple foods or ingredients are processed, and when allergenic foods/ingredients are processed on the same production line (Jackson et al., 2008).

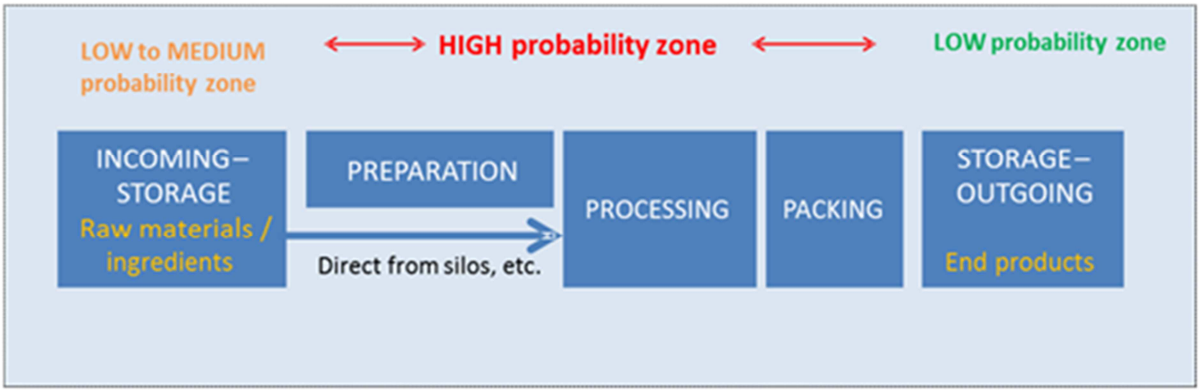



*Figure 1. Risk of UAP in a production location (taken from the iFAAM Allergen Tracking Tool).*

It is of great importance to control UAP by taking risk management measures. When applying the Allergen Tracking Tool or addressing the allergen issue through other guidelines, based on HACCP principles, insight in the (most) vulnerable parts of the process and procedures can help to identify these measures. The matrix presented here is a guide to assist the manufacturer in this.

UAP can be largely reduced or even eliminated by appropriate allergen risk management measures, for which many options have been described in best practice guidance documents (see paragraph

[1] SME = Small and Medium Enterprises

References). These guidelines often provide valuable information, but remain generic (Cucu et al., 2013) and qualitative. A generic approach is reasonable to some extent, but need adaptation to local and company-specific circumstances, since food companies are different in production, processing and factory design. Food Business Operators (FBO) need to extract the right and applicable information to create, implement and validate their measures and procedures. These measures and procedures incur (high) cost and rely on availability of resources.

The options matrix tool presented here summarises risk management measures taken from literature, guidelines and practice. Measures are organised by their 'place' in the process or facility. An indication of cost and efficacy of the measure has been added to allow the best choice based on needs and resources.

This matrix **ADDS** to general allergen management which should be part of basic QA standards, such as HACCP.

## 2. Purpose of the options matrix in short

The RM options were extracted from multiple guidelines (FARRP, FDE, FSA, VITAL) and reformulated to short measures. A brief explanation of the measures is presented in an Excel® document. A cost and efficacy indication is specified for each risk measure on the basis of expert estimation.

The matrix can be used both as a checklist to determine if all relevant risk management options needed are met and as a solution driven guide if UAP is clearly present and needs to be reduced.

The EFFICACY estimation relates to the individual measure applied at one specific point (unit operation) in the process or procedure (this could be a vulnerability as assessed by the iFAAM Allergen Tracking Tool). It addresses the effect of reduction at that point and the (semi)product from that unit operation. The efficacy does therefore not always directly relate to UAP in the final product. Also, it is mostly not dependent of other measures. Sometimes several measures should be taken in parallel or in series. However, a measure taken at an early stage while allergens might still enter the product at a consecutive step could render that measure not useful or not effective. We suggest to refer to the Allergen Tracking Tool for this.

We have divided the efficacy estimation into three levels. There is a need to validate these statements in practice:

- High → **PREVENTION** measure, potential reduction to very low (non-detectable) levels;
- Medium → **REDUCTION** measure, reduction to low but detectable levels;
- Low → **limited reduction**, additional measure(s) required ("in series" or "parallel").

