

Status of risk analysis implementation in Ukraine



International commitments

WTO AGREEMENT on the Application of Sanitary and Phytosanitary Measures 981_006

Article 5

Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

1. Members shall ensure that their **sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks** to human, animal or plant life or health, taking into account **risk assessment techniques developed by the relevant international organizations**.
2. In the assessment of risks, Members shall take into account **available scientific evidence**; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest — or disease — free areas; relevant ecological and environmental conditions; and quarantine or other treatment.



Requirements of national legislation

LAWS OF UKRAINE:

- On Veterinary Medicine No 2498-XII
- On the Main Principles and Requirements for Safety and Quality of Food Products No 771/97-BP
- On State Control over Compliance with Legislation on Food Products, Feeds, Animal By-products, Animal Health and Welfare No 2042-VIII

Law of Ukraine on Veterinary Medicine

Article 12. Development, approval and review of veterinary and sanitary measures

3. Veterinary and sanitary measures shall be developed, approved and reviewed based on the following requirements:

- 1) All the veterinary and sanitary measures shall be based on scientific principles and evidence

Article 13. Risk analysis

1. Veterinary and sanitary measures shall be developed based on the quantitative or qualitative risk analysis.

2. A competent authority shall perform risk analysis with regard to possible import (sending) of food to the customs territory of Ukraine.

6. Risk analysis can also be performed with the purpose of development of veterinary and sanitary measures subject to application in Ukraine in the absence of the approved procedures of antiepidemiological measures or where they should be changed.

Law of Ukraine on the Main Principles and Requirements for Safety and Quality of Food Products

Article 15. Development, approval, review and application of sanitary measures

1. The relevant sanitary measures shall be developed, reviewed and approved by the central executive body according to the following requirements:

3) In the absence of international standards, guidelines or recommendations to ensure proper level of protection of human health or their insufficiency, **sanitary measures shall be developed based on the risk assessment** with account of risk assessment methods according to the standards established by the relevant international organizations;

2. **All the sanitary measures**, including the measures approved under exceptional circumstances, shall be **reviewed and updated** with the purpose of ensuring the conditions under which such measures would be applied exclusively within limits necessary for protection of human health, where:

- 1) new scientific information is received;
- 2) substantive comments from interested trade partners are received.

Law of Ukraine on State Control over Compliance with Legislation on Food Products, Feeds, Animal By-products, Animal Health and Welfare

