Project: Technical assistance to improve implementation of food safety standards and disease crisis preparedness

Activity 1.1.17: Training on topics relevant to food chain safety including processed food of non-animal origin and composite food

Module: Planning, organisation and implementation of 'official' controls; 'official' sampling procedures

- Planning frequencies of 'official control' and example of categorization of the establishments

Lecturers: Dr Lence Jovanovska

Dr Mina Barova

Date: ……

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Planning ‘official’ controls on a risk-base

- Risk based OCs and OCs’ prioritization - local level
- Provided that legal requirements constitute the basis for any further decision on risk ranking, when planning controls on establishments and operators at local level other data, beyond those included in the national plans, shall be taken into consideration (based on the knowledge of the local situation/history).
- Risk categorisation is a tool to program and perform ‘official’ controls on a risk base.
- ‘Official’controls performance and ‘official’ control frequencies are planning on a risk-base.

Risk categorisation of establishments

Many factors can be considered to determine the category into which a particular business falls

Risk criteria: two groups

- Activities and nature of the food business (type of products, amount, possibility of product contamination,)
- FBOs' actions, processes in production (these are based on the FBOs' actions and compliance with food hygiene requirements).

Risk categorisation of establishments

- According to the possibility of food contamination, the products used in production have been categorized into three categories: high, medium and low risk.

Risk category	Category description
High risk	Products that may contain pathogenic or conditionally pathogenic microorganisms that support the formation or growth of pathogenic or conditionally pathogenic microorganisms.
Medium risk	Products that are unlikely to contain pathogenic or conditionally pathogenic microorganisms due to the type of food or processing, but may support the formation of toxins or the growth of pathogenic or conditionally pathogenic microorganisms, as well as foods in which chemical contamination is possible.
Low risk	Products that eliminate the possibility of contaminating products or leading to the growth of pathogenic or conditionally pathogenic microorganisms, their toxins, and physical and chemical contamination are rare.

Risk categorisation of establishments

- In accordance with the previous table of product categories, a categorization of certain basic types of food has been made, shown in the following table.

Risk by type of food		
I Category High risk	II Category Medium risk	III Category Low risk
Meat Milk Fish Eggs	Herbs Grains Fruits Vegetables Fats (oil) Nuts Flour Yeast Coffee, cocoa	Honey Water Salt Sugar Mushrooms Vinegar Food contact materials

Risk categorisation of establishments

Categorizing food establishments based on risk requires a complex approach due to the diversity of products and product handling. Food poisoning risk factors associated with food businesses are also important and are most often related to handling or processing and are most often applied in primary or secondary operations. Some of those identified are:

- cross-contamination (e.g., from raw material to finished product);
- food from unsafe sources;
- improper cooking;
- improper temperature maintenance;
- contaminated equipment;
- poor human hygiene;
- health status of those handling it;
- water quality; and
- presence of pests.

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Risk categorisation of establishments

- According to the possibility of food contamination during the production process, the processes applied in production have been categorized into three categories: high, medium and low risk, shown below.

Category of processes	Category description
High risk	Processes where the possibility of product contamination is very high or leading to the growth of pathogenic_or conditionally pathogenic microorganisms and their toxins is high, as well as a high possibility of physical and chemical contamination.
Medium risk	Processes where there is a high possibility of contaminating products or leading to the growth of pathogenic or conditionally pathogenic microorganisms, their toxins, as well as the possibility of physical and chemical contamination.
Low risk	Processes that eliminate the possibility of contaminating products or leading to the growth of pathogenic or conditionally pathogenic microorganisms, their toxins, and physical and chemical contamination are rare.

