

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: Overview of food safety legislation framework

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Date: .....

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# **Module 1: Legislation in force - Registration and approval of FBOs**

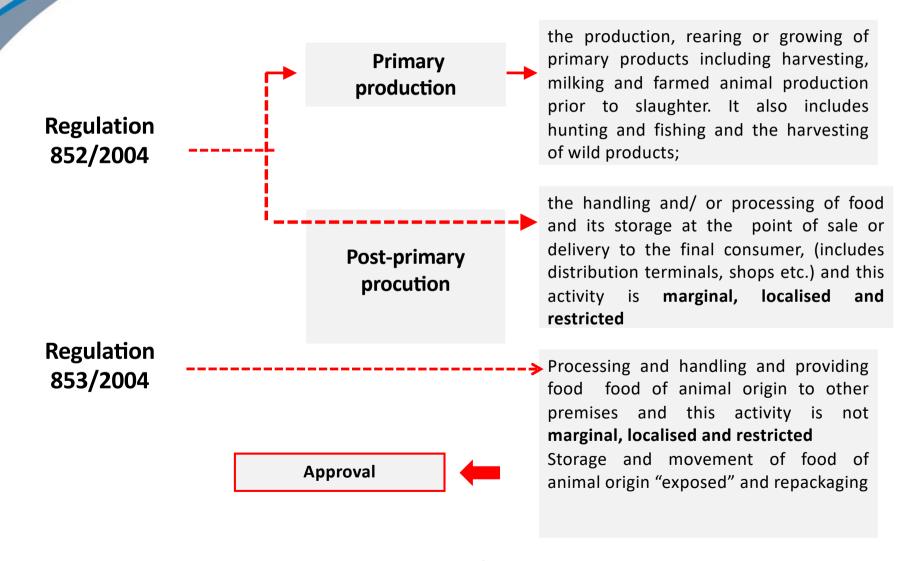


- ✓ Regulation (EC) No 852/2004 hygiene of foodstuffs
- ✓ Regulation (EC) No 853/2004 hygiene rules for food of animal origin
- ✓ Regulation (EC) No 625/2017 official controls
- ✓ Registration and approval of FBOs





## Food production activities covered by the hygiene package regulations



# Registration and approval of establishments



- Art. 6(3) Reg. No. (EC) 852/2004
- Art. 4 (1 and 2) Reg. No. (EC) 853/2004)

For registration establishments have to fulfil general hygiene requirement in Reg. No. (EC) 852/2004.

For approval establishments have to fulfil general and specific hygiene requirements in Reg. No. (EC) 852/2004 and Reg. No. (EC) 853/2004.



# Registration (Article 6 (2) of Regulation 852/2004)



- FB Operators (along with those who perform primary production) are obliged to inform the appropriate competent authorities for activities carried out in order to be registered.
- The purpose of registration is to allow the competent authorities in the Member States to know where food businesses are situated and what their activities are so as to enable official controls to be carried out whenever judged necessary by the national competent authority and in accordance with the general principles laid down in Article 31 of Regulation (EC) No 882/2004 which requires competent authorities in the Member States to establish procedures for feed and food business operators to follow when applying for registration.



# Approval (Art. 4 (1 and 2) Regulation 853/2004)



Establishments handling, preparing or producing products of animal origin (there is no limitation for capacity) for which specific requirements are laid down in Regulation (EC) No. 853/2004, must approved by the departments in charge for control of food of animal origin.



# Procedure for approval of establishments (Reg.625/2017, Art. 148)



The competent authority shall make an on-site visit

- Approve only: when the food business operator has demonstrated that it meets the relevant requirements of Regulations (EC) No 852/2004 and (EC) No 853/2004 and other relevant requirements of food law.
- Conditional approval if: it appears from the on-site visit that the establishment meets all the infrastructure and equipment requirements.
- Full approval only: if it appears from a new on-site visit carried out within three months of the granting of conditional approval that the establishment meets the other requirements referred to in (a). If clear progress has been made but the establishment still does not meet all of these requirements, the competent authority may prolong 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.





