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THE RISK ANALYSIS OF METALLIC FOREIGN BODIES IN FOOD PRODUCTS

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ABSTRACT

The aim of this study was to elaborate and validate the risk analysis procedure of metallic foreign bodies' occurrence in food. The enterprise selected for the study was a company processing dry foods. The procedure was based on Failure Mode and Effect Analysis. The implementation of the procedure allowed to find two production stages at risk of metallic particles' contamination, which were: reception of raw materials into the plant and packaging of finished products. The group of products at the highest risk of contamination was: buckwheat, prunes, brown cane sugar, brown flax and "tropical" muesli. The methods of risk management and the risk communication were established. The procedure may be a convenient tool for better food safety assurance and can be used in many food processing enterprises where the risk of metallic foreign bodies' occurrence in finished products is high.

PRACTICAL APPLICATIONS

Metallic foreign bodies are common in some kinds of food. Occurrence of metallic foreign bodies significantly decreases food safety. The procedure elaborated and validated in this study is based on Failure Mode and Effect Analysis. The implementation of the procedure allows to find production stages at risk of metallic particles' contamination. The procedure may be a convenient tool for better food safety assurance and can be used in many food processing enterprises where the risk of metallic foreign bodies' occurrence in finished products is high.

INTRODUCTION

The presence of foreign bodies in food is one of the main problems in food industry and the number of notifications filed to the Rapid Alert System for Food and Feed (RASFF) confirms the importance of the problem (European Commission 2015). In many countries the occurrence of foreign bodies is the most common cause of detected defects in foods. The range of contaminants is very diverse and depends on the specific product. Usually, the term "foreign body" refers to any unwanted objects in food, even if it comes from the same product (i.e. meat products containing bones, fruit products containing seeds) (Graves *et al.* 1998). Foreign materials in foods (glass, plastic, metal, etc.) are the biggest source of customer complaints received by many food manufacturers, retailers and enforcement authorities (Edwards and Stringer 2007).

Foreign bodies are extremely undesirable elements in food, some of which may cause serious health hazards. Depending on the type, size and structure foreign bodies may cause larynx and oral cavity injuries, teeth damage, choking, suffocation, damage to the tissues of the digestive tract, internal bleeding, throat discomfort, dysphagia, odynophagia, drooling and regurgitation, as well as death (Waltzman 2006; European Commission 2015). Intake of the most of foreign bodies passes through the gastrointestinal tract without surgical assistance (80–90% of cases).

Others need to be removed with an endoscope or some other surgical intervention. It is estimated that 1–5% of ingested foreign bodies can be linked to serious health consequences (Olsen 1998). Most injuries occur after ingestion of slender, pointed or sharp metal objects. Metallic objects pose a great risk of perforation of the gastrointestinal tract tissue and require surgical removal. Moreover, these metal fragments can also damage valuable machinery and shut down production lines leading to significant financial losses.

To eliminate foreign bodies contamination risk in food products adequate control methods should be applied, which choice depend on the type of risk (Edwards and Stringer 2007). Devices used for the control and elimination of metallic foreign bodies are metal detectors. These devices enable detection of metallic particles inside the products (Graves *et al.* 1998; He and Yoshizawa 2002). Other, very sophisticated detection method may be pulsed terahertz spectroscopy (Jőrdens and Koch 2008). However, it is expensive and difficult to use in production line.

In food processing plant appropriate methods and procedures preventing physical contamination of the product should be used. Physical hazard must be included in the Hazard Analysis and Critical Control Point (HACCP) system (Codex Alimentarius 2003) but not all enterprises perform the necessary due diligence. Not every enterprise has a device for the detection and elimination of foreign bodies. However, due to the high risk of loss of food security caused by the occurrence of metallic foreign bodies in foods, it is important to carry out risk analysis.

Risk analysis is a process consisting of three components: risk assessment, risk management and risk communication (Schlundt 1999), and Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 defines the concepts of risk analysis. The approach to food risk analysis focuses primarily on the identification of potential risks and their assessment (Kleter and Kuiper 2010). In food industry risk management decisions can influence all other hygiene initiatives. Information generated as part of the risk management process can be used in the design of HACCP systems. Some of the risk assessment information can be used as part of the input into the hazard analysis step of HACCP (Schlundt 1999). However, there are the hazards that are most commonly omitted during the implementation of the HACCP system. Very often they are taken into account, but usually not in the full extent.