Risk categorisation of establishments

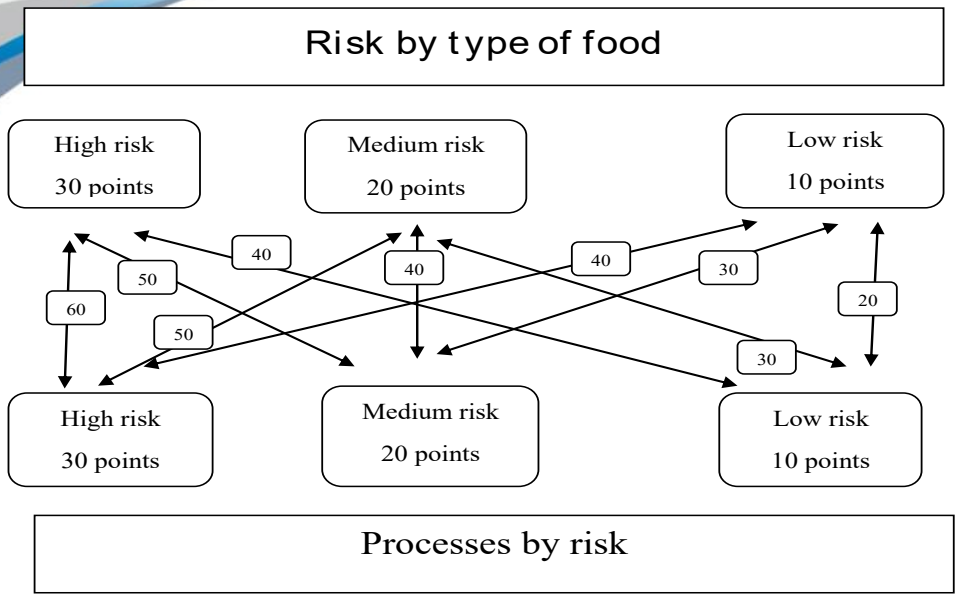
- In accordance with the previous table of process categories, a categorization of certain basic types of production processes has been made. The processes are categorized into three categories shown in the following table.

Processes by risk		
I Category High risk	II Category Medium risk	III Category Low risk
Cutting Grinding Mixing Shaping Marinating	Repackaging Pasteurization Peeling Fermentation Distillation Canning	Packaging Storage Transport Sale Sterilization Quick Freezing Seeding Drying Dilution Aeration Filtration Pressing Baking Frying Boiler Refining Serving

Risk categorisation of establishments

- To enable an objective approach to determining the frequency of controls, a scoring system has been introduced to indicate the categorization of the facility by risk, which must be feasible and understandable and prevent miscalculation.
- The scoring system is designed to assign a number of points, starting from the most risky to the least risky, with a number of points of 30, 20, 10, for both food and processes. The sum of the points obtained by crossing the food categories and the process categories determines the category of the facilities, categorized by risk.

Risk categorisation of establishments



According to the combinations shown in Figure and Table, the categories of the objects based on risk analysis were determined. Risk categorization is a complex process that can be influenced by a large number of factors.

	Processes by risk/points	I / 30	II / 20	III / 10
Risk by type of food/ points				
I / 30		60	50	40
II / 20		50	40	30
III / 10		40	10	20

Risk categorisation of establishments

- Combinations of product risk and process risk, together with the assessment, are used to determine the categorization of establishments by risk.
- The establishments categories are set out in the following table:

Category of establishments	Description of the category
High risk	Food establishments dealing with products and/or operations where there is a serious risk to consumers.
Medium risk	Food establishments including products and/or operations with the potential to pose a risk to consumers.
Low risk	A food business that involves products and/or operations where the potential to cause harm to consumers is low.
Very low risk	A food business that involves products and/or operations where the potential to cause harm to consumers is very low.

Categorization of establishments according to existing criteria

Based on the scoring performed and the results obtained from the cross-referencing of food categories and process categories, the establishments were determined and assigned to the four risk categories shown in following tables

Categorization of facilities by combining product and process risk.

High Risk Establishments (60 points)
Food Risk Category I + Process Risk Category I (30 + 30 = 60 points)
✓ Slaughterhouses
✓ Meat cutting facilities
✓ Butchers
✓ Restaurants / kitchens, inns, pastry shops
✓ Meat preparation facilities
✓ Milk collection centers
✓ Confectionery production facilities
✓ Other high-risk catering facilities
✓ Egg processing facilities
✓ Fish processing facilities

Categorization of establishments according to existing criteria

Categorization of facilities by combining product and process risk.

