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1. Introduction: why this guidance and checklist

A Food Business Operator (FBO) has the food safety responsibility to manage allergens in its products and process environment. Several tools and guidances, including the iFAAM Allergen Tracking Tool (ATT), are available for this purpose. However, the FBO has no direct influence over certain aspects of allergen management of, but needs to understand potential impact on Unintended Allergen Presence (UAP) in ingredients and raw materials used by the FBO. This is a supply chain issue. Additionally, the FBO has limited influence over the manner of use of the product by customers (BtB) or consumers. The product usage is important when calculating the expected consumption of the product and hence potential allergen exposure.

It is clear that any FBO needs to be aware of the overall product supply chain, both backward and forward. Allergen management should be a common and shared responsibility with development of a strong customer-supplier partnership. It is also helpful in the legal responsibility of tracking and tracing. In practice and in most cases the FBO takes responsibility for their own processes and products, while the partnership with customers or suppliers is mostly managed by paper work (questionnaires, guarantees, audit reports, specifications and certificates of analysis) that are exchanged between the partners. However, the functionality and usefulness of this paper work depends on the responsiveness, willingness and technical knowledge of the supplier and a thorough understanding of the FBO's requirements.

Transparent information exchange about allergen food safety risks between partners is paramount. This not only helps the FBO manage allergen food safety impacts and understand the risks but also enables that the allergic consumer has access to consistent trusted allergen information. Cooperation within the chain will also help to identify where in the chain a risk is best managed and from then on most easily controlled.

This guidance serves the purpose of raising awareness of allergen issues and impacts, and supporting FBOs in the process of chain risk analysis and vulnerability assessment.

2. Explanation and background

Managing risks, and specifically UAP, is the responsibility of any FBO, not only producers of finished products for the final consumer. Any FBO and partner in the chain of production has to have a three way perspective for their risk analysis of processes and products, also as part of HACCP and other food safety management systems. First of all, inside the factory, where the main responsibility lies to manage the production process and the products regarding quality and safety. The (risk) management of UAP is broad task that needs to cover more than the specific production process, it includes guarantees (protocols and procedures) on the right ingredient and packaging use¹.



Figure 1: Perspectives of risk management.

Managing the quality and safety of the products is for the benefit of the everyone. One has to have two additional perspectives. The concept of traceability being “one step back, one step forward” as embedded in the EU Food Law, also recognises the shared responsibility of FBOs along the supply chain for ensuring safe food, and appropriate labelling.

Looking forward in the chain means basically thinking about the use of your product by the customer² and communicating with the customer about quality and safety, about risk management and residual risk, such as UAP.

Suppliers are well aware of their customers’ backward looking responsibilities as there is an increasing amount of paper work coming from them. Questionnaires to be filled in and specifications, letters of guarantee, and certificates of analysis to be sent. Audits and/or third party certification are often requested. This creates an enormous work load especially in situations where the FBO produces a large

¹ The far majority of recalls where allergens are involved find their origin in wrong labelling (packaging) and wrong ingredient use. This is explained in more detail in the iFAAM risk management options paper.

² Customer is deliberately used as this paper addresses any FBO, also when producing BtB.

number of products containing a large number of ingredients. There are legal responsibilities to control allergen risks but sometimes FBOs lack expertise to fully assess risk and analyse allergens. This then may lead in some cases to the use of PAL (precautionary allergen labelling, “may contain”, etc.).

There are several science based guidelines , e.g. VITAL, that help FBOs to manage allergens (UAP) for consumer products, based on consumption levels and established reference doses. Programs like these help FBOs establish a basis for allergen control and management, including fundamental communication with partners in the chain and the consumer.

The checklist presented here should enable FBOs to manage the allergens better, specifically with regard to their ingredients and raw materials. It lays down some responsibility on all partners in the food production chain, not only consumer product FBOs. The checklist is a common sense collection of steps to help FBOs in a chain-oriented risk analysis of UAP. It is based on HACCP principles and on a simple two-way approach: information exchange between partners in the chain and a vulnerability analysis of the chain.

There are two specific approaches to gather knowledge as a decision basis for risk management measures.

- Direct information from suppliers (knowledge/specifications on ingredients or raw materials).
- Vulnerability assessment of the (whole) supply chain, general knowledge of it.

These two approaches complement each other. Once an FBO has completed their **internal** risk analysis, as in HACCP, issues regarding risks from **external** sources should be clear or the next point of attention. In case of UAP, when the iFAAM Allergen Tracking Tool has been used, UAP in ingredients or raw materials should be addressed largely as a supplier issue. This implies that customer and supplier communicate on specifications and requirements and the specific use of an ingredient. The latter might help the supplier to understand the issue at the customer. Obviously, the use of an ingredient in a product (recipe), the use by the customer, is (also) an internal or forward-thinking exercise.

The use of an ingredient or raw material impacts on the actual and eventual UAP in end products. The amount of ingredient or raw material in a product recipe determines the UAP in the end product and with that the risk for consumers. For example, an ingredient or raw material with known UAP but minimal dosage can be considered low risk and no priority. Currently however, customers and authorities may consider this otherwise. Thus, the development of target levels will require negotiations within and between partners in the chain, including authorities.