Metallic foreign bodies can occur in foods as a result of contamination of raw materials and their improper quality control during reception into the plant, improperly conducted production processes, employees' negligence, inadequate state of machines and equipment. A large number of foreign bodies occur in raw materials and intermediates. Their presence is commonly associated with improperly carried processing, screening, cleaning, and sorting processes. In addition, improper technical condition of machinery can lead to a lack of effectiveness of these processes. Foreign bodies can also get to the product as a result of improper personnel practices, such as lack of protective clothing, wearing jewelry, careless handling of metallic elements or lack of order in workplaces. Metal fragments can often be inadvertently and unintentionally introduced into food products. This could be a damaged sieve, with pieces of a broken sieve entering the food product. At other times pieces of metallic particles from baking trays, scraped from the surface by mechanical contact, may enter the food product (Edwards and Stringer 2007).

Several methods may be used to determine and improve the value of a product or process by identifying how a ***product*** or ***process*** might ***fail*** and what ***effects*** might occur as the outcome. The examples of these methods are: Value Analysis, Lean Management, Poka-yoke (mistake-proofing) or Failure Mode and Effects Analysis (FMEA) and others (Agbejule *et al.* 2004; Grout and Toussaint 2010; Karstoft and Tarp 2011). However, in comparison to others, FMEA assesses also the criticality of the failure modes on the product or process functionality. It provides basic information for more reliable prediction of the contamination occurrence, and product or process design (Teng and Ho 1996). FMEA enables analysis of the kinds of possible errors and their effects. It is a systematic process meant to analyze reliability, to improve operational performance of the production cycles and to reduce the overall risk level. Therefore, FMEA seems to be the right choice for the risk assessment and management. Because the occurrence of metallic foreign bodies in food may seriously increases the risk of food safety loss, the aim of this study was to elaborate and validate the risk analysis procedure of metallic foreign bodies' detection in food, on the example of dry food processing enterprise, by using FMEA.

MATERIALS AND METHODS

The study consisted of three main steps and each of them consisted of several tasks. The first one was the development of the procedure of risk analysis. The next one was the research carried out in a selected food processing plant, which involved the identification and recording of metallic foreign bodies in the finished products In the third step, the obtained results were used to validate the procedure including establishing methods of risk management and risk communication. The scheme of the study was given at Fig. 1.

The food processing enterprise selected for this study was located in central part of Poland. The production range of enterprise included packaging cereal products (flour, groats, cereal, bran, rice), dried fruits (apricots, figs, dates, prunes, raisins), dried vegetables (tomatoes), legumes (peas, beans, chickpeas, soybeans), nuts (walnuts, cashew nuts, brazil

