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RISK ASSOCIATED WITH FOREIGN BODIES IN FOOD IN THE CZECH REPUBLIC

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ABSTRACT
The food safety is the main concern of the politicians and inhabitants in whole Europe. According the currently valid legislation the food should be save. The food should be safe from all aspects: chemical, microbiological, physical and radiological. Physical hazard/foreign body in food is perceived by public as something to be very simply solved by food business operators. However, foreign body is the biggest single source of customer complaints received by food business operators, retailers and enforcement authorities. In even the best-managed processes, the accidental presence of unwanted items could occasionally occur. Foreign body in food is believed to be a matter of concern to all food business operators. However, the level of inclusion of physical hazards by Czech food business operators in the hazard analysis is still low. Consumers experience with foreign bodies in food or even health problems caused by foreign bodies is continuing high level. Consumer complaints regarding foreign bodies reported from food products should be an important question for the food industry that should implement corrective actions to prevent such unwanted events.

Keywords: physical hazards; foreign bodies; hazard analysis; health risk; HACCP

INTRODUCTION
People expect, that food they eat is hygienically and health safe. Mass consumption of food is the cause of a high risk to human health, but only in the case of harmful food. Protection of human, animal and plant health is one of the main economic priorities of each country. The political objective of the European Union is therefore to ensure that European Union citizens have access to safe and nutritious foods, so it must meet strict safety standards. In ensuring food safety, it is necessary to consider all aspects of the food production chain, because each subject can have a potential impact on food safety **(Nagyová et al., 2019)**. The issue of food safety and quality is very important in view of the growing globalization of economy, whose mission is to encourage food businesses to improve the production process and competitiveness **(Nagyová et al., 2018)**.

The aim of this study is to present results of a survey on the experience of the food business operators in the Czech Republic and consumers with the physical hazards/foreign bodies in food. According currently valid legislation namely **Regulation (EC) No 852/2004** on food hygiene Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the hazard analysis and critical control points (HACCP) principles. The HACCP principles include identifying any hazards that must be prevented, eliminated or reduced to acceptable levels. The HACCP requirements should take account of the principles contained in the *Codex Alimentarius* **(Regulation (EC) No 852/2004)**.

According the ***Codex Alimentarius*** **(1969)** Code of practice CAC/RCP1-1969 – General principles of food hygiene the HACCP should list all the hazards that may be reasonably expected to occur at each step according to the scope from primary production, processing, manufacture, and distribution until the point of consumption. In conducting the hazard analysis, wherever possible the following should be included: the likely occurrence of hazards and severity of their adverse health effects; the qualitative and/or quantitative evaluation of the presence of hazards; survival or multiplication of micro-organisms of concern and production or persistence in foods of toxins, chemicals or physical agents. However foreign bodies are in the Czech Republic still present in food on the market: RASFF annual report 2016 reported 106 notifications due the presence of foreign bodies. In 2017 there were 131 notifications **(European Union 2017; European Union 2018)**.

In the report prepared by Food and veterinary office is stated: "Better HACCP implementation/Final overview report the state of implementation of HACCP in the EU and areas for improvement "**(European Union, 2015)** identified as a major problem hazard analysis. There is a widespread lack of understanding of how to undertake a hazard analysis correctly and this process creates difficulties particularly for

small FBOs due to lack of available expertise. In many cases, the assessment of the likely occurrence of any hazard and the severity of their adverse health effects was not properly undertaken. In general, operators were better equipped to address microbiological hazards. Analysis of physical contaminants that is foreign bodies representing a food safety hazard, has not been so far reported. Gap analysis showed that for EU a comprehensive analysis of incidents of physical hazards is missing and that this information is available may provide clues on actual risks and possible contingency measures that can be related to type of physical hazards, type of food and regional specificities **(Djekic, Jankovic and Rajkovic, 2017)**.

