

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, organisation and implementation of 'official' controls

Lecturers: Dr Lence Jovanovska

Dr Mina Barova

Date:

Place: Nicosia, Cyprus

Project funded by the European Union within the scope of the Aid Programme for the Turkish Cypriot community, implemented by NSF Euro Consultants Consortium



Disclaimer: This presentation has been produced with the financial support of the European Union. Its contents are the sole responsibility of NSF Euro Consultants Consortium – Contractor, and do not necessarily reflect the views of the European Union.

ON THE WAY TO EU STANDARDS



‘OFFICIAL’ CONTROL PLANNING: MAIN PRINCIPLES





- ‘official’ control planning and programming
 - main principles,
 - goals and
 - steps of planning;
- the control plan on foodstuffs,
- what is risk-based planning of ‘official’ controls;
- risk-based planning of ‘official’ controls in the EU legislation;





Abbreviations

Please note in the presentation the following abbreviations will be used:

OC(s) – ‘Official’ Control(s)

OOA(s) – Other ‘Official’ Activities

CAs – Competent Authorities

MS(s) – Member State(s)

OCR – EU Official Controls Regulation

OV(s) – ‘Official’ Veterinarian(s)

NC – non-compliance

COMM – European Commission

EP – European Parliament

GMO - Genetically Modified Organism



'Official' control planning –main principles



'official' control planning: why?

- Regulation (EC) 625/2017 on official controls defines that each Member State shall elaborate a single integrated multi-annual control plan.
- The multi-annual plan (MACP) contains general information on the structure and organisation of control systems covering all the areas governed by agri-food chain legislation.
- MACP is the instrument through which each country should ensure that 'official' controls are performed in a manner that is risk-based and efficient across its territory and the entire agri-food chain, in compliance with Regulation (EC) No. 625/2017.





- General goal - to foster a coherent and integrated approach of 'official' control of foodstuffs with the aim to protect consumer health
- Specific goals:
 - Ensure the uniform and coordinated implementation of control activities
 - Raise the respect of operative criteria established in the Regulation (EC) 625/2017
 - Improve the efficiency of 'official' control
 - Define the priorities based on the risks
 - Raise the visibility of services.





Basic criteria:

- Each inspection shall be documented
- Control's frequency (average) shall be established
- Controls shall be prioritised (Risk categorisation of establishments)
- Check list and templates for 'official' control shall be developed and implemented



'official' control planning – steps:

- definition of structures subject to controls
- definitions of control procedures and forms
- assessment of available resources
- assessment of level of risk of the activities
- programming of 'official' control activities
- implementation of 'official' controls
- documentation of activities
- reporting
- verification of activities
- reprogramming of activities





1

The preparation of a list of the establishments subject to 'official' control is a prerequisite – **registration of food business establishments:**

- Name, address, responsible, activities, ID number
- Keep updated data on 'official' controls
- Aggregate data
- Analyse data to reprogram activity
- Communicate data at the central level



Approval of food business establishments

Article 148 from Reg. (EC)625/2017

Article 148

Relation with Regulations (EC) No 852/2004 and (EC) No 853/2004 regarding approval of food business establishments

1. Competent authorities shall establish procedures for food business operators to follow when applying for the approval of their establishments in accordance with Regulations (EC) No 852/2004 and (EC) No 853/2004.
2. Upon receipt of an application for approval from a food business operator, the competent authority shall make an on-site visit.
3. The competent authority shall approve an establishment for the activities concerned only if the food business operator has demonstrated that it complies with the relevant requirements of food law.
4. The competent authority may grant conditional approval if it appears that the establishment meets all the infrastructure and equipment requirements. It shall grant full approval only if it appears from a new official control of the establishment, carried out within three months of granting conditional approval, that the establishment meets the other relevant requirements of food law. If clear progress has been made but the establishment still does not meet all of the relevant requirements, the competent authority may prolong the conditional approval. However, conditional approval shall not exceed a total of six months, except in the case of factory and freezer vessels flying the flag of Member States, for which such conditional approval shall not exceed a total of 12 months.
5. The competent authority shall keep the approval of establishments under review when carrying out official controls.