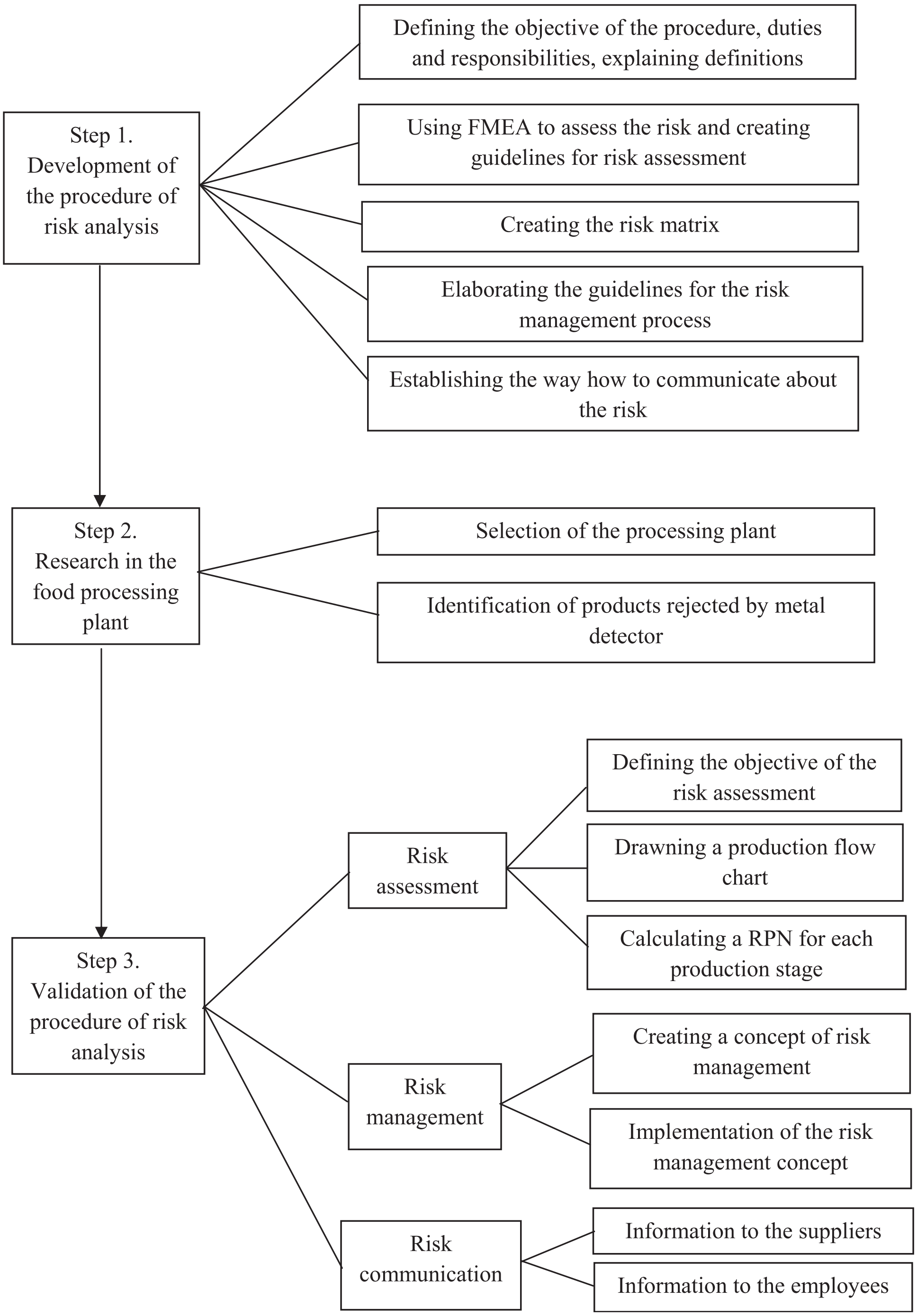

FIG. 1. THE SCHEME INDICATING MAIN STEPS AND TASKS OF THE STUDY
FMEA, Failure Mode and Effect Analysis; RPN, Risk Priority Number.

nuts) and sugar and confectionery products (jellies, jelly). The choice of the enterprise was associated with RASFF reports indicating that foreign bodies are most common in the dry foods of plant origin, such as cereals, fruits, vegetables and nuts (European Commission 2015). The plant was a medium size. 50 workers were employed.

A Cassel Metal Shark metal detector (Casel Messtechnik GmbH, Germany) was installed in the enterprise to detect metallic foreign bodies. Performance of the detector enabled scans of 40 products in 60 s. The sensitivity was high enough to detect ferrous materials larger than 1.5 mm, non-ferrous metallic particles greater than 2.0 mm and stainless steel

TABLE 1. THE GUIDELINES HAW TO ESTIMATE THE COMPONENTS OF FMEA: O, OCCURRENCE, D, DETECTION, S, SEVERITY OF METALLIC FOREIGN BODIES' CONTAMINATION