The COST estimation is purely meant as an indication and is not based on actual cost and experience. It should be read primarily in relation to efficacy. A high or low investment is not only related to the absolute number but also to the return it brings to the exact location or point of application. Obviously, any investment relates as well to the size of a company as to economic conditions. We have established five cost categories (the currency is not of great importance here at prevailing rates, December 2016, for Euros, US Dollars or UK Pounds):

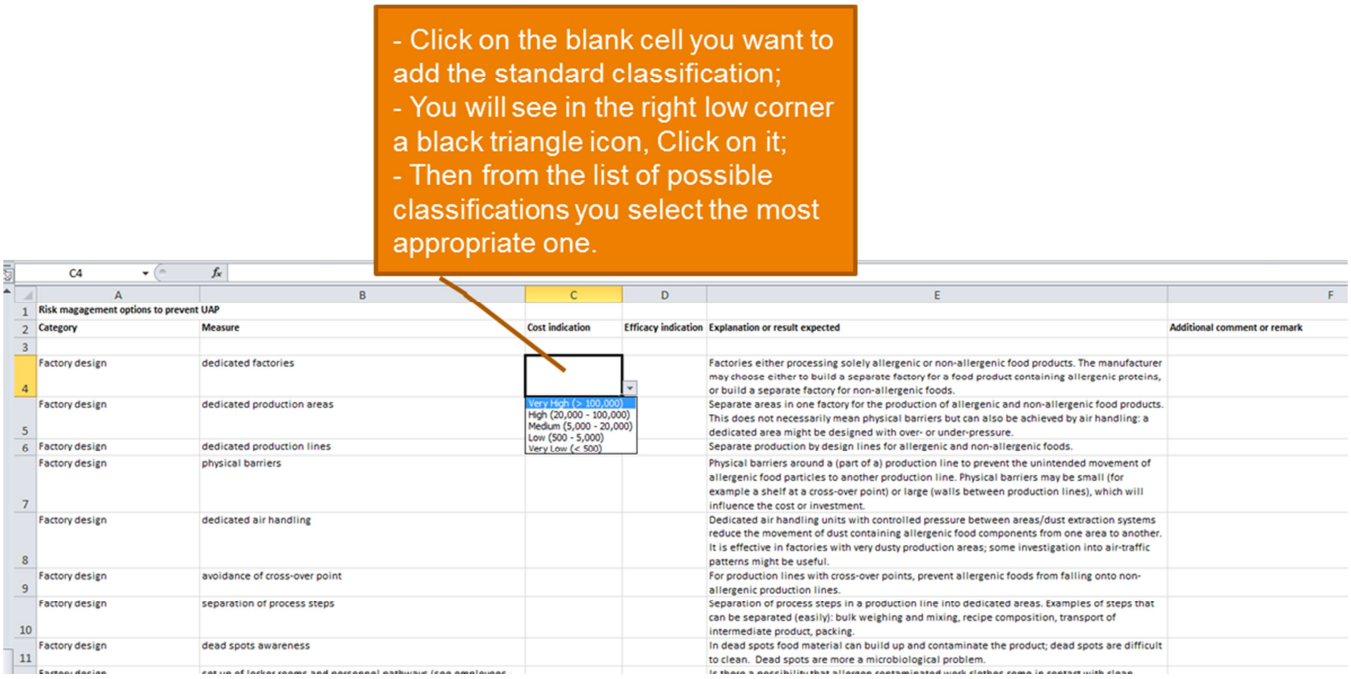
- Very High (e.g. above 100.000);
- High (e.g. between 20.000 and 100.000);
- Medium (e.g. between 5000 and 20.000);
- Low (e.g. between 500 and 5000);
- Very low (e.g. under 500).

This cost estimate only refers to a single investment, some investments may incur extra frequent cost. In the matrix it is possible to customise the cost ranges for internal company use, but the mentioned example numbers above are implemented in the matrix.

## 3. Manual

The options matrix can be used in several ways. First of all it is a list of measures that can be used as a checklist. It contains a few general measures and attention points and some of these are also described in the comments/explanations after each measure. The measures are categorised to their "place" of application in the facility. From left to right the columns are: category, short measure description, cost, efficacy, comments/remarks (see also fig 2).

The matrix is a standard excel file, that can be personalised for internal use. The use of the matrix is self-explanatory because its easy-access Excel® basis. In its basic form the standard excel features allow filtering and ordering modes per column to a user convenient listing. Ideally this results in a matrix where cost and efficacy can be easily identified and weighed. The standard classification as described in paragraph 2 is implemented can be addressed, as is explained in fig 2.