Article 59. State control of the exporting country

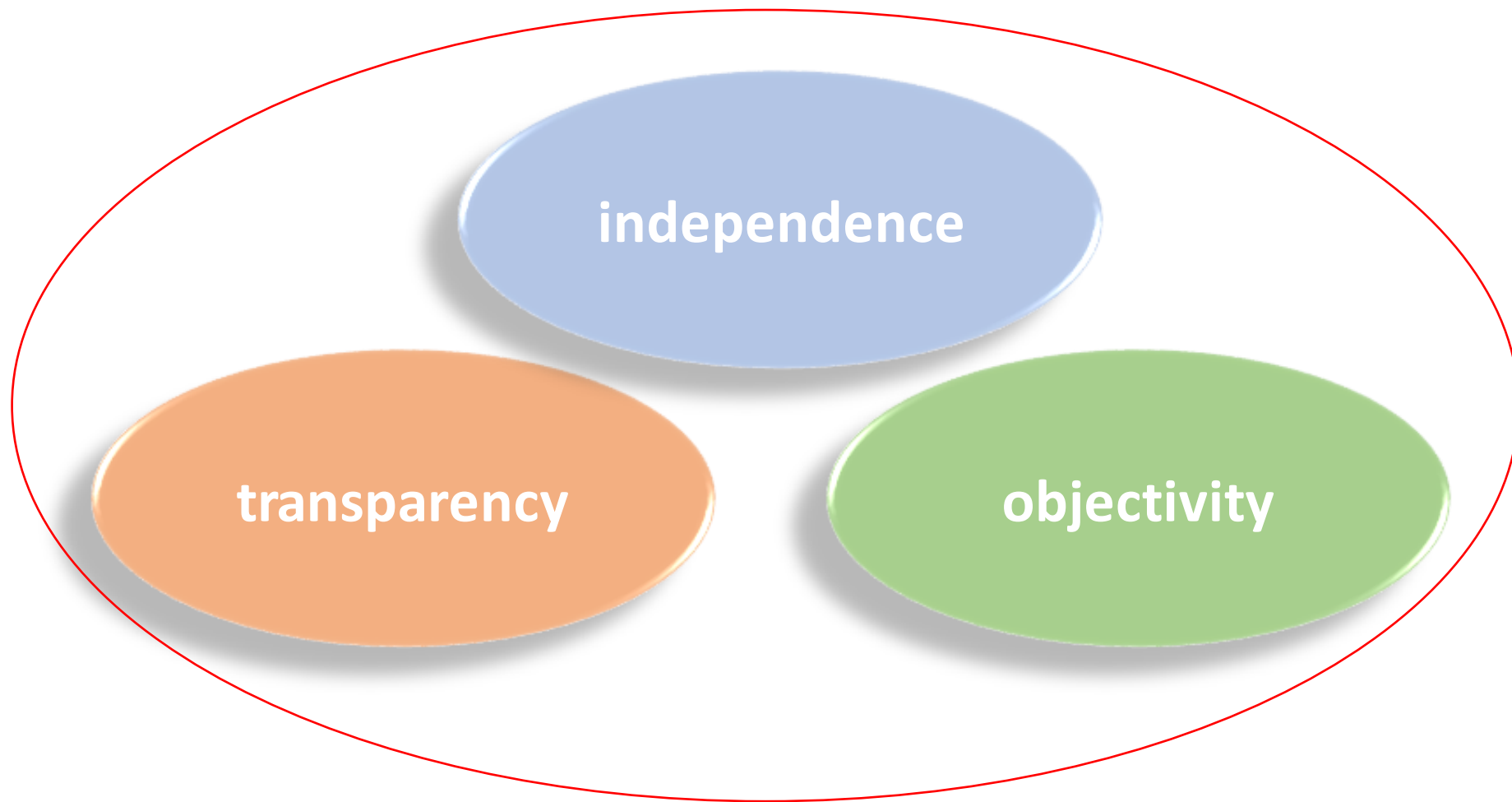
4. The frequency of state control of the exporting country by the Ukrainian competent authority of Ukraine shall be defined based on:

1) **risk assessment** with regard to live animals, food products and feed planned to be imported (sent) to the customs territory of Ukraine;

Article 60. Special conditions of import of food products, feed, animal by-products, biological products, reproductive material and live animals

shall be established based on the risk assessment which confirms existence of relevant threat to human and/or animal health