FMEA component	Level	Meaning	Value
O	Very high	Common and systematic, it is almost impossible not to find any metallic particles, which means 9–10 contaminated packages out of 100 controlled	9–10
	High	Frequent, which means 7–8 contaminated packages out of 100 controlled	7–8
	Medium	Medium, which means 5–6 contaminated packages out of 100 controlled	5–6
	Low	Rare, which means 3–4 contaminated packages out of 100 controlled	2–4
	Very low	Unlikely, which means no more than 1 contaminated packages out of 100 controlled	1
D	Very high	The possibility of metallic particles' detection is very high, the reliability of control measures is 98–100%	9–10
	High	The possibility of metallic particles' detection is high, only a few foreign bodies could remain undetected, the reliability of control measures is 90–97%	7–8
	Medium	The possibility of metallic particles' detection is medium, the reliability of control measures 60–90%	5–6
	Low	The possibility of metallic particles' detection low, the reliability of control measures 50–60%	3–4
	Very low	The possibility of metallic particles' detection is very low, the reliability of control measures less than 50%	1–2
S	Catastrophic	Possible death	10
	Critical	Serious injuries, a disease requiring surgical intervention	7–9
	Medium	Small injuries or illness	4–6
	Minimal	Consumer dissatisfaction	1–3

components greater than 2.5 mm. During one shift five workers, who were trained in the operation of the detector once every three months, operated the detector. The detector was located at the end of the production line and scanned each item of retail packages of food products. To confirm the efficiency of the detector, the specially contaminated sample was tested every hour.

FMEA was chosen for risk assessment and management. The use of FMEA scoring method allowed risks to be calculated as a Risk Priority Number (RPN) (Luning *et al.* 2002; Barends *et al.* 2012). The analysis was based on identification of the three aspects of the failure modes: occurrence (O), detection (D) and severity (S). Explanations of O, D and S parameters as well as assigned values are given in Table 1. The risk priority was calculated with the formula RPN = (O) × (D) × (S) (Leeuwen *et al.* 2009). To calculate the RPN a specially created risk assessment form was used, which was based on the work of Scipioni *et al.* (2002). It consisted of the name of the stage of the process, potential hazards, potential causes of the hazards, possible preventive actions, risk assessment (with separate columns for S, D and O), and finally the calculated RPN values with identified risk resulted from the calculation. The filled-in risk assessment form is presented as table in the "Results and Discussion" section of this article.

To determine the level of risk, an adequate, specially developed risk matrix was used. The risk matrix defined the risk depending on the obtained value of RPN. The risk levels were divided as: "very low," "low," "medium," "high" and "very high." For each of these risk levels adequate corrective actions were indicated (Fig. 2).

To assess the risk of metallic foreign bodies' contamination of food products a special procedure was elaborated. It consisted of six elements: the objective of the procedure, the extent of validity, responsibilities and duties, definitions, description of the activities, attachments. The content of the procedure is given as supplementary material to this article. The procedure was validated in the food processing enterprise selected for this research. The study was conducted from June to September 2013. It consisted of identifying and recording all metallic foreign bodies detected in the finished products assortment packed in retail package units that the metal detector rejected.

RESULTS AND DISCUSSION

During the four months of the research 862,800 products were scanned. Approximately 3,595 products were scanned during each shift. Throughout this period, metallic foreign bodies were identified in 37 finished products package units,

RPN	Risk level				
	Very low	Low	Medium	High	Very high
1-100	An audit of the packaging process recommended				
101-200	Audits of the packaging process and involved employees recommended				
201-500	Audits of packaging process and employees required, increase in frequency of additional trainings				
501-800	As above and also: increase in frequency of the detector work and sensitivity checking, issuing warnings to the relevant suppliers				
801-1000	An audit and repeated analysis of the process absolutely mandatory, increase in frequency of observation of the detection process mandatory, increase in frequency of the detector servicing mandatory, if all these fails installing additional detection devices and changing the relevant suppliers necessary				

FIG. 2. RISK MATRIX SHOWING CORRECTIVE ACTIONS AT DIFFERENT RISK LEVELS
RPN, Risk Priority Number.

but their amount in each month varied. In the first month of the study, the detector found 12 metallic particles contamination incidences, while in the second one there were only 5. Finally, 20 metallic foreign bodies incidences were found in the third and fourth month, 10 each. The items found ranged in size from 5 mm (metal balls) to 15–70 mm (wires, hair clips). Photos of these foreign bodies are presented in Fig. 3.