Medium Risk Establishments (50 points)	
Food Risk Category I + Process Risk Category II (30 + 20 = 50 points)	**Food Risk Category II + Process Risk Category I (20 + 30 = 50 points)**
✓ Dairy ✓ Meat repacking facilities ✓ Fish repacking facilities ✓ Meat product facilities ✓ Fish product facilities ✓ Egg product facilities	✓ Facilities for the production of teas, spices, food supplements, additives and salt ✓ Mills ✓ Nut processing facilities ✓ Vegetable processing facilities ✓ Fruit processing facilities ✓ Bread and pastry production facilities ✓ Oil and oil product processing facilities ✓ Coffee and cocoa processing facilities

Categorization of establishments according to existing criteria

Categorization of facilities by combining product and process risk.

Low Risk Establishments (40 points)		
Food Risk Category III + Process Risk Category I points) (10 + 30 = 40 points)	**Food Risk Category II + Process Risk Category II (20 + 20 = 40 points)**	**Food Risk Category I + Process Risk Category III (30 + 10 = 40points)**
✓ Confectionery production facilities ✓ Honey collection and packaging facilities ✓ Ice production facilities ✓ Soft drink and beer production facilities ✓ Mushroom processing facilities ✓ Sugar production facilities	✓ Processing and repackaging facilities (cereals and nuts) ✓ Fruit and vegetable repackaging facilities ✓ Yeast production facilities	✓ Cold stores - frozen products of animal origin ✓ Meat and meat processing facilities ✓ Fish trading facilities ✓ Milk and dairy products trading facilities ✓ Egg collection and packaging facilities ✓ Canned meat facilities ✓ Canned fish facilities ✓ Facilities for the production of durable meat products ✓ Other catering facilities with frying, baking and cooking (gyro, pizzeria, palanquin, grill by the kilo, sandwich shops, kebab shops, buffet) ✓ Facilities for preparation and sale

Categorization of establishments according to existing criteria

Categorization of facilities by combining product and process risk.

Very Low Risk Establishments (30 points + 20 points)		
Food Risk Category II + Process Risk Category III points) (20 + 10 = 30 points)	**Food Risk Category III + Process Risk Category II (10 + 20 = 30 points)**	**Food Risk Category III + Process Risk Category III категорија (10 + 10 = 20 points)**
✓ Food establishments (not mentioned in other categories) ✓ Coffee bars ✓ Wineries ✓ Alcoholic beverage production establishments ✓ Vinegar production establishments ✓ Fruit and vegetable sales establishments - Greengrocers ✓ Green markets	✓ Storage and holding facilities ✓ Sugar packaging and repackaging facilities ✓ Food contact material production facilities ✓ Food contact material trading facilities	✓ Water packaging facilities ✓ Public water supply facilities

Planning and organisation of the 'official' controls

- A lot of other criteria could be applied in planning and organisation of the 'official' control risk-based (Additional criteria)
- The number of controls may be increased or decreased by inspectors from the above-mentioned dynamics depending on whether the checks during 'official' control are satisfactory, partially satisfactory and unsatisfactory.
- At the end of the evaluation process, each establishment get a score and an allocation in one of the three identified risk categories.

Additional criteria

Criteria to be taken into account:

I. The history of compliance of food operators with legal provisions

- Type and number of legal sanctions within a certain period and their timely implementation
- Number of products not in compliance with applicable legal provisions combined with the possible danger to human health
- Respecting the deadlines given by the local body for the elimination of identified deficiencies

Additional criteria

II. Application of HACCP procedures

- quality, adequacy and operational reliability of the system (critical control point analysis),
- determination of limits, methods for checking critical control points, procedures for non-compliance
- maintenance and updating of documentation

Additional criteria

III. Employee training

- training on basic minimum food safety requirements
- maintaining personal hygiene
- maintaining hygiene in the facility and preventing possible cross-contamination.

Additional criteria

IV. Cold chain maintenance

- compliance with temperature requirements
- keeping records of temperature control

V. Construction and technical conditions

- facility maintenance
- equipment maintenance.

Risk categorisation of establishments

CLARIFICATIONS

Risk categorisation of Food establishment is **NOT** risk analysis defined in Regulation (EC)178/02

- Risk categorisation must be based on objective criteria.
- It is necessary to carry out an inspection/audit in the establishment.
- Take into consideration also documentation.
- The word “risk” doesn’t necessarily mean a negative evaluation.
- A criterion can influence another criterion.

The term “risk” should not be confused with a positive or negative assessment of an establishment.

Frequency of ‘official’ controls

The risk categorisation of certain food establishments determines the frequency of ‘official’ controls.

