meat technology
*Founder and publisher:*
*Institute of Meat Hygiene and Technology, Belgrade*

*UDK: 616-056.3:663/664*
*COBISS.SR-ID: 196310025*
*https://doi.org/10.18485/meattech.2026.67.1.6*

*Original Scientific Paper*

# Implementation of an on-site allergen control plan based on risk assessment according to International Food Standard (IFS) guidelines

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ARTICLE INFO

*Keywords:*
IFS standard
Risk assessment
Allergens
Cross contamination
Swab testing

ABSTRACT

This paper outlines the requirements, methodologies, and practical considerations for conducting allergen risk assessments in compliance with IFS standards. IFS Food Version 8, effective January 2024, provides a comprehensive and standardized framework for risk assessment, process control, and compliance in food manufacturing. Compliance with IFS Food Version 8 requires a systematic and risk-based approach aligned with global food safety standards. By following the described requirements and methodologies, food manufacturers can ensure compliance, protect consumer health, and maintain the highest food safety levels across the supply chain. Validation of an established allergen control system in a food business operator's production premises was conducted by taking 100 swabs from surfaces with potential allergen contamination; no positive results were obtained, which demonstrated the functionality of the implemented control system. The monitoring results from swabs and the evaluation of allergen presence and contamination risks served as the basis for developing the food business operator's allergen control plan as an integral part of its self-monitoring plan.

## 1. Introduction

Rising customer expectations and multiple food safety incidents have driven a surge in the adoption of quality assurance schemes (*Schulze et al.*, 2008). The implementation of food safety management systems must be grounded in the principles of food safety and security at a global level (*Lee et al.*, 2023). International Organization for Standardization (ISO) standards serve as the starting point for quality standards in the meat production and processing industry. Previous studies have primarily examined the motivations behind companies implementing ISO 9001 and how different sectors evaluate the standard (*Calisir et al.*, 2001). Certification schemes are designed to ensure product specifications are met and production processes remain consistent. The adoption of these standards is debated both theoretically and practically; consequently, many firms join not by choice but because major buyers, like large processors or retailers, compel them to (*Walgenbach*, 2007).

The most prominent sector-specific quality assurance schemes are Global Good Agricultural Practices (GLOBALGAP), the British Retail Consortium (BRC) global standard and the International Food Standard (IFS). Complete removal of risk from food cannot be guaranteed; rather, food safety

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Paper received: January 22nd 2026. Paper accepted March 3rd 2026.
Published by Institute of Meat Hygiene and Technology — Belgrade, Serbia.

depends on stringent controls throughout the food chain to lower public health hazards, reflecting a multifaceted, interdisciplinary approach (*Pacala et al*., 2024). Standards share common objectives, so their requirements overlap and show substantial similarity; major differences appear at the audit level, with differing scopes, criteria and categorizations. Requirements are organized into mandatory and recommended sections, allowing organizations to implement changes progressively. IFS, Food Safety System Certification (FSSC) and International Organization for Standardization (ISO) follow the High Level Structure (HLS), a shared framework that eases integration of multiple management systems for monitoring, corrective actions, and audits (*Bomba et Susol*, 2020).

Risk assessment is central to food safety management, enabling improved identification, evaluation, and control of hazards across the food production chain. IFS Food Version 8, released April 2023 and effective from 1 January 2024, offers a detailed framework for performing risk assessment in food manufacturing (*Kiwa*, 2023; *Elpress*, 2023). IFS Food Version 8 emphasizes a risk-based approach to food safety, aligning with global standards, such as *Codex Alimentarius*, ISO 22003-2, and Global Food Safety Initiative (GFSI) benchmarking requirements (*IFS Certification*, 2023). IFS standard requires organizations to: conduct a hazard analysis for each step in the production process; determine critical control points (CCPs) and other control measures; establish validated critical limits for each CCP; develop a monitoring system for each CCP; implement corrective actions and; validate the HACCP plan (*IFS Certification*, 2023a, *SafetyCulture* 2023).

Food allergy is an increasing worldwide public-health issue. Undeclared allergenic ingredients or trace contamination during food processing present significant health risks to sensitized individuals (*Janković et al*., 2024). IFS Food Version 8 states that for every raw material, a risk assessment must be conducted to determine which allergens must be declared, including accidental or technically unavoidable cross-contamination with legally declared allergens and trace amounts (*IFS*, 2023). Allergen cross-contamination happens when a food or ingredient that contains an allergen is accidentally mixed into another food that is not meant to include that allergenic component (*Codex Alimentarius*, 2020). All needed relevant information must be available for the country(ies) where the finished products will be sold, and be documented and up-to-date for all raw materials. Food business operators (FBOs) must:

- Maintain a continuously updated inventory of all on-site raw materials containing allergens, including any blends and formulations that incorporate allergenic raw materials (*IFS*, 2023a);
- Implement and sustain risk-based controls from incoming goods through dispatch to minimize possible allergen cross-contamination;
- Consider cross-contamination risks at least for: environment, transport, storage raw materials, personnel (including contractors and visitors);
- Track and monitor the effectiveness of the measures put in place.

In accordance with IFS requirements, all potential allergenic risks must be assessed, covering food-contact and packaging materials and the workplace, in order to evaluate their probability and severity, specify targeted control measures, and apply risk-based controls from receipt through to dispatch to reduce allergen cross-contamination (*IFS*, 2023a). Performing a risk analysis regarding allergen presence in meat products in accordance with IFS and *Codex Alimentarius* involves several critical steps. Firstly, the scope of the risk analysis must be defined (type of meat and meat product and population at risk, e.g., consumers with specific allergies), and then, possible routes of cross contamination (environment, transport, storage, raw materials, personnel including contractors and visitors) are considered.

