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FOOD ALLERGEN CONTROL AT MEAT PROCESSING ENTERPRISE: SCIENTIFIC RATIONALE AND PRELIMINARY HAZARD ANALYSIS

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Abstract
From a public health point of view, the control of food allergens in enterprises is one of the main methods of food safety management required by national and international standards. The implementation results of measures for allergen control and identification of noncompliance are presented using the developed checklist, which includes 41 questions. The survey was conducted at meat processing plant in the Moscow region, which is certified for compliance with the requirements of ISO 22000:2018 "Food safety management systems — Requirements for any organization in the food chain" and FSSC22000 certification scheme. Compliance with the criteria included in the checklist was assessed by the method of interviewing employees at the enterprise and direct on-site observation. The highest level of noncompliance according to 7 groups of criteria established in the checklist was identified in the following sections; "Cleaning", "Transport and storage" and "Hazard awareness". Factors complicating the implementation of allergen control activities include available methods to assess cleaning effectiveness when removing specific allergens, experience in separating allergen-containing and allergen-free products and raw materials during transport and storage, and staff training in allergen control. At the same time, the PCR method was used to study 15 samples of meat products manufactured at the selected enterprise for the presence of legumes (soybeans), gluten, mustard, and peanuts. In six samples, undeclared allergens were detected in quantities hazardous to the health of the consumer. The results obtained indicated the need to develop and implement measures aimed at minimizing the risk of allergen transfer to the meat products during their production. Based on the results of the research, a procedure for allergen control has been developed, including additional measures for the control of food allergens.

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Introduction

Food allergens have a negative impact on health and quality of life of people with hypersensitivity to certain food ingredients.

The reaction of an allergic person consumed soy-containing food products may be different. Examples include loose stools, abdominal pain, asthma attack, exacerbation of eczema, difficulty in breathing and anaphylactic shock [1].

Gluten allergy is usually associated with gastrointestinal dysfunction (cheilitis, gastritis, colitis, gastroenteritis, irritable bowel syndrome), skin manifestations (atopic dermatitis, urticaria, angioedema) and, less commonly, with respiratory dysfunction and systemic manifestations such as anaphylactic shock [2].

Symptoms of a true food allergy to mustard most often develop within a few minutes or, less often, in a couple of hours after contact with it. Mild symptoms may include tingling or itching in the mouth, nausea and abdominal discomfort, and rashes in various places (also similar to urticaria). More severe symptoms include face, throat and/or mouth swelling, difficulty in breathing, and status asthmaticus. In some cases, there is a severe decrease in blood pressure (anaphylactic shock). Most often, this is accompanied by severe weakness, dizziness, and rapid heartbeat [3].

Peanut is a strong allergen containing up to 32 different proteins, of which at least 18 are capable of causing an allergic reaction. Among them, vicilin, a reserve protein of seeds, a heat-resistant main allergen (amounts up to 12–16% of the total protein in peanuts); conglutin; profilin; albumin, a heat-resistant protein that does not break down during digestion; lipid transfer protein. From a biological point of view, it is not a nut, but a seed of a plant from the legume family. It is widely used in the food industry and is often a "hidden" allergen in products that, at first glance, do not contain it. Among all legumes, it has the most allergenic properties and may cause life-threatening allergic reactions, allergic shock, angioedema, urticaria, exacerbation of respiratory allergies and atopic dermatitis. With a

certain heat treatment, the allergenic properties of peanuts are enhanced. The allergenicity of peanuts depends on the degree of heat treatment: dry roasting increases the allergenicity, although it decreases during the cooking process as, presumably, part of the protein transfers into the water [3].

Time period of the peanuts introduction into the diet significantly affected the prevalence of peanut allergy among Israeli schoolchildren [4]. Israeli children consumed more peanuts during their first year of life than the British children, and the prevalence of peanut allergy was 0.17% in Israel versus 1.85% in the UK; while changes in atopy, social class, or genetic background had no significant effect [4]. In the US, in just 4 years (2006–2010), the number of people with peanut allergies doubled. At the same time, the number of cases of anaphylactic shock caused by peanuts doubled over a five-year observation period [5]. In addition, the form in which peanuts are consumed may determine whether an allergic response occurs. The stability and allergenicity of allergenic proteins may be altered during food processing. For example, roasting of peanuts affects the stability of peanut allergens through the Maillard reaction, and modified peanut allergens have an increased ability to bind IgE [6]. However, there is no conclusive evidence to link changes in eating habits or in the food industry with an increase in the prevalence of food allergies [4].

In the US, milk, eggs, and peanuts are the most common allergenic foods in children, while adults are more likely to be allergic to shellfish, peanuts, and tree nuts [5]. Many children will get through food allergies and become more tolerant to milk, eggs, soy, and wheat. Allergies to peanuts, tree nuts, and shellfish rarely decrease with age [5].

In the Russian Federation, the mechanisms for controlling the content of allergens (including gluten) in food products, unfortunately, still need to be addressed.

Clause 13 of part 4.4 of article 4 of CU TR 022/2011 "Food products in terms of their labeling"[1] contains a requirement to indicate in the composition of food products components (including food additives, flavors), biologically active additives, the use of which may cause allergic reactions or is contraindicated in certain types of diseases and which are specified in clause 14 of part 4.4 of article 4 of CU TR 022/2011, regardless of their amount.

In addition, in accordance with the Technical Regulation of the Customs Union CU TR 027/2012 "On the safety of certain types of specialized food products, including therapeutic and preventive nutrition"[2], gluten-free food products must be made from one or more components that do not contain wheat, rye, barley, oats or their cross-bred variants and/or must be made in a special way (to reduce gluten levels) from one or more components that are derived from wheat, rye, barley, oats or their cross-bred variants, in which the level of gluten in ready-to-eat products is not more than 20 mg/kg.

A number of publications by foreign authors contain the results of studies to establish the concentrations of food allergens that may cause an allergic reaction [7,8,9,10].