Principles of risk assessment



In order to comply with the principle of

independence

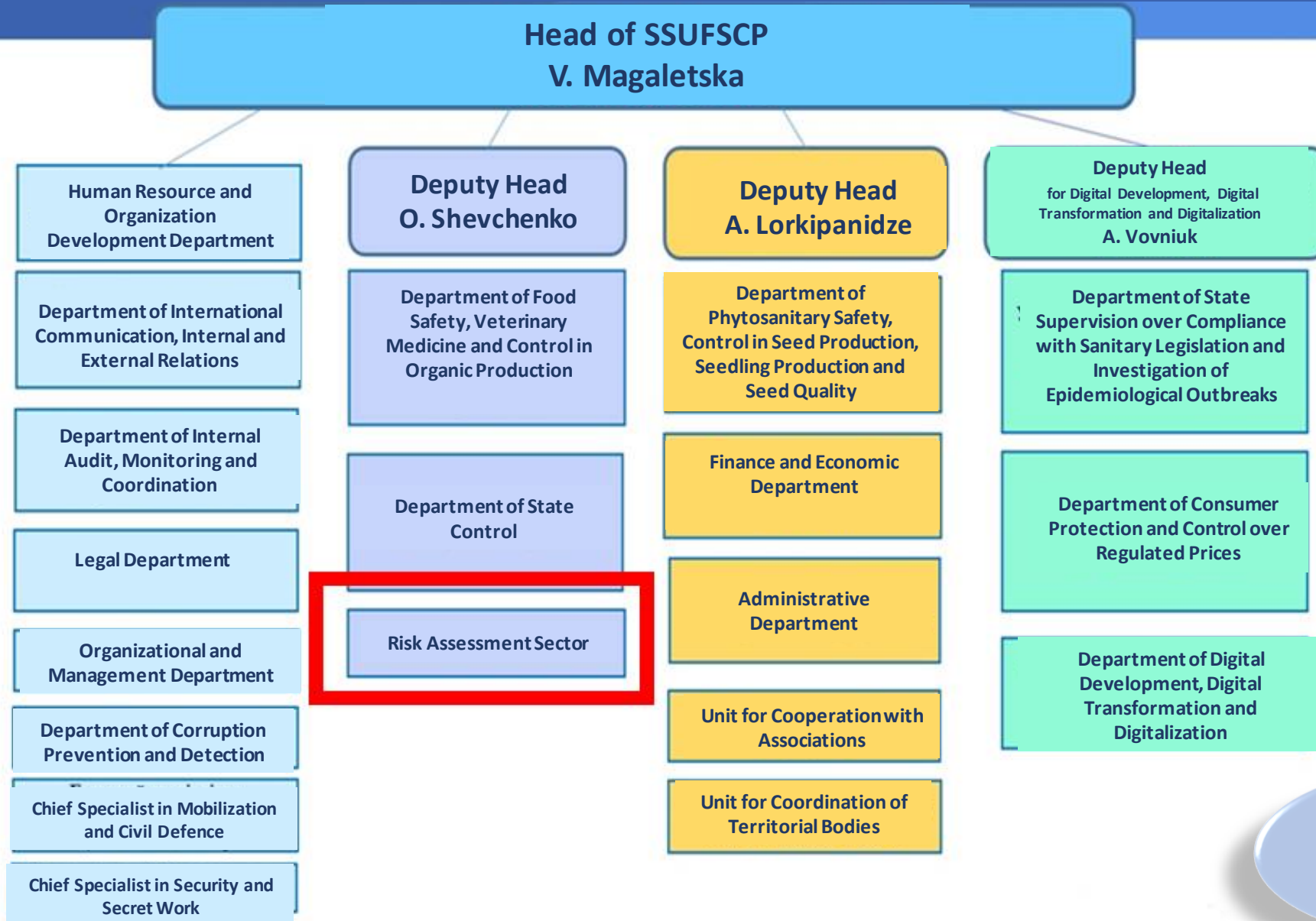
Codex Alimentarius clearly defines that:

- For proper risk analysis there should be **a functional separation of risk assessment and risk management**, in order to ensure the scientific integrity and to reduce any conflict of interest.
- A relevant risk assessment unit within the competent authority was first established in 2016 and was within the structure of different directorates,
but in order to comply with the principle of independence

starting from 01.10.2020 the Risk Assessment Sector is an independent structural unit of the State Service of Ukraine on Food Safety and Consumer Protection and has 2 full-time employees:

- ✓ Head of Sector
- ✓ Chief Specialist

State Service of Ukraine on Food Safety and Consumer Protection (SSUFSCP)

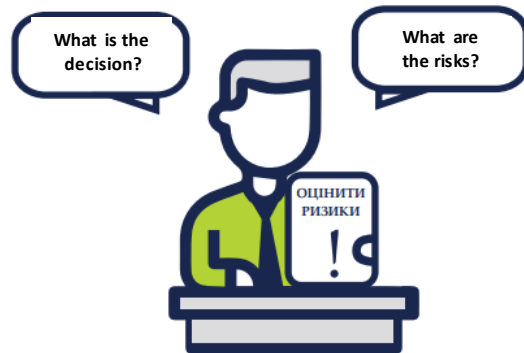


Independence



RISK MANAGER AND RISK ASSESSOR IN SSUFSCP: ROLES AND RESPONSIBILITIES OF THE PARTICIPANTS OF THE RISK ASSESSMENT PROCESS IN FOOD SAFETY AND ANIMAL HEALTH

Who acts as a risk manager?