The current version of IFS Food Version 8 emphasizes the need to validate the absence of allergens at every step of the production process. This specific requirement is novel and must be considered during each product's risk assessment. At that time, a specific control measure should be prescribed for each identified potential hazard (*IFS*, 2023a). IFS Food Version 8, Section 4.19 specifically addresses the prevention of risks posed by the presence of allergens in production. The main risk is cross-contamination, which can originate from the work environment, transportation, storage, raw materials, and personnel in the production facility, including both employees and external visitors. Therefore, allergen risk management requires specifically defining sampling locations that will indicate cross-contamination and, within the FBO's self-control plan,

conducting systematic examinations through swab testing for allergens. The obtained monitoring results and checklist evaluation results of potential allergen presence in an FBO's production premises is then used to develop a sampling plan for allergen presence in the production areas, as part of the self-monitoring (HACCP) plan.

Checklist grades are used by auditors during evaluations to gauge how well a facility or process complies with the IFS standards, and they help in identifying areas needing improvement to ensure ongoing compliance and safety. In accordance with IFS Food Version 8, a grade B is considered a deviation (non-critical non-conformity) and requires corrective actions. This approach introduces additional pressure on FBO to achieve the highest possible level of safety and control in producing their products.

While the IFS provides detailed guidance including templates, decision trees, cleaning validation protocols, and analytical testing frameworks (*IFS*, 2023), translating these requirements into consistent practice across organizations presents ongoing challenges. The requirement for a process-oriented HACCP-based risk assessment demands technical expertise and familiarity with quantitative assessment methodologies that not all food producers possess (*Allergenen Consultancy*, 2018). Furthermore, the requirement to evaluate and confirm safety protocols necessitates that businesses perform laboratory testing and internal reviews. These activities impose resource requirements that can fluctuate greatly based on the scale of the company and the intricacy of its manufacturing processes. Clarity on assessment goals is vital; companies must differentiate between the process-oriented assessment required by the IFS to determine cross-contamination prevention and the Voluntary Incidental Trace Allergen Labelling (VITAL) based risk assessments some organizations use for labeling decisions (*Holzhauser et al.*, 2020; *FACTS*, 2022; *Eurofins*, 2025). The key takeaway is that the primary function of the IFS allergen risk assessment is to identify and manage operational dangers, not to provide justification for precautionary labeling. A critical element of IFS 4.19.1 compliance involves maintaining current allergen master lists encompassing all allergenic ingredients and blends used in production (*IFS*, 2023). Meeting this standard requires rigorous supplier oversight to ensure accurate ingredient labeling and to identify manufacturing cross-contact risks. Although IFS provides checklists, companies must actively engage with suppliers to secure the specific allergen data necessary for a complete risk assessment (*ECA Academy*, 2020; *Health Canada*, 2025). As it is stated in IFS White Paper (*IFS*, 2025), where the summary of existing guidance documents regarding allergen control are summarized, environmental monitoring and testing for allergen residues provide objective evidence that cleaning protocols are effective and that segregation measures prevent unintended allergen presence. This data-driven approach to verification supports compliance demonstration and identifies areas requiring corrective action. The convergence of IFS Food Version 8 and subsequent versions toward GFSI-benchmarked requirements reflects broader international harmonization efforts. Risk assessment is an ongoing process that requires continuous improvement. Organizations should regularly review and update their risk assessments to reflect changes in production processes, regulatory requirements, and emerging risks (*Safety Forward*, 2025)

Food allergies, conditions in which the immune system reacts to specific foods, are a growing concern worldwide in terms of food safety. They pose significant public and individual health challenges. Although they impact a small segment of the population, the reactions can be extremely severe or even life-threatening. Additionally, it is clear that food allergies can drastically reduce quality of life for sufferers, a situation that could be improved with a consistent strategy for managing allergens throughout the food production and distribution processes (*Codex Alimentarius*, 2020). Although IFS standard states that in cases of accidental presence, the labeling of legally declared allergens and traces must be based on a risk analysis (*IFS*, 2023a), the zero tolerance policy as part of legal obligation forces FBOs to increase the level of security and safety regarding the presence of undeclared allergens in final products. The zero tolerance policy regarding undeclared allergens in final products is primarily addressed in the Food Safety Modernization Act (*FSMA*, 2011) in the United States. This act emphasizes the importance of preventive controls to ensure food safety, including allergen management. Additionally, in the European Union, Regulation (EU) No. 1169/2011 on the provision of food information to consumers mandates clear labeling of allergens and outlines the legal responsibilities of food businesses to avoid cross-contamination and ensure that allergenic ingredients are declared. These regulations

collectively establish a framework to which food producers must adhere, reinforcing the principle of zero tolerance for undeclared allergens in food products. In order to handle allergen risk especially in a young population, FSMA advises an individual approach to create voluntary guidelines to assist in developing plans for managing the risks of food allergies and anaphylaxis in schools and early childhood education programs (*FSMA*; 2011). These guidelines sholud be accessible to local educational agencies, schools, early childhood education programs, and other interested parties.

The labelling of food allergens on pre-packaged products is crucial for safeguarding individuals with food allergies, especially since there is no clinical treatment to prevent these reactions at present. Where accidental or technically unavoidable cross-contamination could introduce traces of these allergens, that must be indicated and based on a risk assessment, taking into account allergen cross-contamination from raw materials processed on-site. Finished products containing allergens that require declarations must be declared in accordance with legal requirements.