Voluntary Incidental Trace Allergen Labeling (VITAL®) is a scientifically based standardized allergen risk assessment process used by the food industry in Australia, New Zealand and a large number of companies in other countries. The VITAL® program is based on scientific research by a group of scientists from New Zealand and the USA to establish threshold doses of allergens that may cause an allergic reaction [7,8,9,10]. The goal of the VITAL® program is to ensure that manufactured foods are safe for the majority of consumers suffering from food allergies by providing precautionary labeling criteria that enable consumers with allergies and their caregivers to avoid purchasing foods that may be hazardous for them.

To date, an updated version of the VITAL® program is in use, i. e. VITAL® 3.0. Changes in allergen doses that may cause an allergic reaction in sensitive people in the new version 3.0 of the VITAL® program compared to version 2.0 are shown in Table 1.

Table 1. Changes in allergen doses that may cause an allergic reaction in sensitive people in the new 3.0 VITAL® program compared to version 2.0 [11]

Allergen	Reference Dose (mg of protein)		Comment
	VITAL 2.0	VITAL 3.0	
Reference Dose has decreased			
Cereals containing gluten (including wheat)	1.0	0.7	Labelling outcomes may have shifted from Action Level 1 to Action Level 2 — check for affected recipes. *Refer to information below about changes to tree nuts.
Soy	1.0	0.5	
Sesame	0.2	0.1	
Lupin	4.0	2.6	
Cashews & Pistachio nuts	0.1	0.05	
Pecan & Walnut	0.1	0.03	
Reference Dose has increased			
Egg	0.03	0.2	Labelling outcomes may have shifted from Action Level 2 to Action Level 1.
Milk	0.1	0.2	
Fish	0.1	1.3	
Crustacea	10	25	
New Reference Dose			
Celery/Celeriac	None	0.05	
Reference Dose is unchanged			
Peanuts	0.2	0.2	
Other tree nuts (Almonds, Brazil nuts, Hazelnuts, Macadamia or Queensland nuts)	0.1	0.1	
Mustard	0.05	0.05	

[1] Technical regulations of the Customs Union CU TR 022/2011 "Food products in terms of its labeling" (Adopted by The decision of the Council of the Eurasian economic Commission of December 9, 2011 № 881). Moscow, 2011. Retrieved from https://docs.cntd.ru/document/902320347. Accessed May 24, 2021 (In Russian)

[2] Technical regulation of the Customs Union CU TR 027/2012 "On safety of certain types of specialized food products, including dietary therapeutic and dietary preventive nutrition" (Adopted by The decision of the Council of the Eurasian economic Commission of June 15, 2012 № 34). Moscow, 2012. Retrieved from https://docs.cntd.ru/document/902352823. Accessed May 24, 2021 (In Russian)

It is important to note that some reference doses have increased, some reference doses have decreased, and some have remained the same. So, for example, for pecans and walnuts, the reference dose decreased by 3 times from 0.1 to 0.03 mg of protein. The reference dose for fish increased 13-fold from 0.1 to 1.3 mg of protein; for eggs, the reference dose increased 6-fold from 0.03 to 0.2 mg of protein. Reference doses for peanuts, other nuts and mustard have not changed.

To reduce the risk of adverse allergic reactions in consumers with hypersensitivity, it is necessary to eliminate certain food allergens from the diet [12]. Such an elimination diet will not be effective unless the person with a food allergy is reliably informed by food manufacturers about the allergens present in food [13]. In this regard, the legislation of a number of countries establishes a list of components, the use of which may cause allergic reactions or is contraindicated in certain types of diseases, as well as the requirement for mandatory information on the presence of such components in the labeling of food products [14].

Such food allergens have been identified as a major food safety hazard and their control is one of the main areas of food safety management systems [15, 16, 17, 18, 19]. Regardless of mandatory food law provisions, food allergen surveillance is required by all voluntary standards that set requirements for food safety management systems such as ISO 22000[3], FSSC 22000[4], BRC[5], IFS[6] и SQF[7]. However, the scope of control measures applied to the control of food allergens arising from the requirements of these standards is much wider than just food labeling required by food regulations [17, 20].

Control measures include such issues as identification of food allergens, prevention of cross-contamination with allergens during transportation and storage of raw materials, during production, and also during storage of finished products [17, 18, 20, 21]. Important issues are the separation of food products containing allergens from those that do not contain them, as well as the removal or reduction of allergen residues from food contact surfaces by cleaning and disinfection [22], the prevention of cross-contamination with allergens [16,19]. Cross-contact may be prevented by appropriate production planning: first, products that do not contain allergens or contain allergens that are present in all products are manufactured, and only then products containing specific allergens that are present only in some products are manufactured [17].

Considering the fact that insufficient allergen control may adversely affect the health and quality of consumer's life it is necessary to determine the scope of food allergen control measures and their effectiveness.

[3] ISO 22000:2018 Food safety management systems — Requirements for any organization in the food chain. ISO/TC34/SC17 Management systems for food safety, 2018.

[4] FSSC22000 version 5.1 (Food Safety System Certification 22000). Foundation for Food Safety Certification, 2020.

[5] Global Standard Food Safety (Issue 9). BRCGS, 2022

[6] IFS Food version 7. IFS Management GmbH, 2020.

[7] SQF Code Edition 8.1. Safe Quality Food Institute, 2019.

Previously, currently available methods for the determination of allergens in food products, their advantages and disadvantages were considered [23,24].

The purpose of the study was to analyze the products of the selected enterprise for the presence of allergens, assess the effectiveness of control measures implementation in relation to food allergens at the meat processing enterprise, as well as identify significant noncompliance and take corrective measures developed based on the results of employee survey at the enterprise and direct observation of the production process aimed at improving the control of food allergens.

Materials and methods

A meat processing enterprise located in the Moscow region was chosen as the object of the study. Since 2013, the enterprise has implemented a food safety management system certified for compliance with FSSC 22000 certification scheme and the international standard ISO 22000:2018 "Food safety management systems — Requirements for any organization in the food chain". The enterprise has previously developed and implemented an allergen control program, as required by FSSC 22000 certification scheme and ISO 22000:2018 "Food safety management systems — Requirements for any organization in the food chain".