The most contaminated products were cereal products: 19 incidences. These were: oat flakes, black quinoa, buckwheat, oat bran, gold flax, white quinoa, brown flax, red rice, "tropical" muesli. 9 incidences were recorded for dry fruits packages. These were: raisins, dried figs, dried goji berries, prunes, dried dates. Metallic foreign bodies in different types of food products were identified with varying frequency, between one and four times throughout the 4-month period of the study. The group of products, in which metallic foreign bodies were identified every month were dried prunes from the U.S.A. and buckwheat from Poland. Products in which metallic foreign bodies were found 3 times were: Indian brown cane sugar, brown linen from Kazakhstan and "tropical muesli" which was a compound product, with approximately 50% of the raw materials (flakes) from Germany (Table 2).

After identification of metallic foreign bodies contamination degree, the risk analysis was made. Its objective was to estimate the risk concerning the occurrence of metallic foreign bodies in the products, as well as establishing methods for risk management and risk communication. In accordance with the procedure, a technological flow chart was developed. It included all of the stages of food processing and was presented in accordance with EN ISO 22000 (2005) and EN ISO 5807 (1985) (Fig. 4). The raw materials, the packaging, the entire production environment and the state of machinery were also taken in to account

During the 1st stage of the procedure, i.e. risk assessment, the following foreign bodies were identified: metal shavings, metal beads, pellets, pieces of wire, machine parts and hairclip. Estimation of the exposure to identified risks was correlated to sensitivity of the metal detector. The detector was able to detect metallic foreign bodies at size larger than 1.5 m and it was assumed that even one foreign body with such size, as well as a rough and irregular surface, would be enough to cause significant health hazard to ones consuming the contaminated foods.

During implementation of the second stage of the procedure, i.e. risk management, the data was collected and a risk assessment form was filled, taking into account the procedure guidelines. Collected results, as filled-in form of metallic foreign bodies' risk assessment, are shown in Table 3. In two particular stages of the production process, i.e. reception of raw materials in to the plant, as well as packaging into retail packages units, the risk was assessed as "medium." However, for all incoming raw materials, the risk was assessed as "high." The other stages did not pose a significant risk of the occurrence of metallic foreign objects in end products.

Based on the obtained results the raw materials with the highest risk to the safety of the final product were identified.

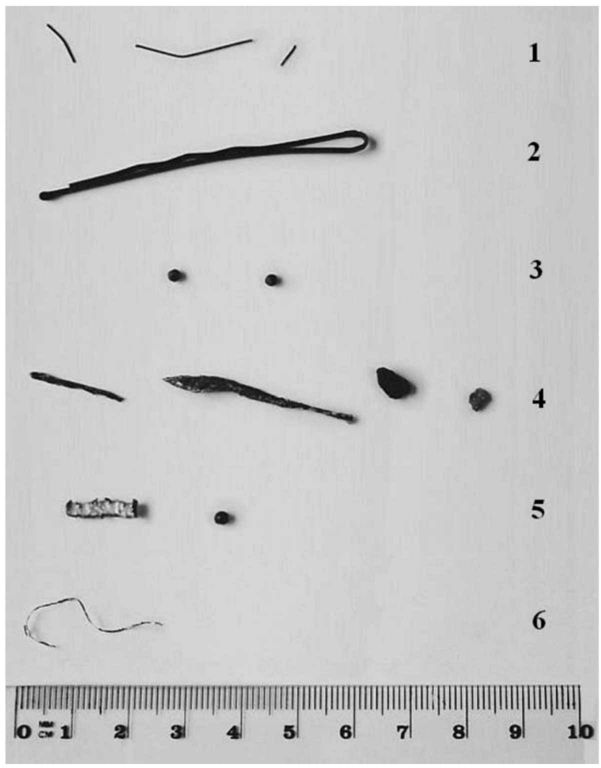

FIG. 3. EXAMPLES OF METALLIC FOREIGN BODIES DETECTED DURING THE STUDY
1, wire in brown cane sugar; 2, barrette hair in buckwheat; 3, shot in dried plums; 4, unidentified metal particles in buckwheat; 5, shot and metal particles in dried figs; 6, wire in raisins.