- ✓ Head of SSUFSCP and deputies
- ✓ Heads of structural units

Who acts as a risk assessment coordinator?



- ✓ Head and specialists of the SSUFSCP Risk Assessment Sector

Who acts as a risk assessor?

Expert working group



- ✓ Scientists
- ✓ Experts who have experience and expertise in a certain field

Responsibilities of risk assessment participants

Who acts as a risk manager?



- ✓ Head of SSUFSCP and deputies
- ✓ Heads of structural units

- **Initiates** risk assessment
- **Clearly defines goal/objectives and type** of risk assessment, including timeline
- **Makes decisions** after risk assessment with account of the data found as a result of risk assessment
- **Implements measures** aimed to eliminate the risks found or mitigate them
- **Monitors and reviews** the decisions made and measures implemented
- Ensures **communication of the managerial decisions** based on the results of risk assessment to interested parties.

Who acts as a risk assessment coordinator?



- ✓ Head and specialists of the SSUFSCP Risk Assessment Sector

- Organizes and **coordinates** risk assessment
- Works jointly with a risk manager **to frame risk questions** within their mandate
- **Forms an expert working group** and involves them in risk assessment
- **Coordinates the data collection process**
- **Reports** on the risk assessment to risk managers
- Ensures **publication of risk assessment results**.

Who acts as a risk assessor?

Expert working group



- ✓ Scientists
- ✓ Experts who have experience and expertise in a certain field

- **Develops risk pathways and need for data**
- **Collects and analyses necessary data**
- Coordinates and **implements expert knowledge elicitation processes** with the purpose of data collection
- **Conducts risk assessment**
- **Prepares a report** on the results of risk assessment and recommendations regarding elimination or mitigation of the risks found
- **Reports to the coordinator**
- Contributes to preparation of articles and other types of **notification of risks**

To comply with the principles of:

independence



objectivity

✗ WHAT ARE THE RISK ASSESSMENT PARTICIPANTS PROHIBITED TO DO? ✗

Risk manager

✗ Interfere with a risk assessment process

✗ Take part in expert selection, be an expert or delegate the subordinates to the expert group



✗ Conceal information and data necessary for complex risk assessment

✗ Influence results and make any corrections in the risk assessment report

Risk assessment coordinator

✗ Non-transparent and judgemental selection of experts

✗ Influence expert opinions during risk assessment



✗ Change risk assessment results in the risk assessment report

✗ Conceal information and data necessary for complex risk assessment

Expert working group (risk assessors)

✗ Influence risk assessment with the purpose of own interest

✗ Ambiguously ignore the data due to own subjective beliefs



✗ Provide unsubstantiated data and information

✗ Disclose confidential information received in the process of risk assessment beyond this context

To comply with the principles of:

independence



objectivity

- **It is necessary to select independent scientific experts** to prepare impartial and documented basis for risk managers to make decisions
- ✓ The Risk Assessment Sector initiates formation of scientific expert risk assessment groups in:
 - Animal health and welfare (including zoonoses)
 - Biological hazards
 - Contaminants in food chain
 - Nutrition, innovative food products and food allergens
 - Food additives and flavourings
 - Feed and feed supplements for animals
 - Materials that come in contact with food, enzymes, technological substances
 - GMO



To comply with the principles of:

independence



objectivity

- A scientific expert risk assessment group will operate as a permanent working group and meet on request of SSUFSCP, where necessary.
- In addition, a general data base of scientific and technical experts will be formed. When necessary, these experts will support a scientific expert risk assessment group in some specific issues.
- The experts will be selected in a transparent manner based on their professional knowledge, experience and independence of interests.
- The selection procedure will be documented, including a declaration of possible conflict of interests.