This cross-sectional study tried to evaluate situation in the Czech Republic (CZ), three years later after publication of above-mentioned EU publication. Since then EU created on webpages platform for HACCP implementation wit aim to help small and medium size FBOs, however, no significant progress in CZ was not noted by our study. Quarter of the FBOs did not consider physical hazards/foreign bodies as a problem. To verify existence of this problem we carried out study among CZ population on their experience with foreign bodies in food and 67.91% of them had in past five year at least one experience with foreign bodies and four of them had health problem caused by foreign body in food. The results showed, that there is still gap in the hazard analysis carried out by the food business operators concerning physical hazards/foreign bodies and consumers still experience foreign bodies in food.

Scientific hypothesis

Hypothesis 1: We assume, that all CZ food business operators included in their hazard analysis risks associated with foreign bodies/physical hazards. During development their permanent procedure or procedures based on the HACCP principles .

Hypothesis 2: We assume, that all CZ food business operators correctly implemented during establishment of their permanent procedure or procedures based on the HACCP principles all steps as described in **Regulation (EC) No 852/2004** for physical hazards.

Hypothesis 3: We assume, that the average CZ citizen has no experience with foreign bodies in food.

MATERIAL AND METHODOLOGY

The cross-sectional study aimed at the experience of the food business operators (FBO) and consumers with foreign bodies/ physical hazards in food. The questionnaire for producers focused on hazard analysis done by FBOs and establishment of critical control points (CCPs) and critical limits (CL). The questionnaire was distributed by e-mail, or by post to 100 FBOs within whole CZ. The FBO were randomly selected from list of food producers registered in trade register. The second part of study was questionnaire for consumers. We distributed 200 questionnaires to randomly selected visitors of food festival, which took place in Moravia-Silesian region. Questionnaire focused on their experience with foreign bodies in food and adverse health effect of consumption of such food.

Statistic analysis

Chi-squar test was used to determine whether there is a significant difference between the the observed frequencies in two or more categories between men and women experience with foreign bodies. The level of statistical significance was set at 0.05. Statistical processing was performed using Stata v. 13 (StataCorp).

RESULTS AND DISCUSSION

The questionnaire to FBOs returned fully filled in 54%. Out of 54 questionnaires only 40 FBOs (75%) evaluated in their hazard analysis foreign bodies/ physical risks. Out of these FBOs, that included in their hazard analysis also physical hazards, assessed the most frequently these materials of foreign bodies: glass 31x (77%), hair, nails 28x (70%), metal, plastic, small bugs 22x (55%), stones and personal belongings 16x (40%). See also Table 1. Out of 40 FBO, who included in hazard analysis physical hazards, only 14 (35%) of them based on the hazard analysis identified critical production steps (CPS) in relation to physical hazards.

The identified CPSs were preparation 10x, reception of raw material nine times, expedition/delivery eight times, storage six times, personal hygiene twice, and cleaning one times. Some FBOs identified as critical more production steps. 14 (35%) FBOs identified CPSs in connection with physical hazards.

Out of them 10 (46%) only identified CPS, two (9%) established in these steps CCP but without CL. The last two (9%) established CPS with CCP and CL. Four (18%) FBO established CCP without CPS and CL, two (9%) defined CCPS with CL but without CPS. The same number of FBOs (2, 9%) established CL without CPS and CCP. See Table 2. For some materials as metal, glass, plastics, organic parts, small bugs, stones, wood or inner undesirable parts there were cases, when CCP was established without their assessment during hazard analysis. See Table 3.

In total 12 FBOs established CCP to manage/control physical hazards in their production, 10 of them carried out hazard analysis, two did not carried out hazard analysis for physical hazards at all. In one such case the CCP was established based on internal procedure and in the other case the CCP was established by supplier of the HACCP plan. The most frequently were CCPs established for hair, nails (12x), and glass (10x) metal (eight times). The only material for which any FBO decided to establish CCP was rubber. To prevent or eliminate a hazard or to reduce it to acceptable levels, the FBOs decided for stones (44%) hair, nails (43%) and inner undesirable parts 40% establish the CCP. For other materials it was lower percentage. See Table 4.

Only six FBO replied, that they do have established critical limits for CCPs in connection with physical hazards. In all cases they choose limit not present. Two of them established critical limit without establishing CPS, and two without defining CPS or CCP. The next question verified how the critical limit was validated and in total 25 FBOs replied, that they had their CL validated. 19 of them did not answered previous question “what is your critical limit“. Out of them 20 had CL established by supplier of the HACCP plan, three times it was done by FBO based on previous experience, in one case limit was based on internal procedure, ones it was chosen based on external cooperation.