To assess the relevance of the issue of the allergen control at this enterprise, a study of the manufactured products for the presence of allergens was carried out. A sample in the form of a packed product in the amount of at least 500 g was taken directly at the enterprise in the storage warehouse. Samples were transported in a refrigerated container and stored until testing at a temperature of 2 °C to 4 °C for not more than 24 hours. For the study, 8 types of meat products (15 items) were selected, since they are in the greatest demand among consumers:

1. Small sausages "Molochnye". Grade B meat product;
2. Small sausages "Slivochnye". Grade B meat product;
3. Frankfurters "Doktorskie". Grade B meat product;
4. Cooked sausage "Doktorskaya". Grade A meat product;
5. Cooked sausage "Molochnaya". Grade B meat product;
6. Cooked sausage "Telyach'ya". Grade A meat product;
7. Cooked sausage "Lyubitelskaya". Grade A meat product;
8. Cooked sausage "Russkaya". Grade B meat product;
9. "Ham for breakfast". Grade A boiled pork meat product;
10. Semi-smoked sausage "Krakovskaya". Grade B meat product;
11. Fried sausage "Ukrainian fried". Grade B meat product;
12. Boiled-smoked sausage "Cervelat". Grade A meat product;
13. Boiled-smoked sausage "Bavarskaya". Grade C meat product;
14. Boiled-smoked sausage "Moscovskaya". Grade A meat product;

15. Sausages for frying "Adzharian sausages with herbs". Semi-smoked sausage, Grade C meat product.

Examination of enterprise products for the presence of allergens by high-quality PCR

Products have been tested for the presence of DNA from gluten-containing cereals, soy, mustard and peanuts.

Sample preparation

From each sample of sausages, 100 g were taken. The resulting sample was ground in GRINDOMIX GM 200 homogenizer (Retsch, Haan, Germany) to a homogeneous state. Weight measurement was carried out on HR-150AZ balance (AND, Korea), 150 g weighing limit, accuracy class I.

Extraction of DNA

100 mg samples were taken from the objects of study for DNA extraction. The process itself was carried out using Sorb-GMO-B commercial kits (Sintol CJSC, Russia) according to the instructions. The principle of the method is based on the sorption of free DNA on silica particles.

Real-time PCR conditions

The 30 µl reaction mixture contained 2.5 µl 10x PCR buffer, 2.5 µl MgCl2 at a concentration of 2.5 mM, 2.0 µl dNTP, nucleotides at a concentration of 25 mM, SynTaq polymerases 2.5 EA, and 2 µl of isolated DNA. Primers species-specific to the mitochondrial region of COX1 gene were added to the mixture at a concentration of 300 nM. Reagents were produced by Sintol CJSC, Russia.

Amplification mode: preliminary denaturation at a temperature of 95 °C for 420 s; annealing-elongation at a temperature of 60 °C for 40 s, denaturation at a temperature of 95 °C for 15 s; the duration of the amplification program is 45 cycles. Limit of detection (LOD) of the method is ≤ 0.001%. The sample was amplified in triplicate. Real-time PCR was performed on ANK-32 amplifier (Sintol CJSC, Russia).

Development and verification of the checklist

The study was conducted by interviewing employees of the enterprise and direct on-site observation.

The checklist is based on available literature on the control of food allergens and on the requirements set out in food safety management system standards such as ISO 22000 (ISO/TS 22002–1), FSSC 22000, BRC, IFS.

11 persons were interviewed. These are members of the food safety group, management, and staff of the main workshops.

Results and discussion

The results of the study for the presence of allergens in the products by PCR are presented in Table 2. It was found that two samples contained soy; three samples contained gluten, which may be due to the presence of wheat flour impurities in such ingredients used in the recipe of these sausages as dry milk and dry egg powder; six samples contained mustard; one sample contained peanuts in a small concentration.

The results obtained indicate the presence of allergens in meat products, which, according to the recipe, should not contain them. This, in turn, indicate the need to develop

Table 2. PCR results for the presence of allergens in the products

Sample No.	Sample name	Legumes (soy)	Gluten	Mustard	Peanuts
1.	Small sausages "Molochnye". Grade B meat product.	DETECTED	DETECTED	DETECTED	Not detected
2.	Small sausages "Slivochnye". Grade B meat product.	DETECTED	Not detected	DETECTED	Not detected
3.	Frankfurters "Doktorskie". Grade B meat product.	Not detected	DETECTED	DETECTED	DETECTED
4.	Cooked sausage "Doktorskaya". Grade A meat product.	Not detected	Not detected	Not detected	Not detected
5.	Cooked sausage "Molochnaya". Grade B meat product.	Not detected	Not detected	Not detected	Not detected
6.	Cooked sausage "Telyach'ya". Grade A meat product.	Not detected	Not detected (at the limit of detection)	Not detected	Not detected
7.	Cooked sausage "Lyubitelskaya". Grade A meat product.	Not detected	Not detected	Not detected	Not detected
8.	Cooked sausage "Russkaya". Grade B meat product.	Not detected	Not detected	Not detected	Not detected
9.	«Ham for breakfast». Grade A boiled pork meat product.	Not detected	Not detected	Not detected	Not detected
10.	Semi-smoked sausage "Krakovskaya". Grade B meat product.	Not detected	Detected	Detected	Not detected
11.	Fried sausage «Ukrainian fried». Grade B meat product.	Not detected	Not detected	Detected	Not detected
12.	Boiled-smoked sausage «Cervelat». Grade A meat product.	Not detected	Not detected	Detected	Not detected
13.	Boiled-smoked sausage "Bavarskaya". Grade C meat product.	Not detected	Not detected	Not detected	Not detected
14.	Boiled-smoked sausage "Moscovskaya". Grade A meat product.	Not detected	Not detected	Not detected	Not detected
15.	Sausages for frying "Adzharian sausages with herbs". Semi-smoked sausage, Grade C meat product.	Not detected	Not detected	DETECTED (is labeled)	Not detected

and implement measures aimed at minimizing the risk of allergen transfer during production and the risk of allergen cross-contamination at the selected enterprise.