2

‘Official’ control planning: how?

- ‘Official’ control **procedure** in the food safety field
- **Operative instruction:** audit
- **Operative instruction:** inspection of food establishments
- **Forms** to be used in ‘official’ control

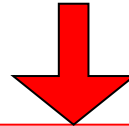


'OFFICIAL' CONTROL PLANNING: WHO?

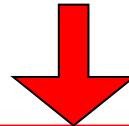
3

ASSESSMENT OF AVAILABLE RESOURCES

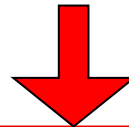
Number and type of establishments



Type of controls to be carried out



Time to be allocate for each type of control



Adequateness of human resources



4

‘OFFICIAL’ CONTROL PLANNING: WHEN?

RISK CATEGORISATION OF ESTABLISHMENTS

Premises must be rated in a scheme of priority categorisation (Reg. (EC)625/2017)

- Art. 9 (2): controls shall be carried out regularly, on a risk basis and with appropriate frequency
- Art. 110 (2,b): Each national control plan shall contain information on the risk categorisation of the activities concerned





'OFFICIAL' CONTROL PLANNING: WHEN?

4

RISK CATEGORISATION OF ESTABLISHMENTS

HOW?

Find objective tool to classify food establishments according to the risk, useful to increase or decrease control's frequency on the basis of uniform criteria

Final goal



Food industries with the same risk are controlled in a homogeneous way and with same frequency.



5

WHAT

Types of controls to be carried out

WHO

Responsibilities for the conduction of controls

Define, for each type of establishment

HOW

Forms to be used, operational procedures, check lists, reports, recordkeeping

WHEN

Minimum frequencies of controls on the basis of risk categorization of the establishments

INDUSTRY FOOD PROCESSING ESTABLISHMENT, PRODUCTION OF FOOD OF NON-ANIMAL PRODUCTS AND PRODUCTION OF COMPOSIT FOODSTUFFS

	Activities	Responsibilities	Duration	Forms	High risk	Medium risk	Low risk
1	Inspection of raw materials and semi-finished products	Local Inspector Local Inspector	1 h	Report Check list	Three times per year	Twice per year	Once per year
2	Inspection of general hygiene conditions		1 h				
3	Control of finished products and storage conditions		1 h				
4	Labelling and packaging materials		1 h				
5	Control of commercials documents		1 h				
6	Control of CCP monitoring and monitoring records		1 h				
7	Verification of hygiene and functional conditions, hygiene of processing and hygiene of the personnel		1 h				
8	Follow up inspection for the checking the non-compliance and taken measures and verification of hygiene and functional conditions, hygiene of processing and hygiene of the personnel	Local Inspector	2 h	Check list and report	Within the time frame set by the inspector		
9	Inspection of structural requirements and equipment	Supervisor	8 h	Check list	Once after registration of the establishment	Once after registration of the establishment	Once after registration of the establishment



7

Each entry of the inspectors in the establishment must be adequately documented

- Minutes of OC
- Check list
- Report
- Certificate
- Control register
- Record for sampling
- Sampling register



8

Create an adequate flow of information from the local level to the central level

- A scheme should be drafted which summarises the activities carried out within the Annual control plan (ACP)
- The scheme shall be filled in by the responsible person of the **corresponding service** with annual frequency, and sent to the central departments
- All data should be collected, analysed and published in an annual report (transparency and visibility).

9

In order to
verify



- That program is respected
- Results of controls
- Effectiveness of adopted measures

Verification is carried out revising documentation and performing on-site visits in the plants

10

Based on the outcomes of verification, controls programme can be adjusted

At plant level, program shall be changed...