In total 60 complaints concerning foreign bodies in food were received by FBOs during 2016. The highest number of complaints received by one producer was 20 and the lowest was one. The out of 54 participants on the study only 10 FBOs received consumers' complaint. Three of them had not included physical hazards in their hazard analysis. The FBO, that received highest number of complaints (20), did not evaluate physical hazard during hazard analysis and as corrective action this FBO choose the training of the staff. The most frequently compliant was due the presence hair or nails in food (nine times) or bugs (three times). Corrective action implemented all FBOs after compliant. In majority it included stricter control by supervisor during production (13x) or on reception of raw materials (seven times), providing personal with protective cloths (seven times), change of equipment (four times), stricter sanitation (four times) or installation of the x- ray (one times) into the production line. Three FBOs decide to provide staff with further training. The only one produces carried out reassessment of CCP established in the HACCP plan.

The fully filled in questionnaire returned 134 persons, out of them 85 females (63, 43%) and 49 men (36, 56%). The age of participants was mainly between 15 – 65 years – 123 participants, the rest were older people. The majority were with university degree 48% and high school 37%, the rest of participants had lower level of education, and the only person had no education. Out of 134 participants 91 (67, 91%) had experience with foreign body in food during the last five years. The females met foreign body in 58 cases, men in 33. Females met foreign body statistically more frequently than men (tested by ch^2 test on the level of 5%, $p \leq 0.0001$). Out of these 91 participants the majority – 40 persons (43%) discovered foreign body in food 2 – 5 times in the last 5 years, 37 (40%) persons only once and 13 people experienced foreign bodies more than 5 times. The results did not show the statistical difference between females and men concerning the frequency of foreign body discovery in food (tested by ch^2 test on the level of 5%, $p \leq 0.0001$).

Concerning material, the most frequently were notified stones 38x (28.3%), inner undesirable parts 37x (27%) organic parts 36x (26.8%), pests, hair and nails, each by 35 (26.11%) participants. The results show Figure 3.

The questionnaire included also questions on the solution of the discovery of the foreign body in food. Only nine persons solved the problem making complaint, out of them eight made complaint to food business operator and the only person to competent authority controlling food safety.

In the next step the comparison was made between experiences of consumers with foreign bodies founded in food with FBOs assessment done within their hazard analysis. The most frequently assessed material was glass- 31 FBOs and 10 (32%) decided to establish CCP to manage this hazard. The glass was notified only by 4 persons. For plastic 22 FBOs carried out hazard analysis and 6 (27.2%) of them established for this hazard CCP. This material was notified by 23 consumers. Small bugs were assessed by 22 FBOs, 7 (31.8%) managed that hazard by establishment of CCP. Small bugs were notified by 35 persons.

Out of 134 participants four (2, 9%) had adverse health Out of 134 participants four (2, 9%) had adverse health effect after consumption food with foreign body in it. One person had even two cases of health problem. Four times it was broken tooth and in one case it was wooden chip stacked in throat. All cases of health problem needed health care treatment.

For organic parts of food and inner undesirable parts of food only 9, respectively 10 FBOs carried out hazard analysis and 3 (33.3%) respectively 4 (40%) of them established CCP to manage this hazard. These two types of foreign bodies were frequently notified by consumers 36x, 37x. The most frequently notified foreign bodies were stones, while only 7 FBOs decided to manage this hazard by establishment of CCP, while 16 carried out hazard analysis. The hair and nail were assessed by 28 FBOs, 12 managed that hazard by CCP (42.85%).

Table 1 Number of FBOs in relation to material assessed in hazard analysis.

	Total	%*
Metal	22	55.0
Glass	31	77.5
Plastic	22	55.0
Organical parts	9	22.5
Small bugs	22	55.0
Stones	16	40.0
Wood	7	17.5
Textil	5	12.5
Hair, nails	28	70.0
Paper, carboard	12	30.0
Rubber	3	7.5
Inner undesirable parts	10	25.0
Personal belongings	16	40.0
Other	7	17.5

Note: *out of FBOs that assessed physical hazards (N = 40).