The effectiveness of any control system implementation is at least 60% dependent on the human factor; on how much the staff will be aware of the need for this process. To determine the degree of enterprise's personnel awareness of the allergen control importance, a questionnaire was developed consisting of 6 questions covering the amount of employees' knowledge about food allergens and their danger to the health of consumers in case of contact with the products of the enterprise.

To assess compliance with allergen control requirements at the enterprise, a checklist was developed (Table 3). At the moment, the checklist includes 7 evaluation criteria and 41 questions that cover all aspects of the production of meat products at the enterprise. According to the criteria "hazard awareness", "identification of food allergens", "washing, packaging and labeling", 5 questions were addressed; according to the criteria "transportation and storage", "cross-contamination", 7 questions were addressed; according to the criterion "management", 6 questions were addressed. It is planned to update this checklist annually based on the results of performance evaluation by changes in the number of criteria and questions, if necessary.

Justification of the criteria and questions included in the checklist

Hazard awareness (1)

When establishing a food safety management system, awareness of food allergens and knowledge of appropriate allergen control measures contained in legislative documents and management system standards are the basis for allergen control. Thus, a topic on allergen control with a section highlighting the risk of unintentionally introduced allergens should be included in the staff training schedule for the year.

Regarding the current situation with personnel awareness of food allergens, data presented in publications related to food service enterprises suggest that staff knowledge is focused on general knowledge about food allergens and first aid rules for anaphylactic reactions [12, 25]. Based on this, questions 1.1 to 1.4 were included in the checklist (Table 3).

As practice shows, visitors to the enterprise may be sources of unintentional introduction of allergens into products and often not all visitors have information about the risks of food allergens and measures to control them. In this regard, question 1.5 was included in the checklist (Table 3).

During the survey at the enterprise under study, it was determined that not all employees were trained in the control of food allergens, but only members. In addition, the Instruction for visitors to the enterprise did not include information about the risks of food allergens and measures to control their transfer into the products of the enterprise.

Identification of food allergens (2)

The presence of allergens in foods may be due to their composition, i. e. intended introduction of allergens, but they may also enter the products as a result of cross-contamination being hidden (unintentionally added) allergens. Complete allergen control requires that both types of allergens are identified [26].

The study by Dzwolak shows that the specifications for purchased raw materials and auxiliary materials were generally absent in enterprises that did not implement food safety management systems in accordance with ISO 22000, BRC or IFS. The implementation of HACCP principles does not lead to the development of specifications for all raw materials and auxiliary materials, since this is not required within the HACCP system [27]. In this regard, questions 2.1, 2.4, 2.5 were included in the checklist (Table 3).

For more than half of the enterprises, the absence of allergens list used in the enterprise is a sign of a significant gap in the control of food allergens, so question 2.2 was included in the checklist (Table 3).

The absence of such a list, which is required by the BRC and IFS standards, contributes to an increased risk of allergen cross-contamination [19,26]. This observation is directly related to the insufficient level of allergen detection when accepting raw materials and auxiliary materials. Therefore, question 2.3 was included in the checklist (Table 3).

Undoubtedly, corrective actions are needed at the sites under study, since full knowledge of allergens upon receipt of raw materials allows to correctly assign a storage location [26]. To avoid cross-contamination, it is also important to implement a policy regarding food brought in by staff, food used in the canteen of the enterprise, and food in vending machines installed at the enterprise. According to a study by Dzwolak, the lack of such a policy in most of the enterprises studied contributed to an increased risk of uncontrolled contact with allergens [27].

Transportation and storage (3)

The transport of raw materials and auxiliary materials is one of those links in the food chain where there is a risk of cross-contamination, but which is often overlooked in a systematic approach to allergen control [28]. If allergenic and non-allergenic ingredients are not separated during transport and storage, this may minimize the effectiveness of Good Manufacturing Practices in subsequent product manufacturing steps. According to [12], the lack of separation of raw materials and auxiliary materials during transportation is a serious gap in preventing cross-contamination with allergens. In this regard, question 3.1 was included in the checklist (Table 3).

A similar problem has been observed with separate storage of raw materials and ancillary materials, where good allergen practice was applied only in some enterprises with current BRC and IFS standards [27]. Therefore, questions 3.3 to 3.6 were included in the checklist (Table 3).

Table 3. Checklist for assessing the control of food allergens at meat processing enterprises

