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Hazards identification and characterization along the dairy production chain in Ukraine

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Two first steps of Risk Assessment (CAC)

Step 1.

Hazard identification

- Identify all the hazards which might be associated with the commodity in question
- This might be done by risk managers and/or risk assessors
- For example **Aflatoxin** and **Listeria monocytogenes**

Step 2.

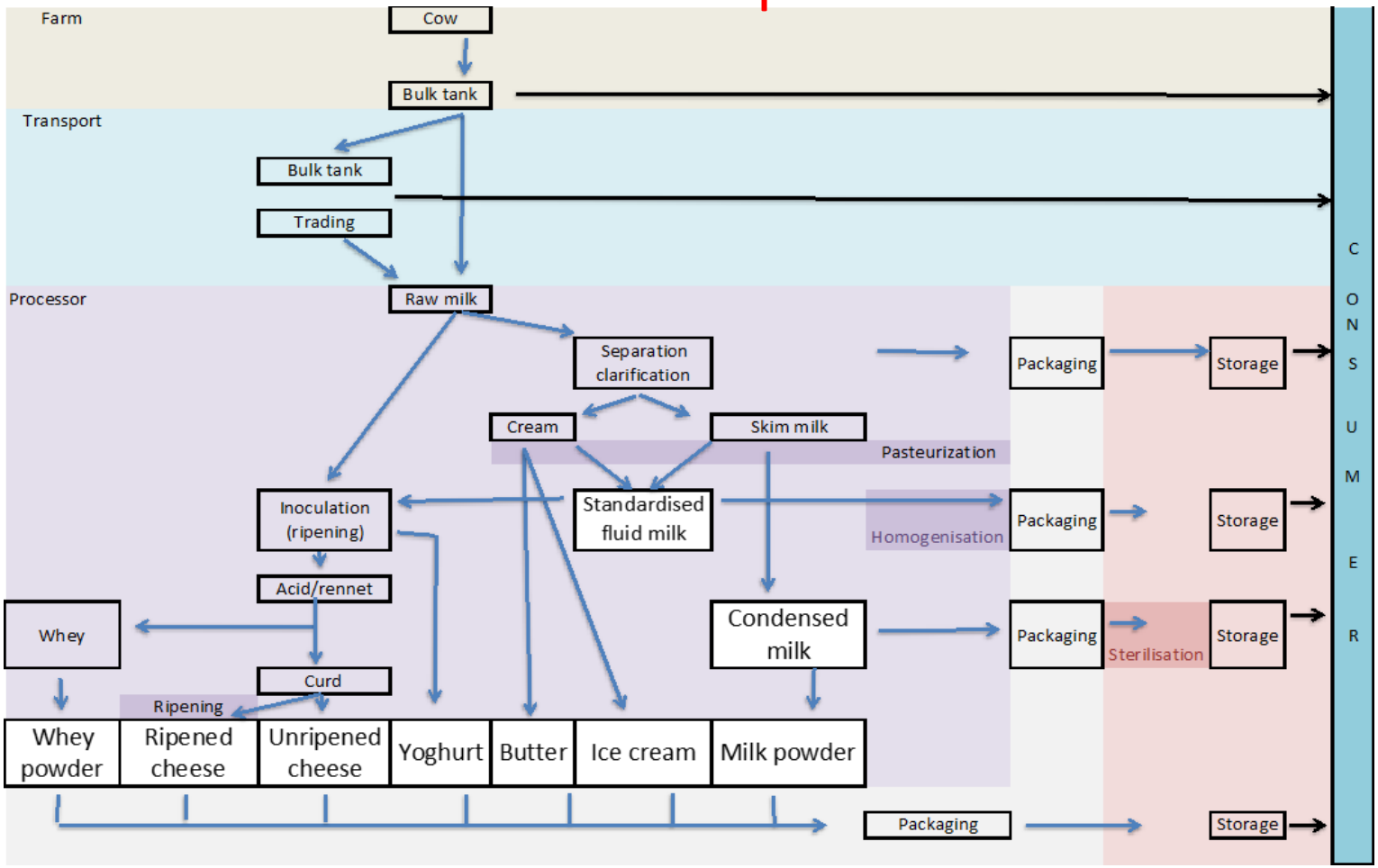
Hazard characterization

- For each hazard gather information about growth, inactivation and survival parameters; disease features; habitat, transmission, occurrence in humans, animals and dairy products, dose-response relationship.
- Also check for threshold values etc. in OIE code, EU regs and Codex Alimentarius, Ukrainian regs
- For each hazard, frame a risk question: for example "**What is the probability per year of human exposure/intoxication resulting from aflatoxin M1 in milk/milk products produced and consumed within Ukraine?**

Step 1. Hazard identification

at which level?

in animals or in animals products? or both?