Table 2 Number of FBOs defining CPS, CCP or CL.

Established	Number	%
CPS	10	46
CPS.CCP	2	9
CPS. CCP. CL	2	9
CCP	4	18
CCP.CL	2	9
CL	2	9

Table 3 Materials for which FBO did not carried out hazard analysis however, CCP was established.

Material	Number of FBO
Metal	2
Glass	1
Plastic	1
Organic parts	2
Small bugs	1
Stones	1
Wood	1
Textil	1
Hair, nails	1
Paper, carboard	0
Rubber	0
Inner undesirable parts	4
Personal belongings	1
Other	1

Table 4 Material of foreign body and % of FBOs managing this hazards by CCP.

Material of foreign body	Assesed	CCP established	% of hazard managed by CCP
Metal	22	8	36.36
Glass	31	10	32.25
Plastic	22	6	27.27
Organic parts	9	3	33.33
Small bugs	22	7	31.81
Stones	16	7	43.75
Wood	7	1	14.28
Textil	5	2	40
Hair, nails	28	12	42.85
Paper, carboard	12	3	25
Rubber	3	0	0
Inner undesirable parts	10	4	40
Personal belongings	16	3	18.75
Other	7	1	14.28

Hair or nail were notified by 35 persons. The results did not show the statistical difference between FBO and consumers concerning the frequency of foreign body material assessment in hazard analysis and discovery in food (tested by ch^2 test on the level of 5%, $p \leq 0.0001$). Further details are presented in Figure 4.

A foreign body may be defined as something that the consumer perceives as being alien to the food. The perception of the consumer is important, since not all foreign bodies are in fact alien to the food, though all have the potential to give rise to a consumer complaint. Hence foreign bodies can range from items that are demonstrably alien to the food, such as pieces of glass, metal or plastic through items that are related to the food, such as fragments of bone in meat products to part of the food itself, such as crystals of sugar or salt that are mistaken for glass.

Foreign bodies may get into food at any stage from initial harvesting to final processing or even preparation and consumption by the consumer. Food processing should include procedures to remove foreign bodies incorporated during harvesting of the crop, but it can also give rise to foreign bodies itself, any foreign bodies can be traced back to pieces of food processing machinery **(Edwards M., 2014)**.

In the HACCP Annex, Hazard Analysis and the decision tree for determining CCPs focuses too much on microbiological hazards, while chemical and physical hazards are given less importance. This reflects the historic focus of HACCP when the initial guidelines were being developed, but chemical and physical hazards need to be addressed to cover issues such as, for example, the effective management of allergens with respect to food safety. In revising the GPFH text and the HACCP Annex, consideration should be given to how to incorporate additional guidance on chemical and physical hazards **(*Codex Alimentarius*, 2014)**.

Foreign matter is the biggest single source of customer complaints received by many food manufacturers, retailers and enforcement authorities. In even the best-managed processes, the accidental inclusion of unwanted items may sometimes occur. Foreign matter in foods is therefore quite rightly a matter of concern to all food manufacturers and retailers. Consumer complaints regarding foreign material reported from food products will continue to be a significant issue for the food industry. However, careful study of data from a wide range of foreign matter investigations demonstrates that in many cases the occurrence of foreign matter is far from random **(Edwards and Stringer, 2007)**. 16,878 foreign bodies injuries occurred in children aged 0 – 14 years have been recorded in the SUSY Safe databases. FB type was specified in 10,564 cases, among them 2,744 (26%) were due to a food item **(Van As et al., 2012)**.

Contrary to microbial and chemical hazards, physical contaminants are the most obvious evidence of contamination of product. Regarding types of foreign bodies notified the top three material were pest (54.6%), glass (17.4%) and metal (11.5%) **(Djekic at al., 2017)**. Consumer complaints about foreign bodies are a continuing problem for the food industry. Recent years have seen an increasing emphasis on consumer rights, with frequent encouragement in the media for consumers to complain to food companies about incidents that would in the past have been viewed as trivial **(Edwards, 2014)**.