While recent advances in immunotherapy for food allergens have demonstrated encouraging outcomes, the only effective way to prevent allergic reactions continues to be avoidance of the triggering foods (*FAO and WHO*, 2022). In 1995, the Food and Agriculture Organization of the United Nations (FAO) held a Technical Consultation (*FAO*, 1995) that led to the recognition of eight specific foods or food groups that are responsible for causing food allergies. Those are: cereals containing gluten (wheat, rye, barley, oats, spelt or their hybridized varieties and products of these; crustacea and their products; eggs and egg products; fish and fish products; peanuts, soybeans and their products; milk and milk products (lactose included); tree nuts and nut products; and sulphite in concentrations of 10 mg/kg or more (*FAO and WHO*, 2018). The list covers the most prevalent allergens that account for the majority of allergic reactions, even though approximately 170 different foods have been associated with such reactions (*Boyce et al*., 2011). Today, numerous domestic and foreign legal regulations define strict and clear labelling of all food ingredients that exhibits allergenic properties (*Official Gazette RS*, 41/009 and 17/2019; *Official Gazette RS*, 19/2017, 16/2018, 17/2020, 118/2020, 17/2022, 23/2022, 30/2022 and 61/2024; *Official Gazette RS*, 73/2010; *EU Regulation* 1169/2011, *FALCPA* 2004). In a threeyear study conducted in Belgrade, Serbia (2021–2024) on 212 commercial food items, peanut DNA was found in nine products across the sampled categories. Detection indicated undeclared peanut material regardless of label claims: peanut DNA appeared in frozen desserts (3), biscuits (4) and snacks (2); six of the positive items carried a precautionary allergen label, while three had no indication of peanut presence (*Janković et al*., 2025). In a second study by the same author, 114 out of 179 (63.69%) food products listed allergens on their ingredient labels. The most commonly declared allergen was soy, present in 27.4% of food products, followed by milk in 13.4%, egg in 11.7%, celery in 6.1%, mustard in 5.6%, and sesame in 4.5% (*Janković et al*., 2024).

This paper outlines the requirements, methodologies, and practical considerations for performing allergen risk assessments in compliance with current IFS standards.

## 2. Materials and Methods

A risk assessment regarding the presence of allergens in an FBO's production facility was conducted in accordance with IFS Food Version 8 requirements. The pre-existing checklist, compiled for control of the production premises in the facility, was expanded to contain additional considerations for evaluating potential allergen contamination (*Codex Alimentarius*, 2020). The FBO's food safety team appointed an allergen management team consisting of three technologists, while an external expert team was also appointed. Both these teams carried out the risk analysis in order to balance individual evaluations that can be subjective and differ between observers (*Petrović et al*., 2024). The final checklist was then used under field conditions to assess and determine the potential risk of allergen contamination in the FBO's production facility (Table 1). An explanation of the marking system used, which was in accordance with IFS audit requirements, is presented in Table 2.

The obtained control results were validated by taking swabs from sanitary equipment, tools, and workers' hands and clothing after exiting the kitchen. This approach aimed at providing an objective assessment of the effectiveness of all the changed work practices, as well as evaluating the possibility of allergen contamination by the workers themselves in the production facility, upon returning to their workstations after a break from the kitchen.

**Table 1.** Checklist for evaluation of potential allergen presence in the FBO production premises

| Demand | KO A B C D | Remark |
|---|---|---|
| It is essential to ensure raw material specifications that list allergens requiring declaration. The organization must always have a current and valid list of all raw materials with allergens used on its premises, which also includes all mixtures and formulas to which such allergenic raw materials are added. | | |
| The production of products containing allergens that require declaration must be conducted in a manner that minimizes cross-contamination to the greatest extent possible. | | |
| Finished products with allergens must have declarations in accordance with current legal provisions. In cases of accidental presence, the labeling of legally declared allergens and traces must be based on a risk analysis. | | |
| Production Areas must be segregated, clearly marked. Designate specific areas for the production of allergen-containing products to prevent cross-contact with non-allergenic foods. | | |
| During production, special attention must be oriented to handling spices that contain allergens and are prepared for addition during product formulation. Until the moment of incorporation into the filling, spices must be kept in a closed container that is opened just before use. Care must be taken to prevent airborne contamination of the area. | | |
| When adding spices to the cutter bowl, the lid must remain closed, and the spices should be introduced through an opening in the lid, ensuring that the used packaging is disposed of properly without creating dust. | | |
| All used packaging from allergenic components or spice blends containing allergens must be removed from the production area as soon as possible, placed in a closed bag, and disposed of in accordance with the established procedure for handling packaging waste from the production facility. | | |
| Daily production plan must be scheduled in order primarily produce allergen free foods prior to products with allergens, in order to reduce contamination risk. | | |
| Rigorous and thorough Cleaning and Sanitation procedures must be staged between production runs to remove allergenic residues from equipment and surfaces. Validate cleaning efficacy through swab tests or other verification methods in accordance with self-control plan. | | |
| Where possible, separate, use dedicated, equipment and utensils for allergenic and non-allergenic product in order to avoid shared surfaces. | | |

| Demand | KO A B C D | Remark |
|---|---|---|
| Staff on allergen management must be regulary trained with doccumented outcome of the training (importance of hand washing, changing protective clothing, and understanding cross-contamination risks). | | |
| All ingredients and end products must be clearly and properly Labelled and stored. All allergenic ingredients are stored closed, separately in marked area, below non-allergenic ones to prevent accidental spillage or contact. Where a commodity is bagged, bags should be clean and those used for allergenic commodities should be identified (e.g. with different colours). Bags that have been used for an allergenic commodity should not be reused for a different commodity | | |
| FBOs should ensure that the area where commodities are dried is clean and physical barriers are in place to prevent spillage and allergen cross-contact. Materials or containers used to lay, hang or bag commodities should be cleaned to remove allergenic residue. | | |
| Transportation of foodstuff should be carried out using a clean transport vehicle that is dry and free of the previous load to prevent or minimise the potential for allergen cross-contact. As necessary, transport containers should be cleaned before use. At unloading, transport containers containing allergenic commodities should be emptied of all cargo and cleaned as appropriate to prevent or minimise the potential for allergen cross-contact of the next load. | | |
| All suppliers are listed in the "List of Suppliers", and cooperation is rated through previous trend analysis. Suppliers must ensure they also follow strict allergen management practices and provide detailed allergen specifications for raw materials. | | |
| Management with risk is regularly monitored and documented through Allergen Risk Assessment. Conduct regular risk assessments to identify potential cross-contamination points and develop strategies to mitigate them. | | |
| Physical barriers (walls, partitions) are used to separate allergenic ingredients during storage and processing. | | |
| Allergen Control Program is implemented, developed and maintained as part of broader food safety management system with all necessary data (procedures and corrective actions) | | |
| On the floor of the production area, a yellow line clearly marks the path of allergens in the production facility, including the path of raw materials containing allergens. | | |
| There is a clearly designated and defined production line for the manufacturing of products with allergens, and if this is not the case, the temporal separation and scheduling of production times for products with allergens are clearly documented. | | |