Dairy chains from primary producer to consumer

Step 1. Hazard identification

DATA USED FOR HAZARD IDENTIFICATION?

For many established hazards

- information available in scientific literature
- animal and public health and surveillance data
- foodborne disease reports
- government agencies relating to the amounts, frequencies and sources of the hazard

For new emerging hazards

- clinical studies, epidemiological and animal studies

Examples:

Scientific article

International Dairy Journal 50 (2015) 32–44

Contents lists available at ScienceDirect

International Dairy Journal

journal homepage: www.elsevier.com/locate/idairyj

Review

A review of the microbiological hazards of dairy products made from raw milk

C. Verraes [a, *], G. Vlaemynck [b], S. Van Weyenberg [b], L. De Zutter [c, d], G. Daube [c, e], M. Sindic [c, f], M. Uyttendaele [c, g], L. Herman [b, c]

Food-borne disease report

European Food Safety Authority

EFSA Journal 2015;13(1):3991

SCIENTIFIC REPORT OF EFSA AND ECDC

The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2013[1]

European Food Safety Authority[2,3]

European Centre for Disease Prevention and Control[2,3]

European Food Safety Authority (EFSA), Parma, Italy

European Centre for Disease Prevention and Control (ECDC), Stockholm, Sweden

This scientific output published on 10 March 2016, replaces the earlier versions published on 28 January 2014 and 13 October 2015 (see page 2 for details).

Quiz 1

Can you nominated two hazards in milk or milk product?

EXAMPLE: CHEMICAL HAZARD IDENTIFICATION
AFLATOXINS

Key observations

• Aflatoxins are potent mutagens, i.e. they produce permanent changes in the genetic material

• They have been shown to induce liver cancer in most animal species that have been studied

• Most epidemiological studies show a correlation between exposure to aflatoxin B1 and increased incidence of liver cancer

• Aflatoxins are metabolised in humans and test animal species to produce the same reactive intermediate, which is considered to be responsible for generating changes in the genetic material

• It is estimated that 50–100% of cases of liver cancer are associated with persistent infection with hepatitis B and/or hepatitis C

Hazard identification

• Aflatoxins are considered to cause liver cancer in humans, based upon the weight of evidence

• Uncertainty relates to the extent to which aflatoxins are able to induce liver cancer in the absence of hepatitis infection