Aim of cooperation with scientific organizations

Establishment of
scientific expert risk
assessment groups



Creation of the data base
of experts



Establishment of a
network of scientific
organizations



Data collection, analysis and risk assessment according to the standards and requirements established by relevant international organizations

Scientific and research institutes of SSUFSCP



State Scientific and Research
Institute of Laboratory
Diagnostics and
Veterinary and Sanitary
Expertise



State Scientific and Research Control
Institute of Veterinary Medicinal
Products and Feed Supplements



State Scientific and Research Control
Institute of Biotechnology and Strains of
Microorganisms

Memorandum of cooperation with national scientific organizations

Today, 9 memoranda are signed:



Bila Tserkva National Agrarian University (BNAU)



Institute of Veterinary Medicine of the National Academy of Agrarian Science (IVM)



National Scientific Centre, Institute of Experimental and Clinical Veterinary Medicine (NSC IECVM)



National University of Life and Environmental Sciences of Ukraine (NUBiP)



Odesa State Agrarian University (OSAU)



Polissya National University (PNU)



Poltava State Agrarian University (PSAU)



Sumy State University (SSU)



Stepan Gzhytsky Lviv National University of Veterinary Medicine and Biotechnology

...but networking with other organizations is ongoing ...

Memorandum of cooperation with international organizations

Memorandum signed:



**RISK ASSESSMENT
CENTER ON FOOD CHAIN**

Risk Assessment Centre on Food Chain, Bulgaria

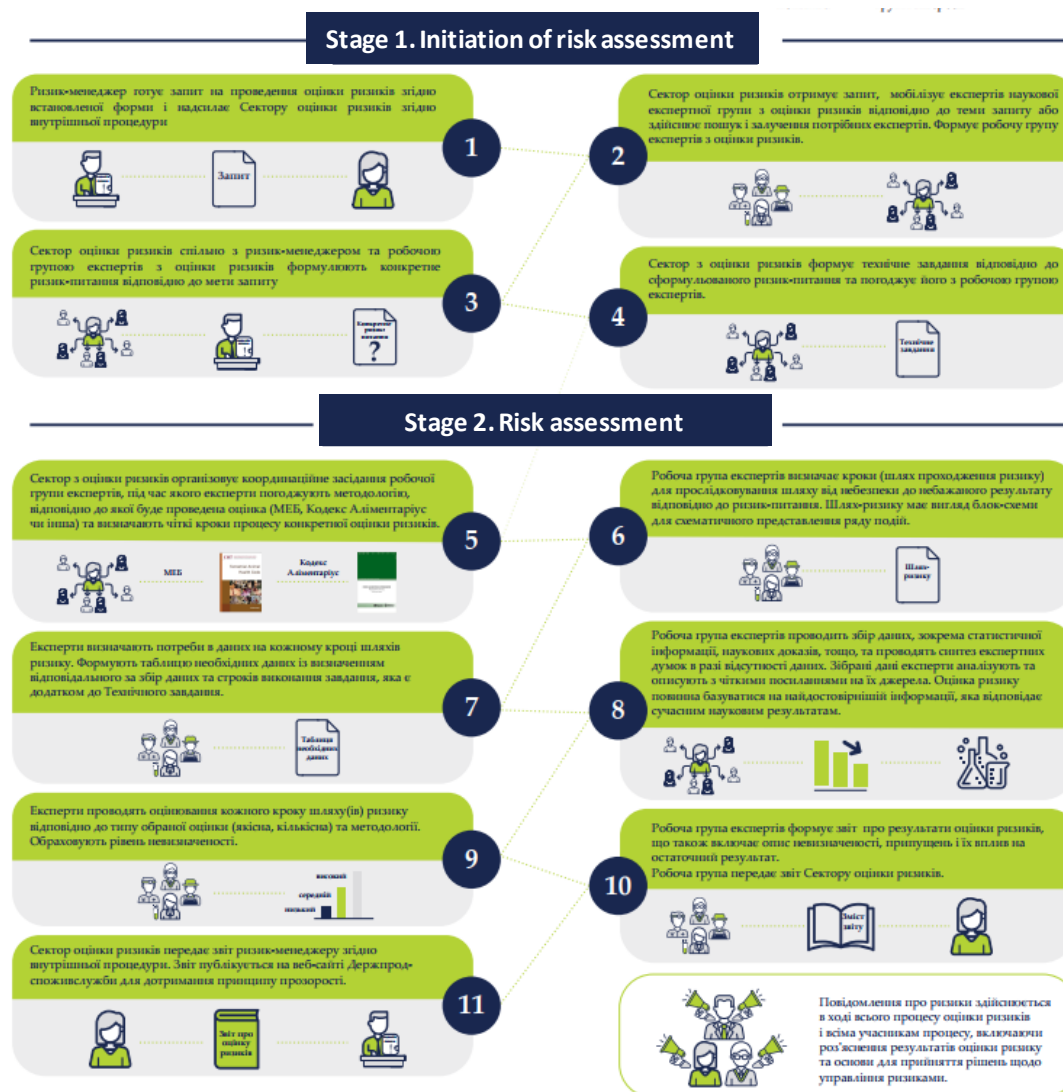
Memorandum negotiated:



European Food Safety Authority

... but networking with other international organizations is ongoing ...

Risk assessment process in SSUFSCP



The entire risk assessment process is divided into two stages:

- initiation of risk assessment
- risk assessment

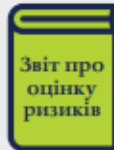
Every step is clearly described with annexes in the **Standard Operating Procedure for a General Approach to Independent Science-Based Risk Assessment in Animal Health, Food and Feed Safety spheres**

To comply with the principle of:

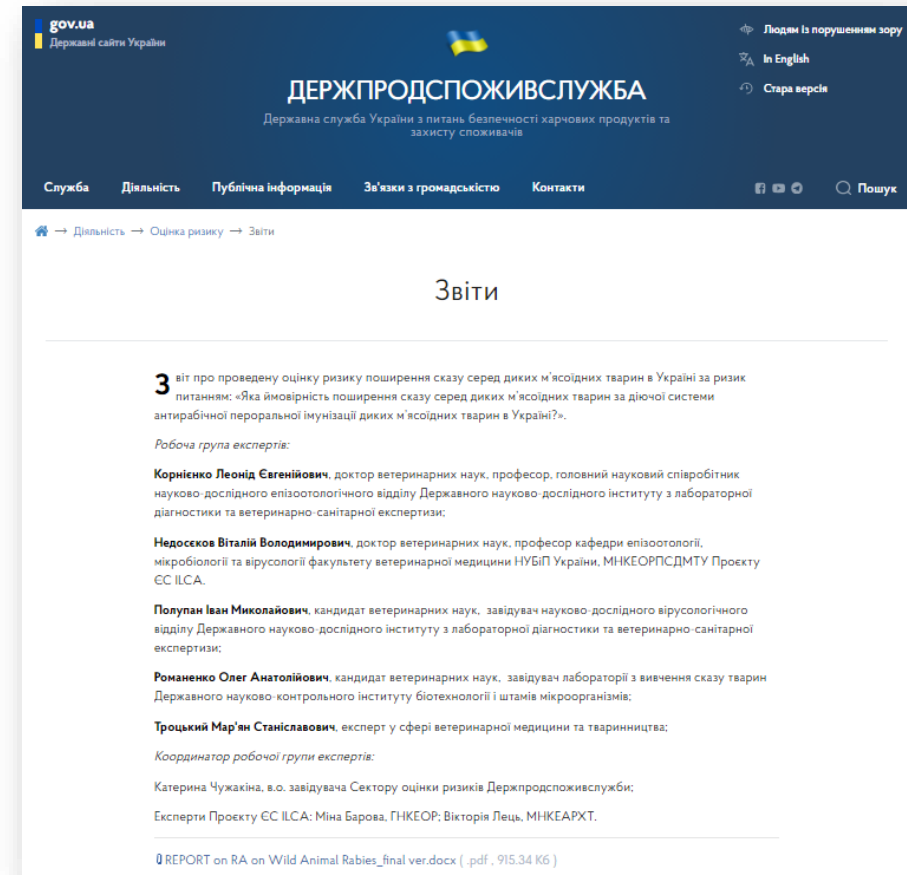
transparency

Stage 2. Risk assessment

The Risk Assessment Unit transfers the report to the risk manager according to the internal procedure. The report is published on the SSUFSCP website to comply with the principle of transparency.