TABLE 2. PRODUCTS, IN WHICH METALLIC PARTICLES' CONTAMINATION WERE DETECTED DURING FOURTH MONTH OF THE STUDY

Product	Frequency of detection	Country of supplier	Country of raw material origin
Oat flakes	2	Germany	Germany
Desiccated coconut	1	The Netherlands	Sri Lanka
Raisins	2	Germany	Turkey
Figs dried	1	The Netherlands	Turkey
Dried goji berries	1	Germany	China
Dried prunes	4	U.S.A.	U.S.A.
Quinoa black	1	Germany	Peru
Dark green pumpkin seeds	2	Germany	China
Brown cane sugar	3	Germany	India
Mung beans	1	Germany	China
Buckwheat	4	Poland	Poland
Oat bran	2	Poland	Poland
Gold flax	1	The Netherlands	China
Quinoa white	2	The Netherlands	Bolivia
Brown flax	3	The Netherlands	Kazakhstan
Hazelnuts	1	Poland	Poland
Red rice	1	The Netherlands	Thailand
"Tropical muesli"	3	Germany	Composed product, flakes which were ca. 50% originated from Germany
Dried dates	1	The Netherlands	Tunisia
Dried tomatoes	1	Germany	Turkey

It was assumed that the ones, in which metallic foreign bodies were identified more than 3 times during the study period, should be categorized as "high risk." This "high risk" group of materials included: dried prunes, buckwheat, brown cane sugar, brown linen and "tropical muesli."

During implementation of the third stage of the procedure, i.e. risk communication, written information was prepared and given to the suppliers of those raw materials regarded as "high risk." These letters included a description of the product, in which the foreign body was found, as well as the batch number and date of delivery. Photos of the identified foreign bodies were also included. Such suppliers were obliged to respond to the letter regarding the identified contamination within 5 days. They were informed that if their raw materials were categorized as "high risk" again, their cooperation with the production enterprise would cease.

When it comes to risk communication to the production employees, a meeting was organized and the workers were informed of the results of the risk assessment part of the procedure. They were requested to pay special attention during raw materials reception into the plant and quality control as well as packaging of the "high risk" products.

In scientific literature concerning food quality and control, there are scant publications discussing the methodology for risk analysis of food regarding foreign bodies, even though the subject is very important due to the possible health problems (Rimell *et al.* 1995; Waltzman 2006; Cutajar *et al.* 2011). The procedure of metallic foreign body detection in production plant, with the use of a metal detector, is crucial for overall food safety. The assessment and removal of metallic foreign bodies' contamination is now standard practice in the food processing industry. Many food producers rank metal detection as critical control point in their HACCP plans (Nagelschmidt *et al.* 2008).

During the conducted research, it was shown that cereals, as well as certain dried fruit products, are linked to the biggest risk of contamination. According to Edwards and Stinger (2007), various complaints concerning all types of foreign bodies had been noted with varying frequency, when it comes to specific food products. According to their compiled data, the food products associated with incidents of foreign bodies contamination were mainly vegetables and vegetable products (20.2% incidences), with cereals and cereal products coming in as the second most common (12.8% incidences). Similar information can be found in the reports filed to the RASFF (European Commission 2015). These show that vegetable products, fruit products, cereals, bakery products and nuts were the most contaminated; however RASFF reports present the information without distinguishing between the types of foreign bodies. Edwards and Stringer (2007) showed also that metallic particles contamination happened in 170 cases out of the 2,347 contamination incidences found in food products (glass, metal, plastic and others), they discovered in their research, which was 7.2%. In their compilation of such data, which includes 14 categories, metals appear at the fourth position, directly behind glass, plastics and animal-related contamination.

The conducted risk analysis showed that cereal products and dried fruit products were linked to the highest risk. The