EXAMPLE: MICROBIOLOGICAL HAZARD IDENTIFICATION
Listeria monocytogenes

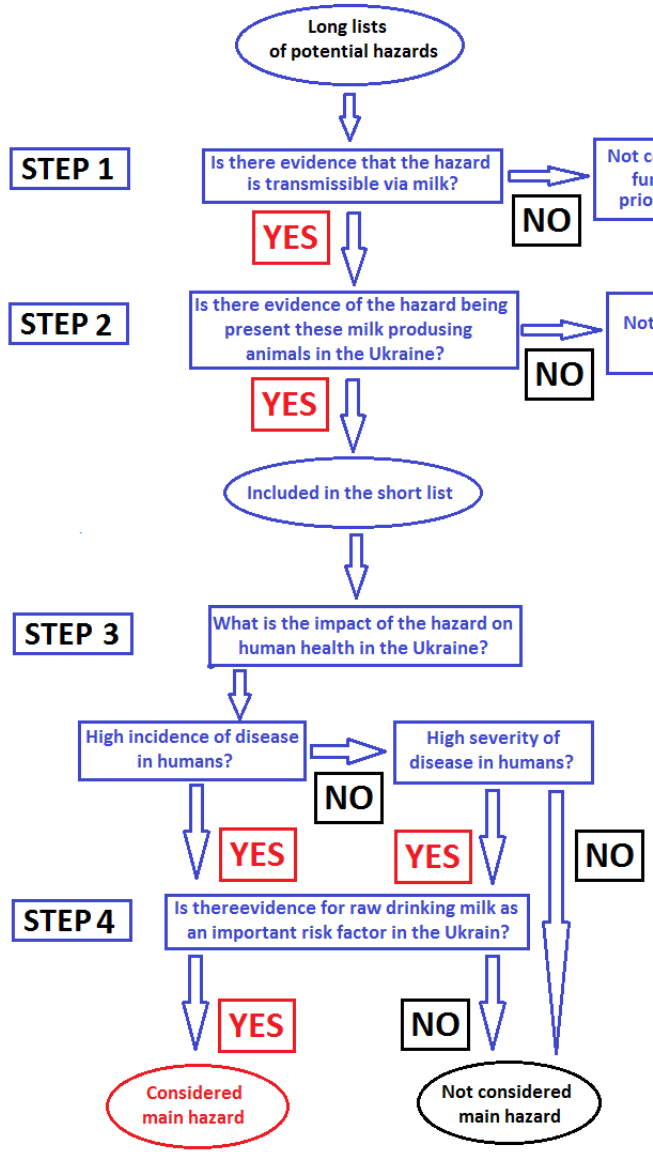
Key observations

- **It causes listeriosis in humans,** with symptoms including mild diarrhoea, meningitis, septicaemia, abortion and stillbirth
- **Epidemiological evidence** suggests that most exposure is foodborne
- **Cases are infrequent** but 20 to 40% are fatal in susceptible individuals
- **Illness is associated** with only a few virulent strains
- **Major risk factors** include immunosuppression, pregnancy and age

Hazard identification

- **Milk and dairy products,** particularly soft cheeses are implicated in outbreaks of listeriosis

Decision tree for prioritization of hazards associated with raw milk and dairy products



EFSA Journal 2015;13(1):3940
(www.efsa.europa.eu/efsajournal)

Step 2. Hazard characterization

Hazard characterization is closely linked to hazard identification

- **Hazard identification:** revealed the type(s) of hazard associated with a particular food or product

- **Hazard characterization:**
  - ✓"The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food"

  - ✓The focus is on the relationship between dose and response that is revealed in these studies and subsequent estimation of dose levels that may cause that response in humans