The foreign bodies statistically were found more by women than men. This is due women are the main chefs at Czech homes. The results of study shoved, that the most frequently met foreign bodies by consumers were stones followed by organic foreign bodies (both inner and outer), followed by hair and small bugs. The difference could be caused by type of foreign bodies, when hair or inner organic parts are not seen by consumers as a problem. Therefore, these materials are not notified by them. The problems with foreign body in food were reported to FBOs only in minority of cases, even in the case of health problem caused by foreign body complaints was not made. This could be caused by no adverse health effect and by consumer's historical experience with their complaint's solution.

Food factory operatives are a major source of foreign bodies, from stray hairs not contained by hairnets or beard snoods to studs or sleepers from earrings. Personnel are a major potential source of foreign bodies in food premises of all kinds **(Edwards, 2014)**. The one of the most frequently founded foreign body by consumers involved in study was hair and nail. That is sign that staff is still one of the major sources of contamination. The root of this could be the staff itself, when the staff turnover in food industry is very high and staff has no specific background in food safety.

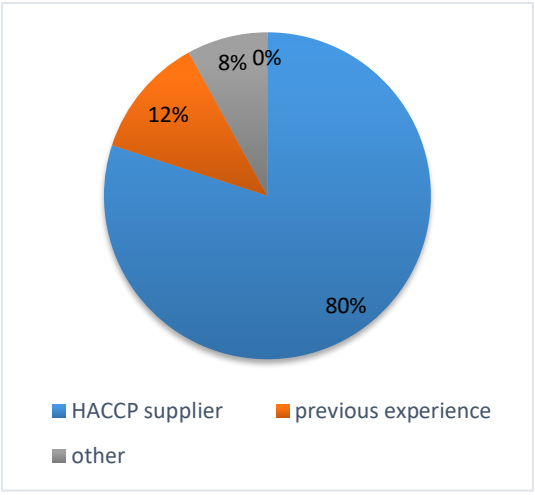

Figure 1 Validation of CL.

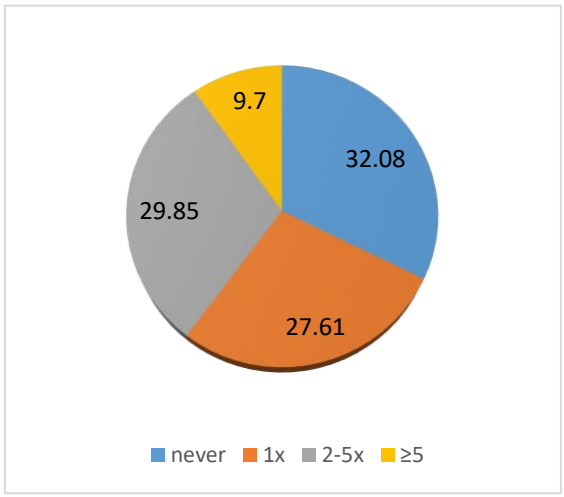

Figure 2 Frequency of foreign bodies founded in food.