	Questions	Completion mark	Notes % completed
1.	Hazard awareness		
1.1	Have production personnel been trained in the control of food allergens?		
1.2	Have production personnel been informed about which food allergens should not be brought into the enterprise with food?		
1.3	Have production personnel been trained in the procedure/program for food allergen handling?		
1.4	Have production personnel been trained in the control of food allergens?		
1.5	Have visitors been instructed on the principles of the control of food allergens?		
2.	Identification of food allergens		
2.1	Have information on hidden allergens been obtained from all suppliers (raw materials, food additives)?		
2.2	Is there a list of allergenic materials used at the enterprise?		
2.3	Are allergenic materials identified upon arrival of raw materials at the enterprise?		
2.4	Do all product specifications/descriptions at the enterprise contain allergen information?		
2.5	Do all specifications of purchased raw materials and food additives contain information about allergens?		
3.	Transportation and storage		
3.1	Are allergenic and non-allergenic materials separated during transportation?		
3.2	Are allergenic materials labeled (e. g. color code, written label) during storage?		
3.3	If raw materials, additives, semi-finished products are stored in the same storage facility, are allergenic materials separated from non-allergenic ones?		
3.4	If raw materials, additives, semi-finished products are stored in the same storage facility, are there separate and properly designated storage areas for allergenic materials?		
3.5	Are there separate storage facilities for certain allergenic materials?		
3.6	If raw materials, additives, semi-finished products are stored in the same storage facility, are food products containing allergenic materials stored at the lowest level?		
3.7	Are opened packages with raw materials or food additives tightly closed (for example, wrapped in foil or placed in an airtight container)?		
4.	Cross-contamination		
4.1	Have potential cross-contamination sites been identified at the site?		
4.2	Is there a risk of allergen contamination during reprocessing?		
4.3	Does the production plan involve production or packaging in a sequence that reduces cross-contamination (i. e. non-allergenic products prior to allergenic ones)?		
4.4	Is there special production equipment (ladles, sieves, containers, etc.) for allergenic materials?		
4.5	Is special production equipment (ladles, sieves, containers, etc.) for allergenic materials permanently labeled (e. g. marking, color)?		
4.6	Are there special facilities/production lines for foods containing allergenic ingredients?		
4.7	Are allergenic production areas separated by physical barriers from non-allergenic production areas?		
5.	Cleaning		
5.1	If there is no special production equipment (ladles, sieves, containers, etc.) for allergenic materials, are items washed before use with non-allergenic materials?		
5.2	Are the production/packaging lines cleaned when the product changes?		
5.3	Are approved cleaning procedures in place to remove/reduce food allergen residues?		
5.4	Has cleaning been proven to be effective in removing allergen residues (e. g. with ELISA test strips)?		
5.5	Does the hygiene instruction for staff contain a recommendation to wash hands after contact with allergenic materials (i. e. raw materials, semi-finished products, products, personal food)?		
6.	Packaging and labeling		
6.1	Is information about intentionally added allergens printed on packages?		
6.2	Is information about unintentionally added allergens printed on packages?		
6.3	Is food allergen labeling checked for correctness?		
6.4	Is the food allergen information printed on packages checked for correctness when they are accepted?		
6.5	Is food allergen labeling checked when a recipe is changed (new food allergen)?		
6.6	Is compliance with food labeling requirements for allergen information checked?		
7.	Management		
7.1	Are there documented procedures/programs for the control of food allergens?		
7.2	Does the HACCP plan address food allergen hazards?		
7.3	Is the control of food allergens included in the programs of mandatory preliminary activities (PRPs)?		
7.4	Are food allergens included in the traceability system?		
7.5	If claims are related to products (e. g. no peanuts), is there a procedure for verifying such claims?		
7.6	Is the control of food allergens included in the internal audit program?		

The lack of such separation results in the absence of color coding or markings at many sites to identify equipment used when working with allergenic materials. This is addressed by question 3.2 in the checklist (Table 3).

Cross-contamination (4)

Cross-contamination is a complex area of allergen control that combines control measures applied during storage and transportation, cleaning, packaging, allergen identification and personnel activities [26]. Thus, questions 4.1 to 4.7 were included in the checklist (Table 3).

In a study [27], the highest level of compliance observed at 8 sites in terms of identifying cross-contamination areas was observed at all BRC and IFS certified sites and at one ISO 22000 certified site. However, the implementation of a food safety management system that complies with ISO 22000, or is based solely on the principles of HACCP, does not require an accurate analysis of processes in terms of allergen cross-contamination, which may also be due to training gaps in the control of food allergens.

Cleaning (5)

Washing and disinfection are considered effective methods to reduce or even eliminate residual allergens from the surface of equipment and vessels [17,22]. The results of the study [27] showed that more than half of the sites studied had some problems related to washing validation or verification. Therefore, questions 5.1 to 5.5 were included in the checklist (Table 3).

Regarding the washing, it is necessary to introduce reliable methods for verifying the reduction/elimination of allergens based on ELISA, PCR or other available methods and pay more attention to the correct planning of food production (i. e. separation, for example, the production of products with allergens after allergen-free products).

Packaging and labeling (6)

The presence of undeclared food allergens in ingredients and products is a critical food safety issue at all levels of the food supply chain requiring strict and robust food safety management strategies [29].

The high level of compliance with claimed allergen information for consumers (checklist question 6.1) (Table 3) is a result of the mandatory nature of this requirement, as it is prescribed in CU TR 022/2011 on providing food information to consumers, and also due to the ease of identifying allergens in the components of the finished product (declared allergens). In the case of unintentionally introduced allergens, this is more ambiguous, since their presence is the result of cross-contamination [18]. In addition, undeclared allergens in the Russian Federation are subjected to hazard analysis mainly at enterprises that implement a food safety management system in accordance with BRC and IFS standards. At enterprises that have implemented only the principles of HACCP, hidden allergens are usually not considered as a serious risk to food safety [12,28].

A study [30] found that in 2016–2019, among 435 product recalls related to food allergens, incorrect labeling (including "not stated on the label", "wrong advice about the allergen", "wrong label", "unintentional presence", "labelling error" and "unintentionally introduced or undeclared sulfites") was the cause in 54% of the total recalls; improper packaging was the cause in 19% of the total recalls; food allergen contamination was the cause in 14% of the total recalls; lack of labeling in English (allergen(s) not mentioned on the label in English) was the cause in 8% of the total recalls; incorrectly added ingredient was the cause in 2% of the total recalls; and unknown reasons were the cause in 3% of the total recalls.

For this reason, questions 6.1 to 6.6 were included in the checklist (Table 3).

Management (7)

Despite the relatively wide availability of literature describing the requirements for allergen control in food production, the results of the study [27] showed that gaps in allergen control were identified in almost half of the enterprises studied. For this reason, issues related to food allergens have only partially been included in the various elements of the food safety management system. Not including allergen control in elements of the food safety management system such as the HACCP plan, PRP, traceability, and internal audits at many sites studied is a sign of limited allergen control, and in some cases, no control at all. In this regard, questions 7.1 to 7.6 were included in the checklist (Table 3).