- when there are substantial changes in production, premises, equipment's.
- when serious non-compliance occurs

Coffee break





THE CONTROL PLAN ON FOODSTUFFS





MAIN PROBLEM: LACK OF DATA

- Responsibilities on 'official' control of foodstuffs and relevant chain of command of competent bodies
- Figures on main food processing establishments across the country, along with an indication of their type and capacity
- Figures on staff in charge of 'official' control on food safety.



ASSUMPTIONS

- The control plan has been drafted according to the principles and criteria included in the Reg. (EC) 625/17.
- There will be at least two levels of responsibilities: “inspector” and “supervisor”
- Before the implementation of the Plan, a MACP should be ‘officially’ approved, containing general information on the structure and organisation of ‘control’ systems.

Includes all the elements necessary to implement 'official control' on food safety according to the principles included in the EU Regulations – the so-called Hygiene Package regulations.

Structure of control plan:

- definition of structures subject to controls
- definition of control activities and relevant frequencies
- a tool for risk categorisation of food establishments
- a tool to calculate the adequacy of human resources
- forms for recordkeeping (checklists and other forms)
- schedule for 'official control' in food establishments
- schedule and forms for supervision of local inspectors.

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).

Different meanings of the word risk in the EU legislation regarding food safety:

- “Food law shall be based on risk analysis”, [Reg. (EC)178/02, art 6.1]
- “CAs shall perform OCs on all operators regularly, on a risk basis and with appropriate frequency” [Reg. (EC)625/2017, art. 9.1]
- “Official controls on animals and goods entering the Union shall be organised on a risk basis” [Reg. (EC)625/2017, art. 43]
- MSs shall have a general plan for crisis management “setting out measures to be applied without delay when food or feed is found to pose a serious risk to human or animal health either directly or through the environment” [Reg. (EC)625/2017, art. 115.1]



- Risk Analysis: a tool to planning, organisation and implementation of 'official' controls
- Risk-based 'official' controls to ensure OCs efficiency and appropriateness
- Planning of OCs takes place at various levels: central, regional, local and establishment level. This entails differences in:
 - Context of reference
 - Available data
 - Planning objectives & timeframe
 - Measure to mitigate risks.



Risk-based planning of 'official controls'



Context generally refer to the **local** and, whenever necessary or appropriate, to **international situation** such as:

- the **epidemiological situation** in relation to
 - Human
 - animal and
 - plants diseases,
- consumption **habits**,
- **exposure** data, etc.

E.g.: the **local features** (epidemiological, economic, social, political) **may influence** risk categorisation and control measures, provided that local and EU criteria are respected (e.g. due to a regional eradication plan for an animal or plant disease the risk attributed to that specific disease could be overweighted).



Planning activities include generally **long term strategic and multi-annual plans** (e.g., a plan to reduce *Salmonella* prevalence in poultry flocks shall be designed to cover many years).





Risk-based planning – examples of mitigation measures

Risk	Central level	Local level
Products and/or process inherent risk	<ul style="list-style-type: none">Establishment of legal requirements, issuance of guidelines	<ul style="list-style-type: none">Knowledge of products and processesThe operator's risk management measures verification
Lack of compliance with the relevant requirements	<ul style="list-style-type: none">Continuous requirement updating to ensure their actual needConsultation with the stakeholder to improve comprehension of and commitment to legal requirements	<ul style="list-style-type: none">Meetings with the stakeholder (information)Controls nature and frequency tailored on each operator history of complianceImposition of enforcement measures to make compliance more convenient than non-compliance
Failure in detecting NC	<ul style="list-style-type: none">Issuing of guidelinesEducational programsCoordination among different CAs	<ul style="list-style-type: none">Development and dissemination of effective control proceduresTraining programsInternal auditing

- Reg.(EC)625/2017 defines that MACP should be elaborated
- A MACP should be available, containing general information on the structure and organisation of control systems of feed and food, animal health and welfare, plant health, etc.
- In this framework, a plan for 'official' control in the food sector should be prepared.
- Following the implementation of the plan, modifications will have to be introduced when preparing the control plans for the following years.