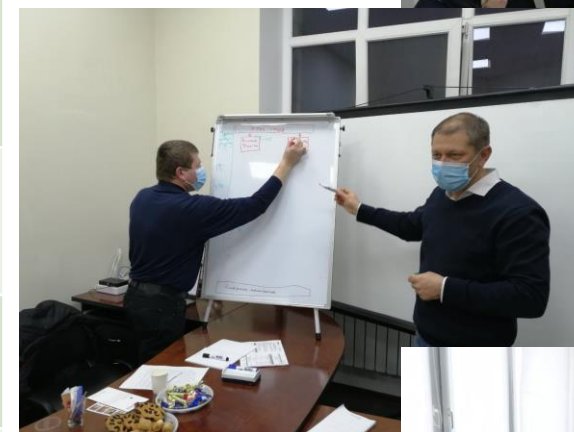
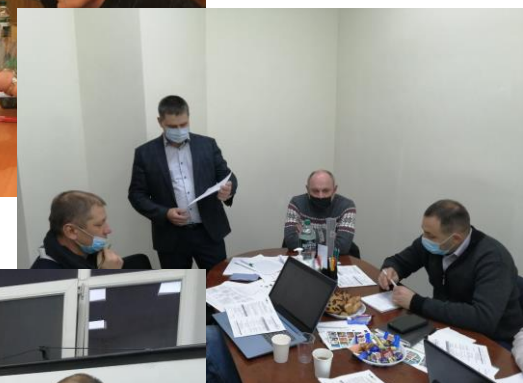


11

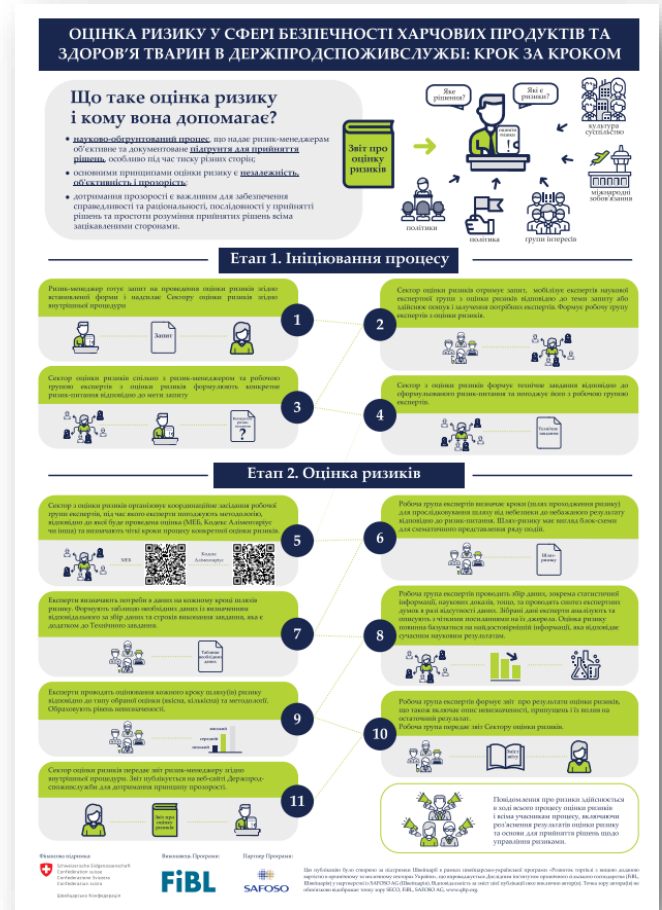
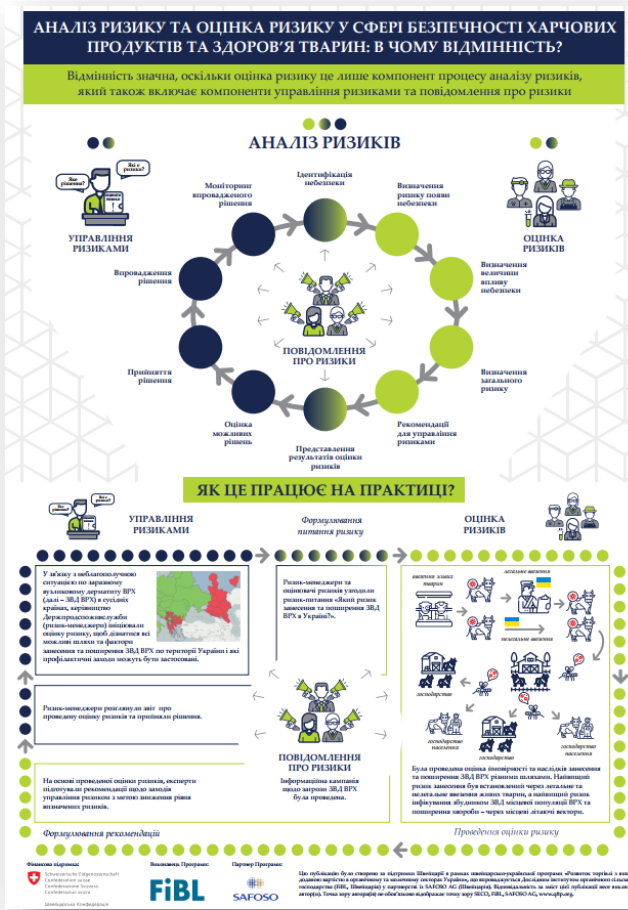