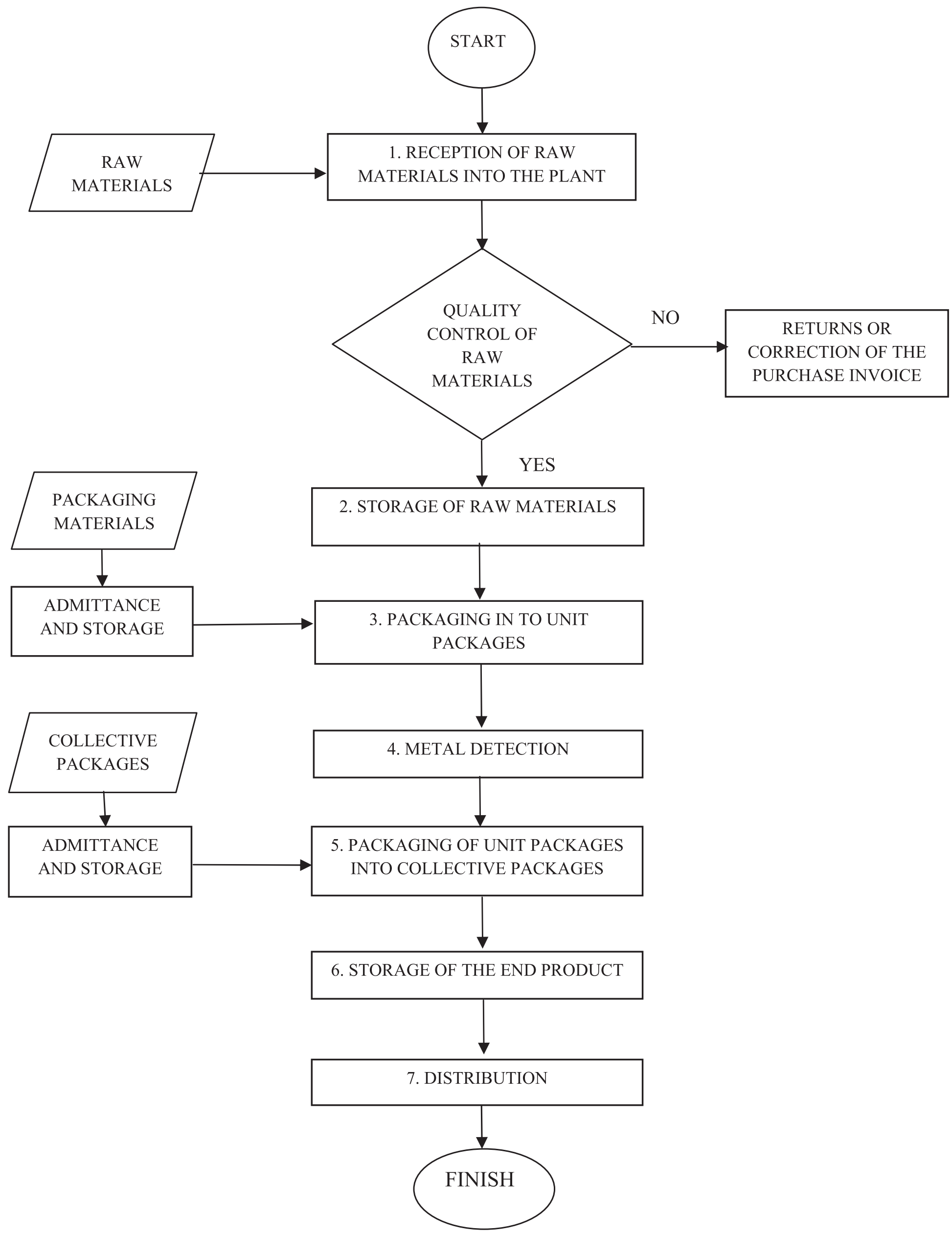

FIG. 4. THE TECHNOLOGICAL FLOW CHART OF THE MANUFACTURING PROCESS DRAWN IN ACCORDANCE WITH EN ISO 22000 AND EN ISO 5807

stage of reception and quality control of raw materials was shown to be the stage of medium risk of foreign body occurrence. However, this stage was performed prior to the stage of metal detection. It suggested that additional metal detector should be installed and its location should be at the start of the production line. This would allow to remove any foreign bodies that might occur in the raw materials. The detector currently in use, which was located at the end of the production line, was supposed to eliminate foreign bodies resulting from food processing, specifically from repacking, which is shown to be linked to a medium risk of foreign body occurrence.