**Table 2.** Marking system for allergen risk assessment for the on-site evaluation (source IFS, Ver 8)

| Mark | Description |
|---|---|
| KO (Knock Out) | These are fundamental requirements. Receiving a KO can result from a critical non-conformity and usually means that the certification cannot be granted until corrective actions are implemented. KOs reflect the most critical points of compliance. |
| A | Indicates full compliance with the requirement. The practice or process meets the standard completely without any issues. |
| B | Represents almost full compliance but with some minor deviation or non-conformity that needs addressing. Recieving a B does not represent a significant risk, but shows improvement is required. |
| C | Shows a clear non-conformity. Recieving a C means the practice does not meet the standard's requirement and poses a certain level of risk, demanding prompt corrective action. |
| D | Reflects major issues or serious non-conformance. Like KO, receiving a D for any requirement likely means failing the audit and requires urgent action to implement corrective measures. |

## 2.1 Study Setting and Sampling Design

A total of 100 environmental swabs were collected from the meat processing facility in accordance with the FBO's established, HACCP-based self-control plan, with ten samples taken at the start of the workday over a period of ten weeks. Sampling was conducted during the 2025–2026 production cycle, specifically targeting periods after wet cleaning and sanitation, but prior to the commencement of allergen-free production runs. The monitoring schedule for determining allergen presence is presented in Table 3.

**Table 3.** Monitoring procedure for allergen presence in the production premises

| Sampling Location | Allergens to Test | Test Method | Frequency | Responsible Personnel | Number of samples |
|---|---|---|---|---|---|
| **Food Contact Surfaces (n=60)** | | | | | |
| Meat Grinders | Soy, Gluten | LFT Swabs*, Swab tests** | Weekly | Allergen Management Team | 15 |
| Bowl cutters | Soy, Gluten | LFT Swabs, Swab tests | Weekly | Allergen Management Team | 15 |
| Stuffers | Soy, Gluten | LFT Swabs, Swab tests | Weekly | Allergen Management Team | 15 |
| Stainless steel preparation tables | Soy, Gluten | LFT Swabs, Swab tests | Weekly | Allergen Management Team | 15 |
| **Non-Food Contact Surfaces (n=40)** | | | | | |
| Employee hands | Egg, Milk, Mustard | LFT Swabs, Swab tests | Weekly | Allergen Management Team | 10 |
| Employee clothing | Egg, Milk, Mustard | LFT Swabs, Swab tests | Weekly | Allergen Management Team | 10 |
| Allergen path floor | Soy, Gluten | LFT Swabs, Swab tests | Weekly | Allergen Management Team | 10 |
| Wall panels | Soy, Gluten | LFT Swabs, Swab tests | Weekly | Allergen Management Team | 10 |

*LFT Swabs — Lateral Flow Test (Limit of detection — LOD ≤ 5 ppm)

**Swab test — ELISA (Limit of quantification — LOQ mg/kg)

### *Selection of Sampling Locations*

Sampling locations were selected based on the risk assessment of the production line. The 100 swabs were distributed across:

Food contact surfaces (n=60) comprised surface swabs from meat grinders (n=15), bowl cutters (n=15), stuffers (n=15), and stainlesssteel preparation tables (n=15). Swabs were taken to determine the presence of those allergens identified by the risk assessment, specifically gluten and soy.

Non-food contact surfaces (n=40) comprised surface swabs from employee hands (n=10), employee clothing (n=10), yellow-taped "allergen path" floor zones (n=10), and wall panels in the production premises (n=10). Swabs were taken from the hands and work clothes of staff immediately following their break and upon exiting the kitchen to return to work, to determine the presence of allergens identified by the risk assessment, i.e., eggs, milk (casein and β-lactoglobulin), and mustard. Simultaneously, the floors and walls of the facility were tested for soy and gluten, allergens for which there was a reasonable suspicion of cross-contamination risk.

### *Swab Collection Technique*

Sterile, pre-moistened allergen collection swabs (Hygiena AlerCheck and 3M™ Allergen Swabs) were used. A standardized area of 10 cm × 10 cm (100 $cm^2$) was swabbed for flat surfaces, while irregular surfaces (e.g., equipment joints) were swabbed thoroughly to capture potential residues. The two test types were conducted at the same locations as a form of additional verification and to evaluate the reliability of the rapid testing method.

### *Target Allergens*

The study focused on the major allergens declared in the FBO's raw material specifications. The primary targets were; soy and gluten – commonly used as binding ingredients in meat processing and egg, milk and mustard (*Sinapis alba*) were used as ingredients in the kitchen for the preparation of employee meals.

### *Analytical Methods*

Two complementary methods were employed for detection to ensure accuracy:

Rapid Lateral Flow Tests (LFT): Used for on-site screening to provide immediate qualitative results (Presence/Absence). The limit of detection (LOD) was set at 5 ppm, in alignment with 2026 industry safety thresholds (*Lupo*, 2025; *Eurofins*, 2026)

Enzyme-Linked Immunosorbent Assay (ELISA): Any swabs yielding weak positive or ambiguous results on LFT were subjected to quantitative ELISA analysis in an ISO 17025 accredited laboratory to confirm the concentration of the allergen protein. Swabs that produced weak positive or ambiguous LFT results were stored at 4 °C and shipped to the ISO 17025 accredited laboratory on the same day under chain-of-custody documentation. ELISA assays were run using a validated commercial kit specific to the target allergen, following the manufacturer's instructions and laboratory SOPs. Each swab was analyzed in duplicate, with reagent blanks, positive controls, and a calibration curve prepared from certified reference standards included on every plate. The laboratory reported concentrations in mg/kg (or ng/mL as appropriate), and results below the assay's limit of quantification (LOQ) were reported as <LOQ while those between the limit of detection (LOD) and LOQ were reported as detected but not quantifiable. Where ELISA results contradicted the LFT, a third replicate or an orthogonal method (e.g., mass spectrometry) was performed to resolve discrepancies. All analytical data, including raw absorbance values, calibration curves, QC performance, and chain-of-custody records, were retained according to ISO 17025 record-keeping requirements (*ISO*, 2017). ISO 17025:2017 specifies record-keeping requirements in clauses 8.4 (management system records) and 7.5 (technical records), including retention, legibility, retrievability, protection, and audit trail provisions.