Risk assessments conducted by SSUFSCP

№	Name	Year
1.	Risk assessment of enterotoxigenic strains <i>Staphylococcus</i> spp. in pasteurized milk in Ukraine (<i>with educational purpose</i>)	2016-2017
2.	Risk assessment of probability of introduction and spread of lumpy skin disease in Ukraine (<i>with educational purpose</i>)	2018-2019
3.	Risk assessment of spread of rabies among wild carnivorous animals under the existing system of rabies peroral immunisation of wild carnivorous animals in Ukraine.	2020
4.	Risk assessment of spread of rabies among pets and domestic animals in Ukraine	2021
5.	Risk assessment of introduction and spread of bovine spongiform encephalopathy in Ukraine	2021
6.	Risk assessment of impact of using live vaccines for poultry salmonellosis in parent flock	Ongoing



Capacity development of SSUFSCP employees and scientists as to risk analysis and assessment



Capacity development of SSUFSCP employees and scientists as to risk analysis and assessment

Distance learning courses:

Course 1. Concept of risk analysis and assessment in food safety and animal health: introductory level

Module	Lesson
Module 1. Concept of risk analysis	Introduction to principles of risk analysis
	Approaches to risk analysis (Codex Alimentarius Commission, OIE)
	Risk assessment and risk management: roles and responsibilities
Module 2 Risk assessment: introductory level	Introduction to principles of risk analysis
	Qualitative risk assessment: introduction
	Quantitative risk assessment: introduction
	How to conduct risk assessment: step by step (within the requirements established by Codex Alimentarius Commission and OIE)
	Rapid risk assessment

Course 2. Risk assessment in food safety and animal health: practical level

Module	Lesson
Module 1. Risk assessment: practical level	Framing a risk question
	Risk pathway
	Data: identification, search and collection
	Data analysis (including basis statistical analysis)
	Methodology of elicitation process
	Risk assessment process (focus on qualitative risk assessment)
	Risk assessment process (focus on quantitative risk assessment)
	Uncertainty in risk assessment
	Risk assessment report



ДЕРЖПРОДСПОЖИВСЛУЖБА

Державна служба України з питань безпеки харчових продуктів та захисту споживачів

Людям із порушенням зору

In English

Стара версія

Служба Діяльність Публічна інформація Міжнародне співробітництво Контакти

Пошук

Діяльність → Оцінка ризику

Оцінка ризику

Анонси

Події

Звіти

Інформаційні матеріали

Мапа порталу



Держпродспоживслужба

01001, м.Київ, вул. Б. Грінченка, 1

Приймальня

(044) 279 12 70

Цілодобова Гаряча лінія
(Call-центр)

(044) 364 77 80, (050)
230 04 28

Електронна пошта

info@dpss.gov.ua



Державна служба України з питань безпеки харчових продуктів та захисту споживачів



Людям із порушенням зору

In English

Thank you for attention!