- Each approved establishment, including those with conditional approval will received an approval number, to which codes may be added to indicate the types of products of animal origin manufactured. (TCc 0112022)
- The VD shall keep the approval of establishments under review when carrying out controls
- If serious deficiencies are identified or establishment repeatedly has to stop production and the food business operator is not able to provide adequate guarantees regarding future production, the competent authority shall initiate procedures to withdraw the establishment's approval
- lists of approved establishments, with their respective approval numbers shall maintained up-to-date



# Annex III to Regulation (EC) 853/2004



Section | Meat of domestic ungulates

Section II
Meat form poultry and lagomorphs

Section III Meat of farmed game

• Section IV Wild game meat

Section V Minced meat, meat preparations and mechanically separated meat

Section VI Meat products

Section VII Live bivalve molluscs

Section VIII Fishery products

Section IX
 Raw milk and dairy products

• Section X Eggs and egg products

Section XI Frogs' legs and snails

Section XII Rendered animal fats and greaves

• Section XIII Treated stomachs, bladders and intestines

Section XIV Gelatine

• Section XV Collagen

# Examples of production facilities which are not subject to EU approval (The risk can be controlled only by applying of the provisions of Regulation 852/2004)



### **Example:**

- Production of <u>tins</u> based on transformed meat and vegetables
- Preparation of <u>pizzas</u> that contain ingredients of animal origin that are transformed (cheese, fish or transformed meat)
- Manufacture of soups based on meat extracts
- Preparing sandwiches with cheese and ham
- Production of <u>ice cream</u> based on milk that is transformed (heat treated milk)
- Production of <u>bakery</u> products
- Preparation or production of <u>ready to eat meals</u> based on transformed products of animal origin (transformed meat) and vegetables
- Production of <u>candies</u> (eg, chocolate, cookies that contain milk)
- Production of <u>mayonnaise</u> based on eggs products



#### Non-exhaustive list of establishments subject to approval under regulation 853/2004



#### Meat

- Slaughterhouses
- Cutting plants
- Slaughter on farm (except in the case of the direct supply by the producer of small quantities of meat from poultry-lagomorphs slaughtered on the farm to the final consumer and to retail establishments)
- Game handling establishment
- Establishments producing minced meat, meat preparations and MSM
- Establishment manufacturing meat products

#### Live bivalve molluscs

- Dispatch centres
- Purification centres

### **Fishery products**

- freezer vessels and factory vessels
- Establishments on land



#### Non-exhaustive list of establishments subject to approval under regulation 853/2004



#### Milk and dairy products

- Establishments processing raw milk into heat treated milk and into dairy products made from raw milk
- Establishments making dairy products from already processed dairy products (e.g. butter from pasteurised cream, cheese from pasteurised milk of milk powder)
- Milk collection centres

#### **Egg products**

Establishments processing eggs

### Frogs' legs and snails

• Establishments preparing and/or processing frogs' legs and snails

#### Rendered animal fats and greaves

- Establishments collecting, storing or processing raw materials
- Stomachs and bladders
- Establishments treating bladders, stomachs and intestines
- Gelatine
- Establishments processing raw materials





## Collagen

• Establishments processing raw materials

<u>Establishments for re-wrapping</u> (whether of not associated with other operations such as slicing, cutting)

### **Cold stores**

(insofar as they are used in relation to activities for which Annex III of Regulation 853/2004 lays down requirements)

#### Wholesale markets

(insofar products of animal origin are manufactured)



### Other establishments for production of food for which the approval is required



The risk for these establishments is identical to that found during the handling of raw products of animal origin such as fresh meat or products based on meat

# **Example:**

- Production of tins based on meat, vegetables and <u>fresh meat</u>
- Ice cream based on raw milk
- Preparation of skewer from fresh meat and vegetables



### **Approval of refrigerators - when?**



# No subject to approval:

- Refrigerators in Retails;
- Refrigerators for storage used in wholesale, which are limited to transport and storage (subject only to conditions relating to temperature).

# **Subject to approval:**

- Refrigerators for storage that are located within the premises working with products that are subject to the provisions of Annex III of Regulation 853/2004
- Refrigerators for storage of packaged meat used in wholesale subject to exchange within the Community or third countries;
- Refrigerators for storage used in wholesale but except the activities of transportation and storage also includes operations such as slicing and cutting of food and rewrapping.



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# THANK YOU FOR YOUR ATTENTION





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