### *Quality Control and Validation*

Negative controls (swabs of unused clean surfaces) and positive controls (surfaces spiked with a known allergen concentration) were processed alongside every batch of 10 samples. Data were recorded within the FBO's food safety management system (FSMS) for traceability.

### *Statistical Analysis*

Statistical data analysis was performed using Microsoft Excel (Windows).

## 3. Results

Alongside the evaluation of allergen contamination in the production department, sampling for allergen presence was conducted. The results obtained are presented in Table 4.

All examined allergens (soy, gluten, egg, milk, mustard) were below detection limits (LOD, ≤ 5 ppm) or quantification limits (LOQ, mg/kg) across all examined surfaces. This indicated, based on the sampling methods and detection limits, that there were no detectable levels of the specific allergens in the monitored areas.

Following the inspection and the collection of results, Table 1 was further adapted by the Allergen Management Team and harmonized to more adequately meet the regular production needs of the FBO. The results of this are presented in Table 5.

Table 5 served as a basis, alongside monitoring via swab tests, for establishing a regular sampling plan for the control of allergen presence in the production premises (Table 6), as part of the FBO's self-monitoring plan.

Table 5 assessed allergen handling in the FBO's production setup, focusing on key areas as specified by the IFS framework. Allergen Management System confirms a documented Allergen Control Program exists within the FBO's food safety system. Raw Material Management validates allergen specifications in raw materials, global compliance and supplier details. Production Process and Control covers cross-contamination reduction, including segregation, production planning, spice handling, packaging disposal, physical barriers, and clear allergen pathways. Cleaning and Sanitation verifies effective,

**Table 4.** Results of the allergen presence monitoring in the FBO's production facility

| Sampling Location | Allergens to Test | Sampling Method | Number of samples | Number of positive samples | Results |
|---|---|---|---|---|---|
| **Food Contact Surfaces (n=60 samples)** | | | | | |
| Meat Grinders | Soy, Gluten | LFT Swabs, Swab tests | 15 | 0 | < LOD* < LOQ** |
| Bowl cutters | Soy, Gluten | LFT Swabs, Swab tests | 15 | 0 | < LOD < LOQ |
| Stuffers | Soy, Gluten | LFT Swabs, Swab tests | 15 | 0 | < LOD < LOQ |
| Stainles steel preparation tables | Soy, Gluten | LFT Swabs, Swab tests | 15 | 0 | < LOD < LOQ |
| **Non-Food Contact Surfaces (n=40 samples)** | | | | | |
| Employee hands | Egg, Milk, Mustard | LFT Swabs, Swab tests | 10 | 0 | < LOD < LOQ |
| Employee clothing | Egg, Milk, Mustard | LFT Swabs, Swab tests | 10 | 0 | < LOD < LOQ |
| Allergen path floor | Soy, Gluten | LFT Swabs, Swab tests | 10 | 0 | < LOD < LOQ |
| Wall panels | Soy, Gluten | LFT Swabs, Swab tests | 10 | 0 | < LOD < LOQ |

LFT Swabs – Lateral Flow Test (Limit of detection – LOD* ≤ 5 ppm)
Swab test — ELISA (Limit of quantification – LOQ** mg/kg)

**Table 5.** Results of the on-site inspection of allergen handling procedures within the FBO production premises

| Demand | Mark | Remark |
|---|---|---|
| **Remark** | | |
| Is there a documented Allergen Control Program implemented as part of the food safety management system? | A | Allergen Control Program is implemented, developed and maintained as part of broader food safety management system. |
| **Raw material management** | | |
| Are raw material specifications in place that list allergens requiring declaration? | A | Raw material specifications are in place with all listed allergens requiring declaration to comply with 2026 global food safety standards. |
| Is there a current and valid list of all raw materials with allergens, including mixtures and formulas? | A | FBO have a current and valid list of all raw materials with allergens used on its premises, which also includes all mixtures and formulas. |
| Do suppliers provide detailed allergen specifications for raw materials? | A | Suppliers follow strict allergen management practices and provide detailed allergen specifications for raw materials |
| **Production Process And Control** | | |
| Is the production of allergen-containing products conducted to minimize cross-contamination? | A | The production of allergen-containing products is organized on separate production days and on dedicated production lines; if this is not possible, it is scheduled after the production of allergen-free products, in the second half of the workday |
| Are production areas segregated and clearly marked, with designated areas for allergen-containing products? | A | Production areas are segregated and clearly marked. Specific areas for the production of allergen-containing products are marked, while the "allergen path" during production is marked with yellow floor tape within the production facility |
| Are temporal separation and scheduling of production times for products with allergens clearly documented if dedicated lines are not used? | A | There is a clearly designated and defined production line for the manufacturing of products with allergens, and if this is not the case, the temporal separation and scheduling of production times for products with allergens are clearly documented |
| Is there a daily production plan that prioritizes allergen-free foods before products with allergens? | A | Daily production plan is scheduled in order primarily produce allergen free foods prior to products with allergens |
| Are special precautions taken when handling spices containing allergens (e.g., closed containers, controlled introduction)? | A | During production, special attention is oriented to properly handling spices that contain allergens. Spices are kept in a closed container. When weighing the necessary spices for each production batch, labelled and sealed plastic containers are used in order to prevent airborne contamination. |
| Is used packaging from allergenic components promptly removed and disposed of properly? | A | All used packaging from allergenic components or spice blends containing allergens are removed from the production area during breaks, while they are kept until that time in closed, dedicated, and labelled plastic containers |