As a result of employee surveys at the enterprise and direct on-site observation using the developed checklist, noncompliance was identified in the work of the food safety management system implemented at the enterprise in the field of allergen control. It was determined that not all employees of the enterprise were trained in the control of food allergens. The instruction for visitors did not contain information about the risk of allergens and measures for their control. There is a risk of cross-contamination for allergen-free products when produced on the same line as allergen-containing products. There is no confirmation of the washing effectiveness in terms of the allergen residues presence. These results largely duplicate the results obtained [27], according to which only at 4 enterprises the staff received written information that it is forbidden to bring products containing allergens to the enterprise. Due to lack of funds or lack of space, half of the surveyed sites did not implement practices to prevent cross-contamination. More than half of the enterprises studied had problems with validation or verification of the washing effectiveness. Thus, it can be concluded that most enterprises have common problems in the development of procedures for allergen control. They may be avoided if there are resources and specific requirements for the structure of allergen control programs and the activities that this program includes.

Procedure development for allergen control in the production of meat products

As a part of the activities to reduce and eliminate the risk of allergens presence in the finished products at the selected enterprise, it was decided to expand the existing food safety management system.

All 11 interviewed employees of the enterprise are aware of the risk to consumer health when using products with allergens. However, only members of the food safety team (7 people) were trained in the control of food allergens.

The likelihood of cross-contamination with allergens was then assessed at each stage of the food production process, from the input control of raw materials to the sale of the finished product. In this case, the physical form of the allergens used must be assessed, for example, liquid and powder have a different risk of cross-contamination. So, milk powder during weighing may get into products through the ventilation system or from personnel clothing, while when adding liquid milk, this risk is lower if certain measures are observed (isolation by physical barriers, distance between products).

In cases where risk of contamination was identified (during the production on the same line of products that do not include allergenic components and allergen-containing products), measures were taken to reduce the unintentional transfer of allergens into the product. For this purpose, the principles of Good Manufacturing Practice (GMP) have been successfully applied within the organization of the production process. To ensure food safety, GMP requires all personnel to maintain strict discipline. Key aspects of allergen control in the production of meat products are shown in Figure 1.

Since the manufacturer is obliged to know about the presence of allergens in all raw materials used, which is achieved during work with the supplier and due to the input control of the transport documents for raw materials, all suppliers were requested to provide information on the content of food allergens in raw materials in the form of:

a) main ingredients indicated in the composition (for example, soy vegetable protein in the composition of a complex food additive);
b) auxiliary ingredients (e. g. food additive derived from an allergenic source, for example wheat amylase);
c) undeclared ingredients introduced due to industrial cross-contamination with allergens.

Suppliers of raw materials have been properly trained and aware of the risks that may result from contamination of products with allergens and provide relevant information. All ingredients are fully described on the label and in the specifications for raw materials, since the use of generalized names, such as, for example, "vegetable oils and fats", is unacceptable.

After the input control, when placed in the manufacturer's warehouses, raw materials containing allergens were identified, and separate storage of such ingredients was also provided.

The only approach to completely avoid allergen cross-contamination during the manufacturing process is to use separate manufacturing sites. However, this was not possible at the selected enterprise. In this regard, measures were taken to separate products that contain allergens from those that do not contain allergens:

— separation of production into different areas; establishing physical barriers between production lines;
— provision of dedicated equipment, inventory and containers;

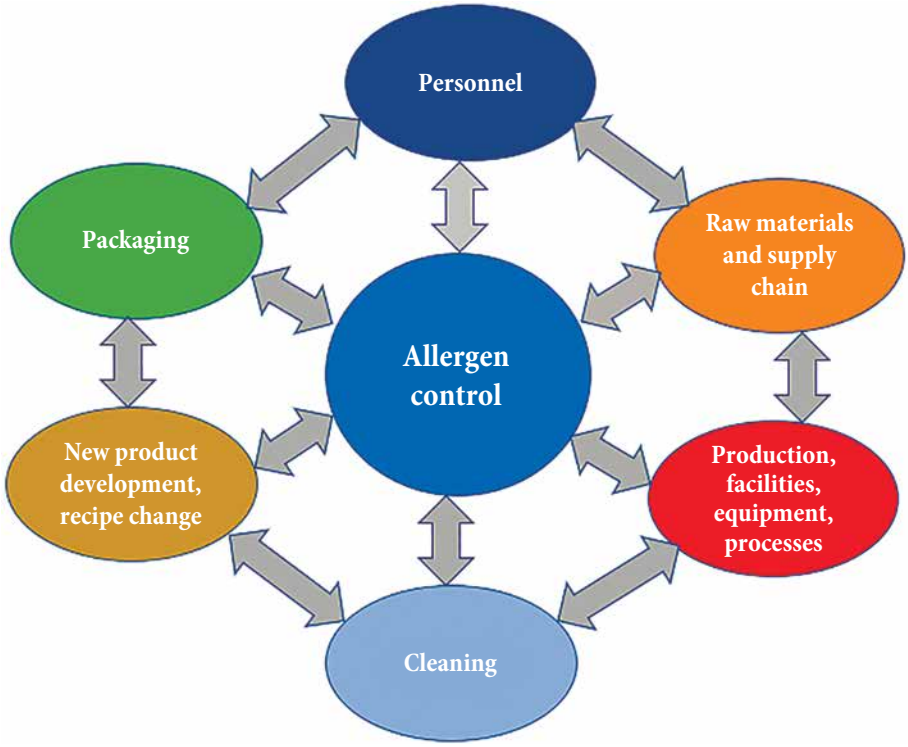

Figure 1. Key areas to consider when establishing the allergen control system (adapted from [31])

— minimization of unnecessary movement of materials; appropriate planning of production cycles, including cleaning of equipment between production cycles;
— organization of a separate air supply, where it is possible.