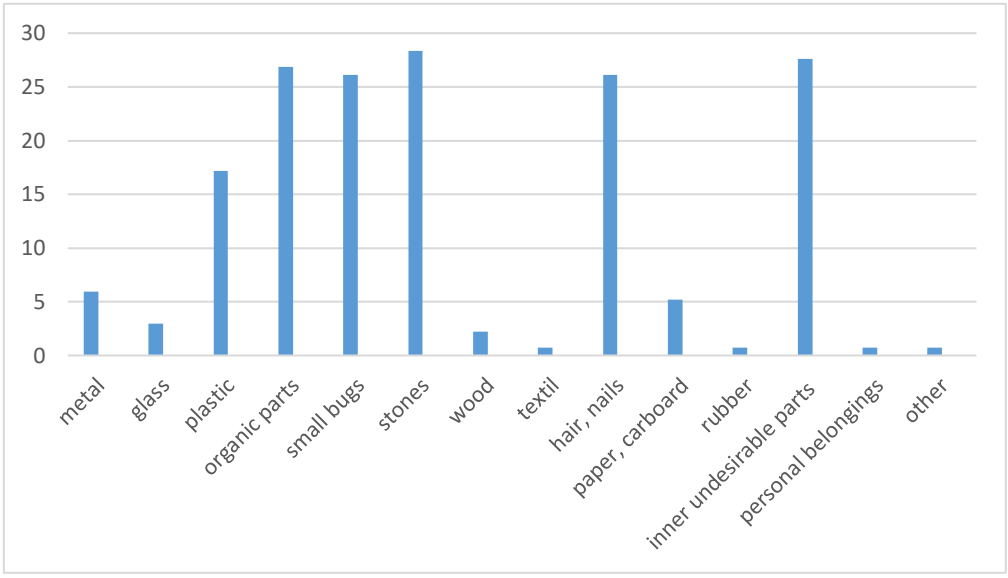

Figure 3 Foreign bodies discovered in food by material in %.

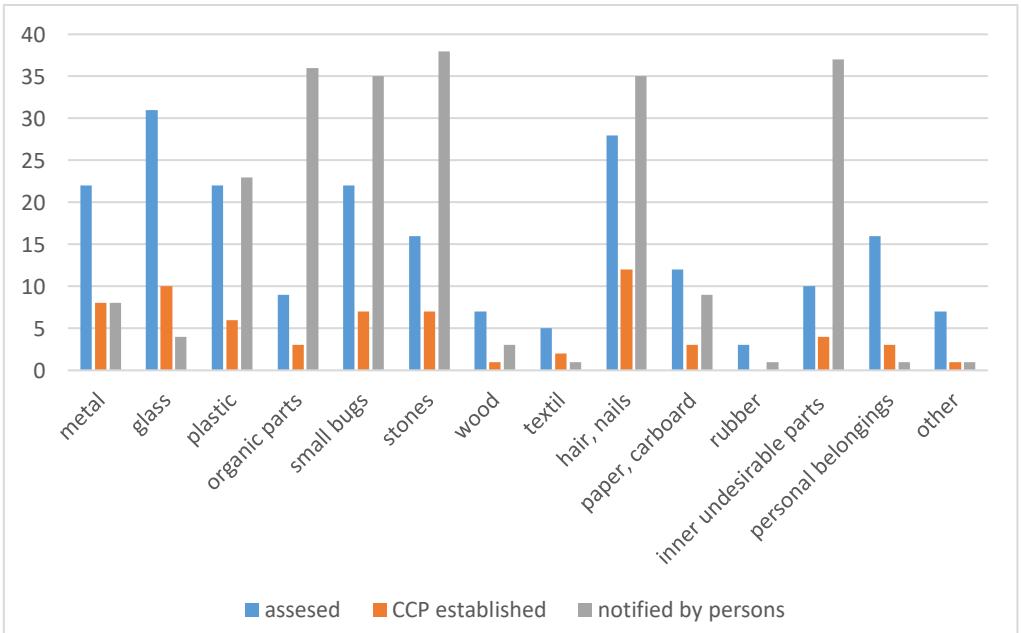

Figure 4 Comparison assessment carried out by FBOs, CCP establishment and consumers experience (total number).

Although, the FBOs provided staff by training as corrective measure in case of non-compliance, the training did not sufficiently prevent occurrence of hail or nail in food. Staff training should go together with thorough control by hierarchy directly on production site.

A good quality management system is vital to the effective prevention and control of foreign bogies in food manufacture. A structured preventive approach is likely to be the most reliable basis for such a system. The traditional approach of sole reliance on finished product analysis and factory inspection is nowadays unlikely to give acceptable assurance and consumer confidence that the process is under control on continuous basis. Hazard analysis is the approach which all companies, whatever their size, should use to identify the points in their manufacturing operations which critically affect product safety. Foreign body hazard analysis of a food product process starts with the identification of the sequential stages in the process from raw materials and packaging materials through to the dispatch, distribution and end use of the food product **(Edwards, 2014)**. Substantial part of the FBOs did not include in their hazard analysis physical hazards at all. The FBOs do not understand importance of hazard analysis, when CCPs or critical limits were in many cases established without carrying out hazard analysis. Some critical limits were established without having chosen critical control points. That is due the not understanding importance of hazard analysis for establishment of CCPs and CLs within the procedures based on HACCP principles.