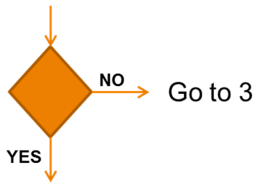

| | A | B | C | D | E | F |
|---|---|---|---|---|---|---|
| 1 | Risk magagement options to prevent UAP | | | | | |
| 2 | Category | Measure | Cost indication | Efficacy indication | Explanation or result expected | Additional comment or remark |
| 3 | | | | | | |
| 4 | Factory design | dedicated factories | | | Factories either processing solely allergenic or non-allergenic food products. The manufacturer may choose either to build a separate factory for a food product containing allergenic proteins, or build a separate factory for non-allergenic foods. | |
| 5 | Factory design | dedicated production areas | | | Separate areas in one factory for the production of allergenic and non-allergenic food products. This does not necessarily mean physical barriers but can also be achieved by air handling: a dedicated area might be designed with over- or under-pressure. | |
| 6 | Factory design | dedicated production lines | | | Separate production by design lines for allergenic and non-allergenic foods. | |
| 7 | Factory design | physical barriers | | | Physical barriers around a (part of a) production line to prevent the unintended movement of allergenic food particles to another production line. Physical barriers may be small (for example a shelf at a cross-over point) or large (walls between production lines), which will influence the cost or investment. | |
| 8 | Factory design | dedicated air handling | | | Dedicated air handling units with controlled pressure between areas/dust extraction systems reduce the movement of dust containing allergenic food components from one area to another. It is effective in factories with very dusty production areas; some investigation into air-traffic patterns might be useful. | |
| 9 | Factory design | avoidance of cross-over point | | | For production lines with cross-over points, prevent allergenic foods from falling onto non-allergenic production lines. | |
| 10 | Factory design | separation of process steps | | | Separation of process steps in a production line into dedicated areas. Examples of steps that can be separated (easily): bulk weighing and mixing, recipe composition, transport of intermediate product, packing. | |
| 11 | Factory design | dead spots awareness | | | In dead spots food material can build up and contaminate the product; dead spots are difficult to clean. Dead spots are more a microbiological problem. | |

*Fig 2: screenshot of matrix file, with explanation of use of standard classifications.*

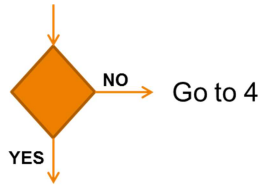
If you want to change (customise) the standard classification, simply go to the worksheet named as such and fill in the appropriate cells in columns C and E, this will immediately be transferred to the primary worksheet.

Before using the options matrix a short decision tree needs to be followed:

1. **Have you fully implemented standard HACCP or other comparable system, including a process (vulnerability) analysis?**




2. **Did you specifically address allergens and potential UAP or did you use the iFAAM Allergen Tracking Tool?**




Go to Options matrix

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3. **Follow HACCP/prerequisite programme guidelines, include allergens at once or as a second phase.**


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4. **Use Allergen Tracking Tool (again)**


5. **Follow the categories (quick overview) of the options matrix to identify potential gaps:**
   a. Factory design
   b. Cleaning
   c. Internal packing and labelling
   d. Production scheduling
   e. Employees
   f. Storage
   g. Equipment
   h. Internal transport
   i. Rework
   j. Labelling
   k. RE-ADDRESS general: contractors, protocols, external transport

6. **Sort (use the embedded Excel® based sort and filter functions) the options matrix to address individual measures per category based on COST-EFFICACY comparison.**

## 4. References

*Primary literature*

Cucu, T., Jacxsens, L., & De Meulenaer, B. (2013). Analysis to support allergen risk management: which way to go?. Journal of agricultural and food chemistry, 61(24), 5624-5633.

Jackson, L. S., Al-Taher, F. M., Moorman, M., DeVries, J. W., Tippett, R., Swanson, K. M., ... & Albillos, S. (2008). Cleaning and other control and validation strategies to prevent allergen cross-contact in food-processing operations. Journal of Food Protection®, 71(2), 445-458.

*Guidances*

Allergen Bureau. (2012). Food Industry Guide to the Voluntary Incidental Trace Allergen Labelling (VITAL) Program, Version 2.0.

Food Allergy Research & Resource Program. (2008). Components of an Effective Allergen Control Plan – A framework for food processors.

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Food Standards Agency. (2006). Best Practice Guidance on Managing Food Allergens with Particular Reference to Avoiding Cross-Contamination and Using Appropriate Advisory Labelling (e.g. 'May Contain' Labelling).

Swedish Food Retailers Federation. (2005). S. F. Swedish Food Sector Guidelines for: Management and labelling of food products with reference to Allergy and Intolerance.