At the stage of input control of the main raw materials and auxiliary materials, their compliance with regulatory and technical documentation, including information on the presence of allergens, was verified. Responsible employees were trained in allergen awareness and control in accordance with their responsibilities. Transport documents were controlled; the incoming raw materials were identified for compliance with the information and visually assessed. Next, clear labeling was carried out, which indicated whether it is a potential allergen (factories may use color coding or other means to identify allergenic ingredients), and there was a separation of incoming raw materials batches. At the stage of production planning, storage and production areas of the main raw materials and auxiliary materials with allergens and free from them were separated. Areas for the storage of allergens were prepared and allocated. Special shipping containers identified by color coding were purchased and used. Allergenic raw materials are placed in a dedicated and marked area of the warehouse, separate from raw materials that do not contain allergens; physical barriers are used. Instructions on the prevention of cross-contamination have been developed and distributed in appropriate sites. When transporting allergenic raw materials from the warehouse to the spice preparation site, special marked closed containers are used. Allergen, finished product and waste routes are separated over time (space) to prevent cross-contamination. After transportation, the premises are cleaned along the route and the transport equipment is sanitized. When storing and using allergens, racks, scales for weighing, inventory (ladles, tanks, bags), storage areas for cleaning equipment and the cleaning equipment itself are marked. Special clothing is used for the personnel and control over the timely shift is carried out. The operation of the exhaust system is controlled. In the production of meat products, it is planned to sequence the production of allergenic products after those free from allergens. After the end of the production process, a thorough washing of equipment and inventory is carried out. It is necessary to draw up sanitization schedules and instructions, control the quality of equipment washing, separate instruments, develop rules for cleaning up spilled substances and unmounting equipment during washing. It is also necessary to carry out identical measures and controls when packaging products with allergens and free from them. All allergenic ingredients are declared on the label; product labeling is carried out in accordance with the requirements of CU TR 022/2011 regarding the indication of allergen contents. Control over the recycling of products and the disposal of food waste is carried out.

The developed Procedure for Allergen Control in the production of meat products complements and expands the previous Allergen Control Program developed and implemented at the enterprise by including additional control points, in particular, confirmation of the cleaning program effectiveness by commercial ELISA test kits, and control over the product recycling and disposal of food waste.

Meat processing enterprises are heavily responsible both for compliance with the requirements of the law and for the health of consumers. Therefore, in order to minimize the unintending transfer of allergens into finished products, it is necessary to develop, implement and maintain an allergen control program, analyze the causes of allergenic products sales and organize resource management.

Conclusion

During this work, the products of the selected enterprise were examined for the presence of gluten, soy, mustard and peanuts. Of the 15 samples studied, 2 samples contained soy, 3 samples contained gluten, 6 samples contained mustard, 1 sample contained peanuts, and 4 samples contained 2 to 3 allergenic ingredients at the same time. These results confirmed the need to develop and implement an allergen control procedure at the selected enterprise. Since the enterprise is certified in accordance with the requirements of the ISO 22000:2018 "Food safety management systems — Requirements for any organization in the food chain" and the FSSC 22000 certification scheme, an allergen control program has been developed and implemented as a part of the implemented food safety management system. However, its effectiveness is rather low, which was shown by employee survey at the enterprise, as well as by allergens found in finished products. Actions to improve the allergen control programs at the surveyed enterprise include activities such as increasing the proportion of staff involved in training on the control of food allergens, creating guidelines to define good practice for allergens, especially with regard to avoiding cross-contamination. These actions also include improving cleaning procedures that use proven cleaning methods and test the effectiveness of reducing/eliminating food allergens. It is planned that washing programs will be supported and validated by precise methods, such as commercial ELISA test kits, instead of non-specific testing methods that are based on total protein determination and visual inspection. The procedure for allergen control in the production of meat products developed based on the results of the research will be tested at the selected enterprise in 3 months. Previously tested products will be sampled and assessed for allergens. Based on the results of the repeated study, a conclusion will be made about the effectiveness/ineffectiveness of the proposed measures.