| Demand | Mark | Remark |
|---|---|---|
| Are physical barriers used to separate allergenic ingredients during storage and processing? | A | Physical barriers (walls, partitions) are used to separate allergenic ingredients during storage and processing. All allergenic ingredients are closed and properly marked in separated dedicated storage areas |
| Is a yellow line clearly marking the "allergen path" on the production floor? | A | On the floor of the production area, a yellow line clearly marks the "allergen path", ensuring that it is not erased or worn off due to mechanical transport or sanitation |
| **Cleaning and sanitation** | | |
| Are rigorous and thorough cleaning and sanitation procedures in place between production runs to remove allergenic residues? | A | Rigorous and thorough documented sanitation (mechanical cleaning, degreasing, and disinfection) procedures are staged between production runs in order to remove all allergenic residues |
| Is cleaning efficacy validated through methods like swab tests? | A | Swab tests for the presence of allergens are performed regularly in accordance with the FBO's self-control plan |
| **Equipment and Utensils** | | |
| Is dedicated equipment and utensils used for allergenic and non-allergenic products where possible? | A | All equipment and utensils for allergenic and non-allergenic product are separated where is possible. In cases where this is not possible, the equipment is labelled and sent for sanitation immediately after use. |
| **Staff Training** | | |
| Is staff regularly trained on allergen management, including hand washing, changing clothing, and cross-contamination risks? | A | Employees undergo regular training on proper allergen handling in production, with a special emphasis on handwashing, replacing soiled equipment, and understanding procedures that can lead to cross-contamination. Training is conducted quarterly by the technologist (internal training), while external training is held annually by external experts, including a test to evaluate employee knowledge, after which certificates are issued. |
| Is the outcome of training documented? | A | Records of each quarterly training session are maintained within the FBO's food safety management system, while certificates are issued annually for external training. |
| **Labelling and Storage** | | |
| Are all ingredients and end products clearly and properly labelled and stored? | A | All ingredients and end products are clearly and properly labelled and stored. All ingredients and end products containing allergens are clearly labelled and kept in sealed, undamaged packaging, ensuring they are clearly visible to all employees who have access to them. |
| Are allergenic ingredients stored closed, separately, and marked, preferably below non-allergenic ones? | A | All allergenic ingredients are stored closed, separately in marked area, below non-allergenic ones |

| Demand | Mark | Remark |
|---|---|---|
| Are bags used for allergenic commodities identified (e.g., different colors) and not reused for other commodities? | A | Plastic containers used for spices with allergenic mixture are red coloured, with 5–10 cm wide yellow track. All other Bags, or differently marked plastic containers, are not reused for keeping or transportation of allergens |
| **Drying and handling commodities** | | |
| Is the drying area clean, with physical barriers to prevent spillage and cross-contact? | A | Dedicated marked sanitation zone where plastic containers for allergen handling are kept during drying is clean and physically separated to prevent cross-contamination |
| Are materials/containers used for commodities cleaned to remove allergenic residue? | A | Swab testing is performed on regular basis to validate that materials or plastic containers are cleaned of allergenic residues |
| Transportation | | |
| Is transportation carried out using clean, dry vehicles free of previous loads? | A | Transportation of end products are carried out with a clean and sanitized transport vehicle that is dry and free of the previous load |
| Are transport containers cleaned before use if necessary and after unloading allergenic commodities? | A | Transport containers are sanitized and dried before use. During unloading, all transport containers containing allergenic commodities are primarily emptied of all cargo and appropriately cleaned |
| **Supplier management** | | |
| Is there a "List of Suppliers" maintained? | A | All suppliers are listed in the *List of Suppliers* |
| Are supplier evaluations conducted on a regular basis? | A | The supplier evaluation system is conducted regularly in accordance with the rating scale specified in Table 3 (A → KO) |
| **Risk assessment** | | |
| Is Allergen Risk Assessment regularly monitored and documented? | A | Management with risk is regularly monitored and documented through Allergen Risk Assessment. Regular risk assessments are conducted yearly, or more frequently as needed, by the FBO Food Safety Team. |
| **Finished Product Labelling** | | |
| Do finished products with allergens have declarations in accordance with current legal provisions? | A | Finished products with allergens have declarations in accordance with current legal provisions. |
| Who is responsible for applying labels to individual and bulk packaging, and who is responsible for the accuracy of the information on the label? | A | The employee is responsible for applying the labels, the Packing Department supervisor is responsible for checking the presence of the labels, while the Food Safety Team Leader and the technologist are responsible for the label content. |
| Is accidental presence of allergens handled based on risk analysis for labeling? | A | In cases of accidental presence, the labelling of legally declared allergens and traces must be based on a risk analysis. |

**Table 6.** Sampling plan for allergen presence in the production premises

| Sampling Location | Allergens to Test | Sampling Method | Frequency | Responsible Personnel | Remarks |
|---|---|---|---|---|---|
| Raw Material Storage Area | Soy, Gluten | Swab tests on surfaces | Monthly, more frequently if needed | Quality Assurance Team | Ensure proper labeling and storage separation. |
| Ingredient Mixing Area | Milk, Egg, Soy | Swabs, Composite sampling | Monthly | Production Manager | Focus on cross-contamination risks. |
| Processing Equipment | All identified allergens | Swab tests | Monthly | Hygiene Supervisor | After maintenance and deep cleaning activities. |
| Finished Product Storage | All declared allergens | End product testing | Monthly | Quality Control Analyst | Verify label accuracy and product segregation. |
| Employee Handrails & Gloves | All common allergens | Swab tests | Monthly | Health and Safety Officer | Ensure consistent hygiene practices. |
| Packaging Area | Gluten, Soy | Air sampling | Monthly | Packaging Supervisor | Monitor airborne allergens during packaging. |

documented cleaning, necessary so the swab tests can remove any allergenic residues from surfaces. Equipment and Utensils ensures dedicated/labelled equipment for allergenic products and immediate sanitation for shared items. Staff Training regulates training courses on allergen management, documented with assessments and certificates. Labelling and Storage defines labels and stores ingredients/products clearly, with proper allergen separation and identification. Drying and Handling Commodities defines practices of cleaning and drying of equipment subjected to swab testing for allergenic residue removal. Transportation covers the use of clean, allergen-free transport vehicles and containers. Supplier Management maintains a supplier list with regular evaluations. Risk Assessment regularly monitors and documents allergen risk assessment. Finished Product Labelling ensures legal allergenic declarations and handles accidental presence through risk analysis.