Coffee break





- The **prioritization** in 'official controls' performance shall be tailored on each sector/business category **according their score** on the basis of the available information and taking into consideration possible restraint at local or EU level (e.g., a minimum control frequency may be defined at local or EU level in relation to the risk level)





On the basis of the attributed score, it shall be possible to define the 'official' controls:

- Frequency,
- Method,
- Scope,
- Extension.



Risk-based ‘official’ control and ‘official’ control methods

- Method: inspection, audit, sampling and analysing etc. (*)
- The most appropriate methods shall be employed **depending on** the ‘official’ control **scope**, the specific **context** and the available **resources**.
- A good deal of **flexibility** in deciding which control method is to be used is advisable



(*) Reg. (EC) 2017/625, art. 14



Risk-based 'official' control scope and extension

- Scope: 'official' controls shall primarily **focus on high risk areas**, as may be identified to use in the framework of the scoring process (e.g., cleanliness, staff training, animal welfare, process control,...).
- Anyhow, **all** the relevant **aspects** of each operator/activity shall be **verified** to use in the framework of the planned 'official' controls activity.

- Some aspects may be **linked each other**. So, focus could be posed only on some aspects that has been proved to be significantly correlated to others.



E.g., it's highly **probable that non-compliance** in the premise and plants **hygiene** are accompanied by some non-compliance in microbiological criteria of food.

Full **compliance with hygiene criteria** shall be linked to compliance in the implementation of the HACCP based procedures.

'Official' controls performance



Similarly, when considering historical data on non-compliances, **some non-compliance** may have a **higher likelihood to recur** in the future due, for example, to major difficulties to overcome them or lack of food safety culture. This shall help in **address 'official' control** on those areas that pose a higher risk of non-compliance.



EU FOOD SAFETY
AB GIDA GÜVENLİĞİ



- As the implemented **OCs frequency** and, possibly, methods, have a clear **impact on the operators** (because of administrative burden and operative disruption, request of payment of charges and fees, loss of goods, etc.), the **process** of coupling risk levels to OCs frequency shall be fully **transparent and unambiguous**
- Document establishing the **correlation between risk level and OCs** shall be made **public**.





- Legal framework for 'official' sampling procedures is in Regulation (EC) on official control 625/2017 – general rules.

CHAPTER IV

Sampling, analyses, tests and diagnoses

Article 34

Methods used for sampling, analyses, tests and diagnoses

1. Methods used for sampling and for laboratory analyses, tests and diagnoses during official controls and other official activities shall comply with Union rules establishing those methods or the performance criteria for those methods.



'Official' sampling procedures

Specific rules for sampling and analysis



Provisions for the sampling and analysis for the 'official' control of the maximum levels for contaminants have been laid down as follows:

- For the control of levels of mycotoxins: Implementing Regulation (EC)2023/2782
- For the control of levels of plant toxins: Implementing Regulation (EC)2023/2783
- For the control of levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs: Regulation(EC) 333/2007
- For the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs: Regulation 2017/644 and repealing Regulation (EC)589/2014
- For the control of levels of nitrates: Regulation (EC)1882/2006

For the control of perfluoroalkyl substances: Reg. (EC)2022/1428.



EU FOOD SAFETY
AB GIDA GÜVENLİĞİ

- Any human activity implicate some risk. The 'official' control system aims to prevent or reduce risks.
- To improve 'official' control efficacy and efficiency, 'official controls' shall be programmed and performed on a risk-base. This entails that any activity shall subject to an 'official controls' frequency related to its "relative risk".
- Establishments' risk categorisation requires data collection and assessment to be carried out in a transparent way and on sound scientific basis.



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

THANK YOU FOR YOUR ATTENTION



*Project funded by the European Union within the scope of the Aid Programme for the Turkish Cypriot community,
implemented by NSF Euro Consultants Consortium*