The investigation of a foreign body incident involves a number of clear stages. The first essential step is to determine all the known facts in the case. It is important that precise details of the circumstances under which the foreign body was discovered are recorded. In particular, it is essential to know whether the foreign body was found when the pack was opened, during food preparation or whilst eating the product, and whether or not the foreign body could have been heated during preparation or mixed with other food products **(Edwards, 2014)**. In case of non-compliance caused by foreign body all FBOs implemented corrective action. However, only few of them applied further training for the staff, although large part of the complaints concerned hair or nail.

While the available technology may not eliminate all foreign bodies from food, the correct application of technology will assist in removing many of them **(Edwards, 2014)**. The critical point in the detection of physical contaminants is nearly always the large variability that it is observed in the distribution of impurities between the repeated determinations carried out on the same sample. This variability is due to the fact this kind of the contaminants do not have a uniform distribution within the sample, thus resulting in the need to transform the data into values that can express a normal distribution; alternatively, it may be necessary to increase the number of determinations in order to ensure a significant result **(Schiavo et al., 2015)**. There are many ways food processors can prevent physical hazards in food products **(CVO/Food Safety Knowledge, 2018)**. The presence of foreign bodies in food is of major concern to the producer. Mechanical separation techniques have been used for many years for foreign bodies in powdered and owing products based on size and weight. Optical inspection techniques extend the range of detectable foreign objects regarding shape and color in free materials. Metal detectors enable metallic particles inside the body of a product to be found. With advances in sensor technologies and computing power more advanced detection systems are becoming available **(Graves, Smith and Batchelor, 1998)**.

Our study has proven that there is still space for improvement from side of the FBOs; some of them do not implement all possible preventive measures in their establishments. There was one FBO did not including in hazard analysis physical hazards, although received 20 consumers complaints. It seems, that preventive measures applied by FBOs are not effective enough and do not prevent occurrence of some foreign bodies such as plastic, small bugs, stones, hair and nail. Organic parts and inner undesirable parts of food are not in focus of FBOs, while they are founded frequently by consumers.

Flour beetles are among the most common pest insects found in stored grain and milled products. Beetles have defensive glands which secret quinones such as 2-methyl-p-benzoquinone, 2-ethyl-p-benzoquionone, hydroquinone commonly referred to as benzoquinones. Benzoquinones have a carcinogenic effect, they are inhibitors of growth of various microorganisms, and they produce a self-defense mechanism in threat situations and affect population aggregation **(Lis et al., 2011)**. Stored product pest may be source of indirect contamination of stored commodities, by pesticide residues of chemical treatment by protectants. Some species of *Acarina, Blattodea, Coleptera, Lepidoptera* and *Psocoptera* may cause allergic reactions in humans exposed to remnants of their bodies. No critical levels are available for contamination of food agrocommodities by allergens of arthropods **(Mattos et al., 2016)**. The presence of pests in food was quite frequent among consumers, although quite substantial number of FBOs assessed hazard associated with them. There should be more focus on presence of pests in food as there is severe chemical risk associated with them.

1,309 complaints reported from 2000 to September 2002, 331 were related to foreign materials (25%), about 6% of those cases resulted in injury. The most common materials were identified as metal, glass and plastic **(Mattos et al., 2016)**. In our study the percentage of injuries was lower, the difference could be caused by the population under investigation. Our study included general population while above mentioned study investigated only cases, when foreign body was notified to the competent authority. However, the health effect of foreign body in food was severe and needed to be solved by health service providers.

CONCLUSION

All of our hypothesis were not proven to be truth. There is high number of FBOs not including physical hazards in hazard analysis or not following correctly all necessary steps in implementation of their procedures based on HACCP principles. As the result there is quite high number of consumers experiencing foreign bodies in food. The problem is also the quality of guidelines for hazard analysis, that do not include physical hazards and especially small FBOs do not have all necessary knowledge to carry out thorough hazard analysis. There should be more focus on physical hazards from competent authorities and producers

associations to develop guides to cover physical hazards in a future.

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