The considerations on UAP in ingredients and raw materials and the relationship with suppliers is summarized in the figure below.

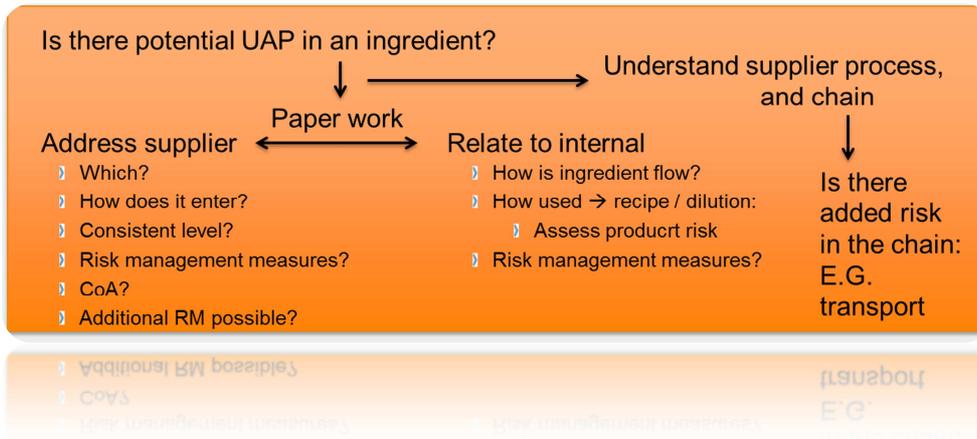


Figure 2: chain risk management of UAP overview.

From this overview follow four main steps to address this specific UAP in ingredients or raw materials, but the order in which to apply them is not strict.

- Identify which food allergens are processed, stored or otherwise present at the suppliers' relevant site, and review their risk assessment and management.
- Communicate on own specifications and supplier specifications and UAP; assess the suppliers' process. Eventually consider a supplier audit.
- Relate the information to the internal process and products, and risk management.
- Assess and address the (whole) supply chain to identify the vulnerable links regarding allergens entering the supply chain and the potential risk management measures (to discuss with partners in the chain).

Only after all four steps have been completed will it be possible to finally decide the risk and priority levels and apply appropriate risk management measures to incoming goods.

It is acknowledged here that it may not be an easy job to set own specifications, especially regarding UAP, and to discuss specifications (own or supplier) with a supplier. There are however guidelines and tools available that can put FBOs on the right track.

If you visualise the production process at the supplier, the whole production chain of the ingredient including transport, storage and transfer/transshipment, and the actual use of the ingredient in the internal process, then you are able to identify vulnerabilities and maybe take the right measures. This is a risk based approach to categorise products and suppliers.

When you identify where allergens in the process occur or are introduced and in what order of magnitude, it is easy to understand the potential risk posed by UAP and the type of measures possible to mitigate this risk.

In short, this is what this checklist helps you to do.

3. Manual

It is important to establish a trusted relationship with your partners, rather than asking for information without common knowledge or understanding. As described above communication between suppliers and customers is crucial.

Figure 3 depicts the complete iFAAM risk analysis procedure. After every step, it is possible that the procedure is complete and the risk is considered acceptable. This manual explains part of the UAP identification step, which is further detailed in the iFAAM Allergen Tracking Tool (ATT).

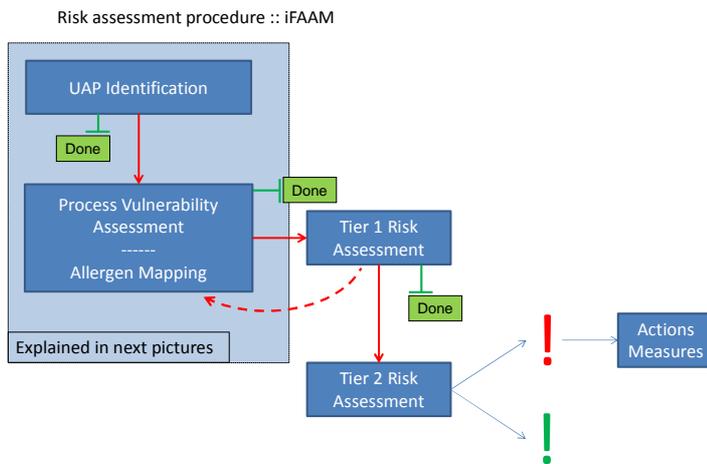


Figure 3: The iFAAM risk analysis procedure.

The UAP identification step needs to be performed for each allergen individually. If it is established that there is, or potentially is, UAP in ingredients, the checklist below can be used for further risk analysis steps. Figure 4 explains the start of the ATT as an illustration.