The sampling plan is an integral part of the FBO's self-control plan, developed in accordance with domestic (*Official Gazette RS*, 19/2017, 16/2018, 17/2020, 118/2020, 17/2022, 23/2022, 30/2022 i 61/2024; *Official Gazette RS*, 30/2024) and international (*EU Regulation* 1169/2011; *EU Regulation* 828/2014) legal regulations. This plan needs regular updates and validation to ensure ongoing compliance and effectiveness. Each production segment, each production unit requires a different approach to risk assessment for the presence of allergens, so the approach must be tailored to the current and real hazards specifically associated with the risk in that production step.

## 4. Discussion

The need for a documented allergen control system, which was the starting point of our research and the first item on our checklist, is also stated by *López-Calvo* et *al*. (2025) as the fundamental problem-solving approach in their study conducted in Costa Rica. The issue of allergies arising from human exposure to specific food components has been recognized as immunologically mediated hypersensitivity since the 1990s (*Muthukumar* et *al*., 2020). On a global scale, the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) have emphasized the significance of addressing this public health challenge. This has led to the establishment of a systemic approach to the control and identification of food allergens, which currently constitutes a fundamental requirement for food business operations. In line with a systemic approach to ensuring

allergen control in production, we emphasized the importance of raw material intake control, a finding corroborated by other studies (*Decker et al.*, 2008; *Röder* and *Weber*, 2016). Control measures encompass aspects such as identifying food allergens, avoiding cross-contamination with allergens during transportation, managing the storage of raw materials and food additives (RW&FA), overseeing the production process, and ensuring proper storage of finished products. The subsequent section of the checklist comprised inquiries aimed at enabling food business operators to clearly define and evaluate all associated risks. This ensures appropriate handling of allergen-containing products, thereby preventing the intermingling of raw materials during routine production and mitigating the risk of cross-contamination. This approach is consistent with methodologies employed in other studies sharing the same objective (*Blom et al*., 2021, *Elrahi et al*., 2023, *Smječanin*, 2023). The necessity of delivering precise and transparent information regarding allergens present in products by individuals in the food industry responsible for market distribution is undeniable. For those with allergies, proper allergen labeling serves as a crucial tool to mitigate exposure risks and avert anaphylaxis. Examining the conditions for the physical segregation of allergens, as specified in the production process control section of Table 5, prevalence of food allergies is reduced or eliminated. Similar approach is used in researches of *Zhou et al* (2024) and *Gunal-Koroglu et al* (2025). We emphasized the necessity for clear and visible marking of allergen transport routes within the production facility, a measure that aligns with the recommendations of *Boye and Godefroy* (2011). Their work highlights the requirement for 'Dedicated Traffic Pathways' as a fundamental control measure. The scientific rationale for this approach lies in preventing the mechanical transfer of allergens via forklift tires or employee footwear. Although specific color is not prescribed, industrial best practices typically utilize yellow lines — the international symbol for caution and boundary — to designate zones where allergens are handled. Furthermore, production shifts or cycles must invariably commence with allergen-free products, ensuring that manufacturing begins when equipment cleanliness is at its peak following the comprehensive sanitation protocols conducted at the end of the previous operational period. This practice is consistent with the findings of *Crevel* (2007). In accordance with IFS standards, food business operators are encouraged to schedule the processing of allergen-containing products at the conclusion of the production day, immediately preceding the primary sanitation and equipment cleaning cycle. We emphasized the necessity of conducting regular employee training on allergen control within the framework of the implemented operational food safety management system. A similar requirement is documented in the research by *Gonzalez-Mancebo* et *al*. (2019). Sanitation protocols within production facilities handling food allergens must be rigorous, comprehensive, and meticulously documented. This documentation should encompass every stage, including preparatory mechanical cleaning and effective sanitation phases such as disinfection. A consistent approach is advocated in the study by *Nantob-Bikatui* (2020). Canadian Allergen management guide (2022) particular attention points toward equipment maintenance, specifically regarding components that are difficult to access for cleaning and maintenance. These areas often contain 'dead zones' where allergens can accumulate, posing a risk of persistent contamination. This approach aligns with the allergen control checklist developed based on the IFS. This framework stipulates the mandatory segregation and dedicated storage of tools and equipment utilized in the manufacturing of allergen-containing products. Furthermore, the storage protocols for allergen-containing products outlined in the aforementioned guide — specifically their placement in clearly designated areas, segregated from non-allergenic goods, and positioned on lower shelving units to prevent cross-contact — align with the criteria established in our checklist derived from IFS standards. These requirements were fully satisfied, as evidenced by the 'A' rating documented in the audit record (Table 5).

Scientific evidence demonstrates that surface swabbing is the most reliable method for identifying 'hotspots' on equipment where meat residues and spice traces may persist, such as joints, blades, and filler corners (*Jackson et al*, 2008). The allergen management team, operating within the FBO's HACCP team and supported by an external expert group, evaluated the risk of allergen contamination in meat products during regular production processes. The risk of allergen presence was assessed based on the IFS Food Version 8 guidelines, which served as the foundation for developing a checklist (Table 1); this was used to evaluate the current state, marked according to Table 2. The results are presented in Table 5. Simultaneously with the evaluation, planned swabbing of potentially contaminated sites was initiated. The sampling procedure was systematically designed and is presented in Table 3. Swabs were collected in ten series of ten samples each; simultaneously, rapid swabs for

immediate allergen detection were performed alongside swabs for ELISA laboratory diagnostics. The obtained test results are presented in Table 4. The results of the allergen risk evaluation (Table 5) and the results of the swab monitoring (Table 4) served as the basis for establishing a regular allergen control plan within the production facility (Table 6) as an integral part of the FBO's self-control plan.