Establishments categorised as high risk will be controlled more frequently than those categorised as low risk.

The frequency of controls is given in the following table.

High-risk establishments (60 points)	Medium-risk establishments# (50 points)	Low-risk establishments (40 points)	Very low-risk establishments (30 points + 20 points)
Frequency of ‘official’ controls			
3 official control per year	2 ‘official’ control per year	1 ‘official’ control per year	1 ‘official’ control per 2 years

Frequency of ‘official’ control

- Taking into account the risk of the facilities and the need for more frequent controls in them, an initial frequency of 3 controls per year in high-risk facilities, 2 in medium-risk facilities, 1 in low-risk facilities and one every 2 years in very low-risk facilities has been taken.
- The frequency of controls may be increased for certain facilities if necessary.
- Controls that arise due to identified deficiencies, as well as unforeseen controls (as reported by customers) are not subject to this planned frequency.

Determining the frequency of controls

- When determining the frequency of controls, in addition to the defined risk of the establishments, the number of registered and approved establishments, the number of inspectors employed, technical support, and working days were also taken into account.
- The number of controls carried out last year has to be taken into account when determining the frequency.

Number of registered facilities	Number of approved facilities	Number of inspectors	Number of 'official' controls carried out last year
12 481	262	100	15 668
(12 481+262) : 100 : 11 = 11,6			

The number of 11, 6 inspections per inspector per month, is arithmetically obtained from the total number of registered and approved facilities, divided by the total number of inspectors and eleven months (minus annual leave). The arithmetic operation shown is with a frequency of one inspection per facility per year without taking into account the risk of the facility.

Determining the frequency of controls

Total number of establishments =12 743				
	Number of high-risk establishments	Number of medium-risk establishments	Number of low-risk establishments	Number of very low-risk establishments
Total number by category	2260	790	2733	6960
Assumed frequency of controls	2260 x 3= 6780	790 x 2 =1580	2733 x 1=2733	6960 x 0,5=3480
	Total number of official controls 14 573			
Arithmetic processing	14 573 : 100 : 11 = 13,25			

Arithmetic processing was performed, and with this frequency of controls, 13.25 controls per month were obtained per inspector.

Organising 'official' control

Check lists

- A check list, reviewing all the different aspect to be evaluated, may help to ensure consistency among different operators performing data assessment, nonetheless a common approach can be granted only by mean of the implementation of stringent procedures & guidelines and the performance of continuous training.

Organising 'official' control

Check lists

Possible advantages of check lists in assessing establishment's/activities' score.

- **Advantages**

- Helps to maintain focus on the objectives of the control
- Helps to ensure all items are covered (assessed)
- Helps to record the outcomes of the control
- Aids consistency between assessors

Disadvantages

- May not be fully comprehensive
- May restrict initiative and judgment
- May lead to "tick-box" approach

Forms to be used in 'official' control

- Form for 'official' control recordkeeping
- Check-list - Verification of hygiene requirements
- Check-list - Inspection of structural requirements and equipment
- Check-list - Audit of GHP and HACCP principles
- ……

…and relevant instructions

Control plan

- The Annual Control Plan provides details on all the ‘official’ control activities that must be carried out.
- Type of controls, responsibilities, time to be allocated to each control and number of interventions have been defined.
- Needs for human resources can be calculated based on the existing food establishments.

Control plan

Before the implementation of the 'official' control plan, it is strongly recommended

- to approve a MACP;
- to draft Standard Operating Procedures for the activities of inspection and audit;
- to carry out specific training session involving local inspectors and responsible of the local services.

Planning ‘official’ control

- Adequateness of human resources
  - number of employees
  - professional background
  - experience
  - trainings of employees
- Calculation of the time required for ‘official’ control

Conclusion

- A lot of criteria could be applied in planning and organisation of the ‘official’ control risk-based.
- A check list, reviewing all the different aspect to be evaluated, may help to ensure consistency among different operators performing data assessment, nonetheless a common approach can be granted only by mean of the implementation of stringent procedures & guidelines and the performance of continuous training.
- Adequateness of human resources are very important for implementation of ‘official’ control .
- Planning and organisation of ‘official’ control is very important for the effectiveness of the services.

CONTACT

Project e-mail: foodsafetyprojectTCc@gmail.com
projects.int@nsf.org

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