REFERENCES

1. Spotz, K. (2018). Allergens: An enhanced focus. *Journal of AOAC International*, 101(1), 56–59. https://doi.org/10.5740/jaoacint.17–0435
2. Martin, H. (2021). Review of celiac disease: Clinical manifestations, diagnosis, and management. *Physician Assistant Clinics*, 6(4), 569–580. https://doi.org/10.1016/j.cpha.2021.06.001
3. Solymosi, D., Sárdy, M., Pónyai, G. (2020). Interdisciplinary significance of food-related adverse reactions in adulthood. *Nutrients*, 12(12), Article 3725. https://doi.org/10.3390/nu12123725
4. Du Toit, G., Katz, Y., Sasieni, P., Mesher, D., Maleki, S.J., Fisher, H.R. et al. (2008). Early consumption of peanuts in infancy is associated with a low prevalence of peanut allergy. *Journal of Allergy and Clinical Immunology*, 122(5), 984–991. https://doi.org/10.1016/j.jaci.2008.08.039
5. Sicherer, S.H., Sampson, H.A. (2010). Food allergy. *Journal of Allergy and Clinical Immunology*, 125(2, Suppl. 2), S116-S125. https://doi.org/10.1016/j.jaci.2009.08.028
6. Maleki, S.J., Chung, S.-Y., Champagne, E., T., Raufman, J.-P. (2000). The effects of roasting on the allergenic properties of peanut proteins. *Journal of Allergy and Clinical Immunology*, 106(4), 763–768. https://doi.org/10.1067/mai.2000.109620
7. Remington, B. C., Westerhout, J., Meima, M. Y., Blom, W. M., Kruizinga, A. G., Wheeler, M. W. et al. (2020). Updated population minimal eliciting dose distributions for use in risk assessment of 14 priority food allergens. *Food and Chemical Toxicology*, 139, Article 111259. https://doi.org/10.1016/j.fct.2020.111259
8. Holzhauser, T., Johnson, P., Hindley, J. P., O'Connor, G., Chan, C.-H., Costa, J. et al. (2020). Are current analytical methods suitable to verify VITAL® 2.0/3.0 allergen reference doses for EU allergens in foods? *Food and Chemical Toxicology*, 145, Article 111709. https://doi.org/10.1016/j.fct.2020.111709
9. Blom, W. M., van Os-Medendorp, H., Bijlsma, S., van Dijk, A., Kruizinga, A. G., Rubingh, C. et al. (2020). Allergen risk assessment: Food intake levels of the general population represent those of food allergic patients. *Food and Chemical Toxicology*, 146, Article 111781. https://doi.org/10.1016/j.fct.2020.111781
10. Houben, G. F., Baumert, J. L., Blom, W. M., Kruizinga, A. G., Meima, M. Y., Remington, B. C. et al (2020). Full range of population Eliciting Dose values for 14 priority allergenic foods and recommendations for use in risk characterization. *Food and Chemical Toxicology*, 146, Article 111831. https://doi.org/10.1016/j.fct.2020.111831
11. VITAL (2022). Further information for VITAL Online Users on the update from version 2.3.30 (previous version) to version 3.0.0 (updated version). Retrieved from https://vital.allergenbureau.net/wp-content/uploads/2021/04/further_information_for_vital_online_users_on_the_update_from_version_2330_previous_version_to_version_300_updated_version.pdf Accessed August 15, 2022
12. Gendel, S.M., Khan, N., Yajnik, M. (2016). A survey of food allergen control practices in the U.S. food industry. *Journal of Food Protection,* 76(2), 302–306. https://doi.org/10.4315/0362–028X.JFP-12–373
13. Dupuis, R., Meisel, Z., Grande, D., Strupp, E., Kounaves, S., Graves, A. et al. (2016). Food allergy management among restaurant workers in a large U.S. city. *Food Control,* 63, 147–157. https://doi.org/10.1016/j.foodcont.2015.11.026
14. Mortimore, S., Wallace, C. (2013). HACCP. A Practical Approach. Third Edition. Springer: New York, Heidelberg, Dordrecht, London, 2013. https://doi.org/10.1007/978–1–4614–5028–3
15. Cianferoni, A., Spergel, J. M. (2009). Food allergy: review, classification and diagnosis. *Allergology International*, 58(4), 457–466. https://doi.org/10.2332/allergolint.09-RAI-0138
16. Crevel, R.W.R., Taylor S. L., Pfaff, S., Alldrick, A. (2013). Managing Food Allergens: Case Histories and How They Were Handled. Chapter in a book: Risk Management for Food Allergy. Academic Press, Oxford, Waltham. https://doi.org/10.1016/B978–0–12–381988–8.00009–9
17. Pachołek, B., Sady, S., Kupińska-Adamczyk, E. (2018). Management of food allergens in the food industry. *Journal of Agribusiness and Rural Development*, 47(1), 73–80. https://doi.org/10.17306/J.JARD.2018.00388
18. Röder, M., Weber, W. (2016). Allergen management in the food industry. *Gesundheitsschutz,* 59(7), 900–907. https://doi.org/10.1007/s00103–016–2367-y (In German)
19. Stein, K. (2015). Effective allergen management practices to reduce allergens in food. Chapter in a book: Handbook of Food Allergen Detection and Control. Woodhead Publishing, UK. https://doi.org/10.1533/9781782420217.1.103
20. Taylor, S.L., Hefle, S.L. (2005). Allergen management. *Food Technology*, 59(2), 40–43.
21. Muñoz-Furlong, A., Sampson, H.A. (2008). The Management of Food Allergy. Chapter in a book: Food Allergy: Adverse Reactions to Foods and Food Additives. Blackwell Publishing Ltd, Massachusetts. https://doi.org/10.1002/9781444300062.ch36
22. Jackson, L.S., Al-Taher, F.M., Moorman M., DeVries J.W., Tippett R., Swanson K. M.J. et al. (2008). Cleaning and other control and validation strategies to prevent allergen cross-contact in food-processing operation. *Journal of Food Protection*, 71(2), 445–458. https://doi.org/10.4315/0362–028X–71.2.445
23. Kryuchenko, E.V., Zamula, V.S., Kuzlyakina, Yu.A., Chernukha I.M. (2020). Overview of modern methods for detecting allergens in food. *Vsyo o Myase*, 5S, 169–172. https://doi.org/10.21323/2071–2499–2020–5S–169–172 (In Russian)
24. Chernukha, I.M., Kryuchenko, E.V., Kuzlyakina, Yu.A., Zamula, V.S. (2022). *Qualimetric assessment of methods for the determination of allergens in meat products*. IOP Conference Series: Earth and Environmental Science, 1052(1), Article 012125. https://doi.org/10.1088/1755–1315/1052/1/012125
25. Dupuis, R., Meisel, Z., Grande, D., Strupp, E., Kounaves, S., Graves, A. et al. (2016). Food allergy management among restaurant workers in a large U.S. city. *Food Control*, 63, 147–157. https://doi.org/10.1016/j.foodcont.2015.11.026
26. Crevel, R., Cochrane, S. (2014). Allergens. In: Food Safety Management. A Practical Guide 529 for the Food Industry [Ed. by Motarjemi, Y. and Lelieveld, H.], Academic Press, London, 2014.
27. Dzwolak, W. (2017). Assessment of food allergen management in small food facilities. *Food Control*, 73, 323–331. https://doi.org/10.1016/j.foodcont.2016.08.019
28. Dzwolak, W. (2022). Allergen cross-contact control plan supporting the implementation of food allergen management (FAM) in small food businesses. *Food Control*, 135, Article 108777. https://doi.org/10.1016/j.foodcont.2021.108777
29. Koeberl, M., Clarke, D., Allen, K. J., Fleming, F., Katzer, L., Alice, L. N. et al. (2018). Food allergen management in Australia. *Journal of AOAC International*, 101(1), 60–69. https://doi.org/10.5740/jaoacint.17-0386
30. Jia, L., Evans, S. (2021). Improving food allergen management in food manufacturing: An incentive-based approach. *Food Control*, 129, Article 108246. https://doi.org/10.1016/j.foodcont.2021.108246
31. Yurchak, Z.A., Kuznetsova, O.A., Starchikov, A.D. (2015). Prevention and minimization of production food allergens. *Vsyo o Myase*, 5, 19-21. (In Russian)

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