Allergen risk assessment represents a fundamental pillar of modern food safety management, and the International Food Standard (IFS) provides a comprehensive framework for implementing these assessments systematically across food production operations. The IFS standard directly addresses allergen risk mitigation through Requirement 4.19, which comprises three interconnected sub-requirements that form a holistic approach to allergen management. Requirement 4.19.1 mandates a thorough risk assessment for all raw materials and allergenic ingredients, requiring documented allergen risks and up-to-date records of allergenic ingredients. This foundational component ensures that organizations have complete visibility into their allergen landscape from ingredient sourcing through finished product declaration. Requirement 4.19.2 obligates companies to implement risk-based measures to minimize cross-contamination, moving beyond the precautionary principle to evidence-based control strategies. These measures include cleaning validation protocols, personnel hygiene training, process zoning, and monitoring across transport, storage, and production environments. The shift toward process-oriented (HACCP-based) risk assessment rather than precautionary labeling represents a significant evolution in allergen management thinking, allowing organizations to implement proportionate controls based on actual contamination risks (*Allergenen Consultancy*, 2018). Requirement 4.19.3 emphasizes evidence-based allergen labeling, leveraging scientific thresholds such as eliciting dose (ED): ED01 and ED05 reference doses to determine when accidental or unavoidable cross-contamination must be declared. ED is a critical metric used for quantitative allergen risk assessment and determining the necessity of precautionary allergen labelling (*IFS*, 2023a) This approach aligns with FAO/WHO guidance on risk-based labeling frameworks, ensuring labels are both accurate and legally compliant. The development of IFS Food Version 8 reflects the industry's recognition that traditional hazard-based approaches to allergen warning statements lack precision and limit consumer choice (*Kiwa*, 2023; *Henderson*, 2025). The FAO/WHO established a scientific framework based on three assessment criteria: prevalence, potency, and severity, in order to determine which foods warrant inclusion on a global priority allergen list (*FAO and WHO*, 2022; *Anaphylaxis Campaign*, 2024). This framework moves away from precautionary labeling toward an assessment of actual risk, considering both the likelihood and severity of allergic reactions (*Henderson*, 2023). Reference doses set by FAO/WHO consultations establish quantitative limits for handling unintended allergen presence (UAP), assisting companies in deciding when warning labels are scientifically supported. Integrating these thresholds into IFS-compliant risk assessments demonstrates that allergen management is based on international scientific agreement, not assumptions.

## 5. Conclusion

A thorough review of the IFS standard requirements enabled the FBO's allergen management team, with support from an external expert team, to assess the potential for allergan contamination of raw materials and finished products. Swab samples taken from food contact surfaces and the environment demonstrated the effectiveness of consistent implementation of IFS Food Version 8 and permitted the development of a tailored allergen control plan as an integral part of the self-monitoring plan. By following the requirements and methodologies outlined in this paper, it is anticipated the FBO will ensure compliance, help protect consumer health, and maintain the highest levels of food safety throughout the supply chain.

The current IFS Food Version 8 framework offers a comprehensive, standardized approach to risk assessment, process control, and compliance in food manufacturing. Performing risk assessment in accordance with IFS Food Version 8 demands a systematic, risk-based approach that aligns with global food safety standards. To manage allergens, FBOs must develop and maintain comprehensive written policies and procedures that are tailored to their own, specific operations. Proper allergen management strategies yield several benefits. They enable a FBO to show it is making all required efforts to eliminate or minimize the chance of an allergen being inadvertently included in food products. They enhance the precision of declarations regarding allergenic ingredients. They offer a chance for FBOs to showcase their competence and understanding of effective allergen management practices. They help mitigate the risks posed to consumers with food allergies by limiting the presence of unintended allergens.

# Uspostavljanje plana kontrole prisustva alergena u pogonu na osnovu analize rizika pomoću odrednica Međunarodnog standarda za hranu (IFS)

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INFORMACIJE O RADU

*Ključne reči:*
IFS standard
Analiza rizika
Alergeni
Unakrsna kontaminacija
Uzimanje briseva na prisustvo alergena

APSTRAKT

U radu su predstavljeni zahtevi, metodologija i praktična razmatranja u vezi sasprovođenjem procene rizika od alergena kod subjekta u poslovanju hranom u skladu sa IFS standardima. IFS verzija 8, koja je stupila na snagu u januaru 2024. godine, pruža sveobuhvatan i standardizovan okvir za procenu rizika, kontrolu procesa i usklađenost u proizvodnji hrane. Usklađenost sa IFS verzijom 8 zahteva sistematičan pristup zasnovan na riziku, koji je integralni deo globalnih standarda bezbednosti hrane. Postupanjem po stavkama zahteva standard i korišćenjem definisane metodologije, proizvođači hrane mogu da unaprede nivo bezbednosti proizvodnje i da doprinesu u zaštititi zdravlja potrošača, uz istovremeno održanje najvišeg nivoa bezbednosti hrane kroz ceo lanac snabdevanja. Validacija postavljenog sistema kontrole alergena izvršena je uzimanjem 100 briseva sa površina na kojima postoji mogućnost kontaminacije alergenima; tom prilikom nisu dobijeni pozitivni rezultati, što dokazuje funkcionalnost primenjenog sistema kontrole. Dobijeni rezultati monitoringa briseva i evaluacije prisustva alergena i mogućnosti kontaminacije su poslužili kao osnov za razvoj sopstvenog plana kontrole alergena kao integralnog dela plana samokontrole subjekta u poslovanju hranom.

**Disclosure Statement:** No potential conflict of interest was reported by the authors.

**Funding:** The results of the research presented in this paper were funded by the Ministry of Science, Technological Development and Innovation of the Republic of Serbia, based on the Agreement on the implementation and financing of scientific research work in 2025, No. 451-03-136/2025-03/200050 dated 02/04/2025.

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