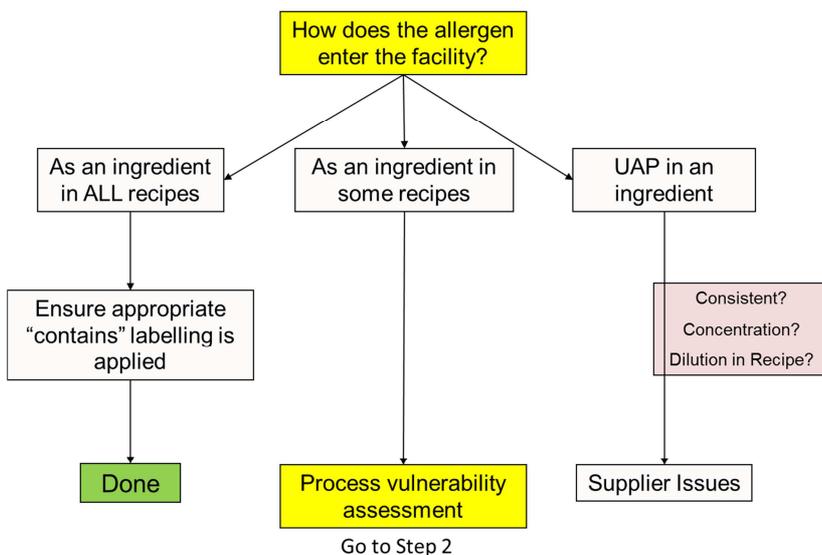


Figure 4: The UAP identification questions.

As explained above, once UAP in an ingredient has been established, identified, assumed or expected, a supplier issue is clear. However, the FBO producing the finished food product for the final consumer retains the primary responsibility. Below are some indications of questions and information gaps to be completed. Again, there is no specific order, as sometimes one relates to the other and, moreover, answers often imply new questions.

The checklist below is very well applicable as well for forward thinking in the chain, especially when assessing what happens to YOUR product when it has left your facility. This might include transport and storage, but also shelf life management by customers, end product labelling and end consumer use.

- **Identify which food allergens are processed, stored or otherwise present at the suppliers' relevant site, and review their risk assessment and management.**
 1. Ask a supplier about the presence of allergens at/on their location:
 - i. In your ingredient / raw material;
 - ii. On shared processing lines;
 - iii. In the shared processing facility;This approach is preferred over simply asking about the potential for UAP in the first place. Know what's happening at the suppliers.
 2. Identify the risk management procedures (risk analysis, HACCP) and measures implemented:
 - i. How/where is the product produced or processed, assess the process UAP risks;
 - ii. What risk analysis was performed and how were allergens dealt with (HACCP, iFAAM ATT, ...);
 - iii. Is the supplier aware of allergens, aware of allergen risks coming from their suppliers, aware of the way their product is used, aware of processes, products and recipes at the customer;
 - iv. Does the supplier monitor (analyse) allergens, are there certificates of analysis.
 3. Assess the vulnerability towards UAP of the process and in the product you buy.

- **Communicate on own specifications and supplier specifications and UAP; assess the suppliers' process. Eventually (ultimately) consider a supplier audit.**
 1. For a supplier, the starting point is the set of requirements that a customer may set, although a customer may have chosen them based on the producer's specifications. This might not always be easy for an FBO, also because of economic reasons (SME <> large supplier). Communication, discussion and explanation however will certainly help the process. A personal approach might be more effective than a questionnaire (working both sides!).
 2. Is there enough awareness and a willingness for discussion and information exchange.
 3. What are the arrangements for supplier audit (auditing standard, etc):
 - i. If UAP is known or assumed, any indication of levels, consistency of levels;
 - ii. What risk management measures are implemented;
 - iii. Any additional risk or measures possible.
 4. Perform (commission) supplier audit.

- **Relate the information to the internal process and products, and risk management.**
 1. Perform additional risk analysis, including scenario calculations (on recipes).
 2. Does information from supplier give reason for changing procedures:
 - i. Potential treatment of incoming materials to reduce allergen risk;
 - ii. Potential re-sourcing / sourcing from a different supplier
 - iii. Potential change in recipe(s)
 3. Address and assess the processes and procedures between supplier and customer:
 - i. Responsibility of transport and (temporary) storage;
 - ii. Transport: HACCP certified, previous cargo registration, ...;
 - iii. Storage at (independent) warehouses: HACCP certified, transfer of cargo/product (hoppers, pneumatic, hoses, ...).

- **Assess and address the (whole) supply chain to identify the vulnerable links regarding allergens entering the supply chain and the potential risk management measures (to discuss with partners in the chain).**
 1. Make an overview of the whole chain, do not only imply supplier responsibility, but do your own chain risk analysis or vulnerability assessment.
 2. A chain overview could follow the ATT as a guideline, implement “chain” or “link” instead of process or unit operation.
 3. Be aware of chain specific characteristics, E.G.:
 - i. Global trade, awareness and (best) practice in other regions;
 - ii. Complex mixtures (seasoning with herbs and spices, e.g.)
 - iii. Co-harvest of primary products (peanut and cocoa beans, e.g.)