To minimize the risk, it is also necessary to take preventive measures associated with operating the metal detector, i.e. to monitor the effectiveness of the metal detector, to service the metal detector in accordance with the technical guidelines, to conduct internal and external trainings of production staff in accordance with the approved schedule and also if needed. Moreover, it was established that the processing staff should be controlled in terms of compliance with the procedures

TABLE 3. THE FILLED-IN FORM OF METALLIC FOREIGN BODIES' RISK ASSESSMENT

Stage of the production process	Hazards	The causes of the hazards	Preventive actions	Assessment O	D	S	RPN	Risk
Raw materials	– metallic particles arising from the equipment used by the producer or supplier and incorrectly implemented procedures – metallic particles introduced by employees	– lack of audits performed in the producers or suppliers enterprises – incorrect technical conditions in the producers or suppliers enterprises – incorrect hygiene of employees	– ordering the raw materials only from well-known controlled producers or suppliers	8	9	9	648	high
Reception of raw materials in to the plant	– metallic particles in raw materials – metallic particles introduced by employees	– negligence of employees – incorrect hygiene of employees – incorrect protective clothes	– employees trainings, – wearing the correct protective clothes, – ordering the raw materials only from well-known suppliers	8	5	9	360	medium
Storage of raw materials	– metallic particles introduced by employees, – metallic particles in the store section	– incorrect hygiene of employees, – incorrect technical condition of the store section	– employees trainings, – maintaining a correct technical condition of the equipment and environment of the store section	1	3	3	9	very low
Packaging into retail package units	– metallic particles present in raw materials, but not detected during the reception stage, – metallic particles arising from the equipment or devices – metallic particles introduced by employees	– inadequate controlling during raw materials reception stage, – incorrect technical condition equipment, – not enough trainings, – incorrect protective clothes, – incorrect technical condition of the packaging section environment	– ordering the raw materials only from well-known suppliers, – strict controlling during admittance, – maintaining a good technical condition of the equipment, – employees trainings, – maintaining a good technical condition of the packaging section environment	5	6	9	216	medium
Metal detection	metallic particles present in raw materials or arising from production equipment	– detector malfunction – negligence of employees	– regular servicing and/or maintenance of metal detector – employees trainings	10	2	8	160	low
Packaging into collective packages	foreign bodies introduced by employees	– negligence of employees – incorrect hygiene of employees	– employees trainings – wearing correct protective clothes	1	7	6	42	very low

TABLE 3. CONTINUED

Stage of the production process	Hazards	The causes of the hazards	Preventive actions	Assessment O	D	S	RPN	Risk
Storage of finished product	metallic particles introduced by employees	– negligence of employees – incorrect hygiene of employees	– employees trainings – wearing the correct protective clothes	1	7	6	42	very low
Distribution to retail	metallic elements or pieces of transporting trucks loading chamber	– incorrect technical state of transporting trucks loading chamber	– trainings for drivers – careful control of transporting trucks during loading	1	7	1	7	very low
Production environment	metallic particles introduced to the processing line by employees	– not enough trainings – lack of employees supervision	– introducing a strict training schedule – employees supervision	1	5	8	40	very low
Machinery	malfunctions	– not enough or irregular servicing of equipment	– introducing a new schedule of machinery regular servicing and/or maintenance	4	2	8	64	very low

O, occurrence, D, detection, S, severity, RPN, risk priority number.

and the hygienic measures and that the correctness of filling registers should be checked. In addition, it was agreed that a review of the plan preventing contamination would be performed at least every 6 months. There should also be a continuous process of raising awareness among employees how important it is the compliance with the adopted and implemented procedures.

Additionally, it is supposed that risk communication acquires a much bigger significance as a tool for effective risk management. Frewer (2004) and Hampel (2006) advised to inform the public opinion on the topic of any threats identified, as a crucial part of the communication process.

CONCLUSION

The results obtained in this study showed that elaborated procedure of risk analysis concerning metallic foreign bodies' contamination of food products worked properly. Implementation of the procedure allowed to find two production stages at a risk of metallic foreign bodies' contamination. These were reception of raw materials into the plant and packaging of finished products. Additionally, a group of raw materials at the highest risk of metallic particles' occurrence was identified, which were: buckwheat, prunes, raw cane sugar, brown flax and "tropical muesli." The methods of risk management were established and a risk communication strategy was created. The procedure may be a convenient tool for better food safety assurance and can be used in many food processing enterprises where the risk of metallic foreign bodies' occurrence in finished products is high.

Nomenclature

HACCP	Hazard Analysis and Critical Control Point
FMEA	FailureMode and Effect Analysis
RASFF	Rapid Alert System for Food and Feed
RPN	Risk Priority Number

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