Step 2. Hazard characterization

Methodology of hazard characterization

Step 1. Process Initiation

Step 2. Data collection and Evaluation

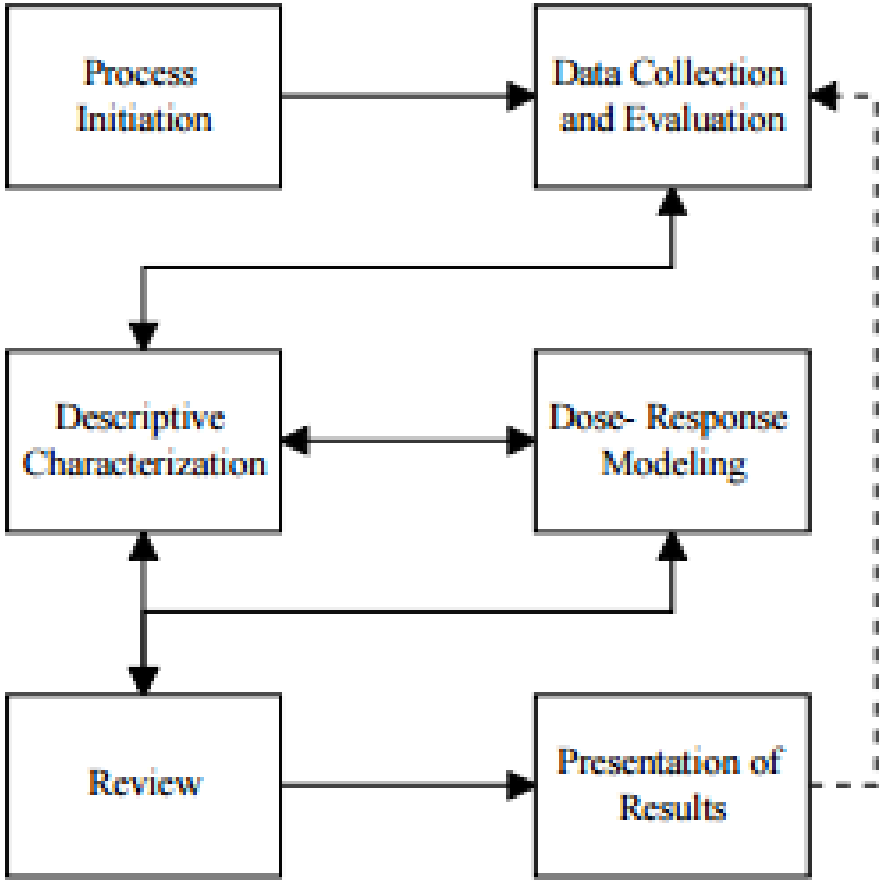
Step 3. Descriptive Characterization

Step 4. Dose-Response Modeling

Step 5. Review

Step 6. Presentation of hazard characterization results

Step 2. Hazard characterization



Process flow diagram for hazard characterization of pathogens

(Hazard characterization for pathogens in food and water : guidelines http://apps.who.int/iris/bitstream)

Step 2. Hazard characterization

Factors that need to be considered in microbiology hazard characterization

- **Factors related to the microorganism**
  - Speed of replication
  - Virulence and infectivity
  - Delay of onset following exposure

- **Factors related to the host (animal and human)**
  - Genetic factors
  - Host susceptibility characteristics
  - Age, pregnancy, nutrition, immune status etc.
  - Population characteristics
  - Population immunity, access to and use of medical care etc.

EXAMPLE: CHEMICAL HAZARD CHARACTERIZATION
AFLATOXINS

Characteristics:

- Animals are exposed to **aflatoxin B1** by consumption of **contaminated feeds**, when molds have produced mycotoxins at growth, harvest or storage.
- Transmission of the **toxin into milk** occurs as the metabolite **aflatoxin M1**. The amount of ingested aflatoxin B1 which is transferred into milk is between 0.17-3.3%.
- The **toxin is not destroyed by pasteurization** of milk.
- International Agency for Research on Cancer classified **aflatoxin M1** as possibly **carcinogenic for humans**.
- **Constant monitoring** throughout the milk production chain was recommended in a study, which found high **levels of AFM1** in investigated samples of milk.
- Chronic exposure is an ongoing issue and the dose-response relationship is therefore difficult to define.
- Code of practice for the reduction of aflatoxin B1 in raw materials and supplemental feeding stuffs for milk producing animals.

Ukrainian/ EU standards and threshold values:

- The Minimum list of analyses (the Order 16) sets a maximum limit of 0.0005 mg/kg for AFM1 in milk
- The European Commission Regulation 1881/2006 sets a maximum limit of 0.05 mg/kg for AFM1 in milk

Risk question:

What is the probability per year of human exposure/intoxication resulting from aflatoxin M1 in milk/milk products produced and consumed within Ukraine?

EXAMPLE: MICROBIOLOGICAL HAZARD CHARACTERIZATION

Listeria monocytogenes

Characteristics:

- Able to survive and grow at wide temperature ranges, pH levels and on many medias. Grows at low temperature (e.g. refrigeration).
- Whether it is killed by pasteurization is debated as a form of thermoresistance may develop under certain conditions.
- Human outbreaks are usually associated with ready-to-eat foods and soft cheeses (higher pH). However there are many outbreaks where no food is implicated.
- Present in the environment and linked to the use of stored forage (e.g. silage).
- Mainly a ruminant disease, causing encephalitis, septicemia and abortion.
- Vaccines difficult to develop. As this pathogen is not host-adapted to humans, but acts as an opportunistic infective agent, it is unlikely to have a single infective dose.

Ukrainian / EU standards and threshold values:

- Recommendation: keep concentration in food below 100 cfu/g

Risk question:

What is the probability per year of human exposure/infection/disease resulting from *L. monocytogenes* in raw or pasteurized milk/milk products produced and consumed within Ukraine?

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Thanks