



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

**Consultation exercise
on annual risk assessment for Bovine Spongiform Encephalopathy (BSE)**

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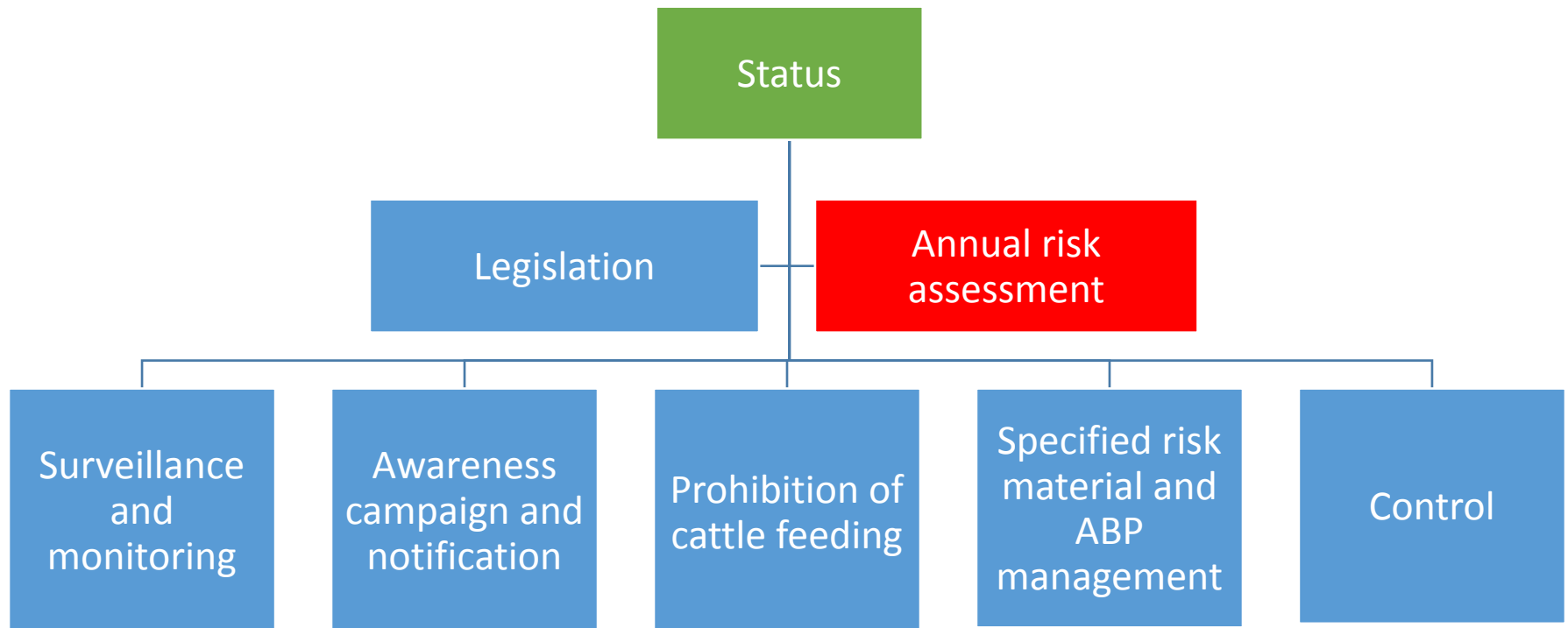


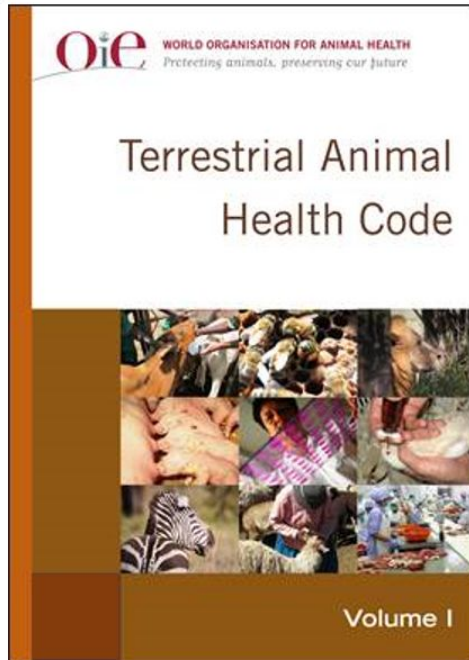
BSE RA based on the Section 2 and Chapter 11.4 of the Terrestrial Animal Health Code:

- formation of risk questions;
- developing of risk pathways;
- identifying the required data at each step of the risk pathway;
- data collection and analysis of necessary data (evidence);
- process of risk estimation;
- calculation and description of uncertainty;
- preparation of the report and recommendations for the improving the BSE control system



The criteria for determination of official status of BSE





CHAPTER 1.8.
APPLICATION FOR OFFICIAL RECOGNITION
BY THE OIE OF RISK STATUS
FOR BOVINE SPONGIFORM ENCEPHALOPATHY

Article 1.8.2

The Delegated Person of the Member State applying for the official recognition of the BSE status of cattle in the cattle population of the country or zone must provide documented evidence demonstrating that a **risk assessment has been carried out in accordance with Section 2 and Section 11.4** of the Terrestrial Animal Health Code.

SECTION 2.
RISK ANALYSIS

CHAPTER 2.1.
IMPORT RISK ANALYSIS

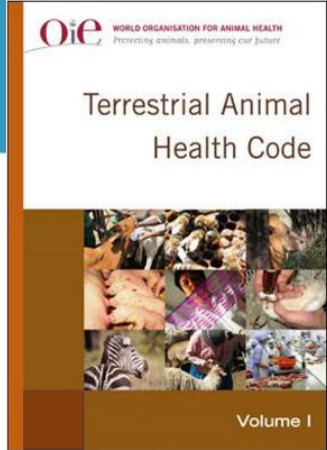
CHAPTER 11.4.
BOVINE SPONGIFORM ENCEPHALOPATHY

BSE risk assessment

SECTION 2.
RISK ANALYSIS

CHAPTER 2.1.
IMPORT RISK ANALYSIS

Article 2.1.3 Principles of risk assessment



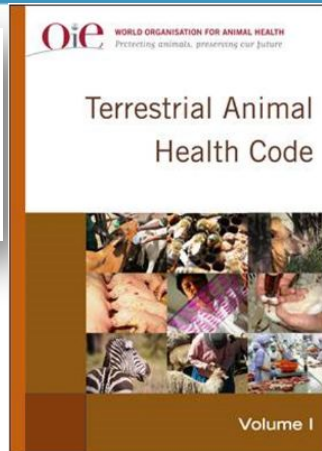
- ✓ **Risk assessment should be flexible to deal with the complexity of real-life situations.** No single method is applicable in all cases. Risk assessment should be able to accommodate the variety of animal commodities, the multiple hazards that may be identified with an importation and the specificity of each disease, detection and surveillance systems, exposure scenarios and types and amounts of data and information.
- ✓ Both qualitative risk assessment and quantitative risk assessment methods are valid.
- ✓ The **risk assessment should be based on the best available information that is in accordance with current scientific thinking.** The assessment should be well-documented and supported with references to the scientific literature and other sources, including expert opinion.
- ✓ Consistency in risk assessment methods should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding by all the interested parties.
- ✓ Risk assessments should document the uncertainties, the assumptions made, and the effect of these on the final risk estimate.
- ✓ Risk increases with increasing volume of commodity imported.
- ✓ The **risk assessment should be amenable to updating when additional information becomes available.**



CHAPTER 11.4.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 11.4.2



The BSE risk status of the cattle population of a country, zone or compartment should be determined on the basis of the following criteria:

- **the outcome of a risk assessment**, based on the provisions of the Terrestrial Code, identifying all potential factors for BSE occurrence and their historic perspective.

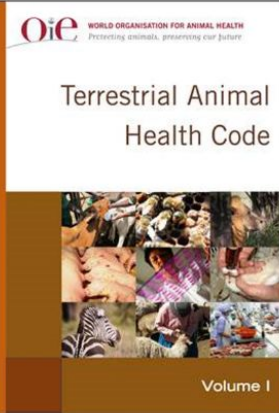
Member Countries **should review the risk assessment annually** to determine whether the situation has changed.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 11.4.2

Entry assessment

- the presence or absence of the BSE agent in the indigenous ruminant population of the country, zone or compartment and, if present, evidence regarding its prevalence;
- production of *meat-and-bone meal* or *greaves* from the indigenous ruminant population;
- imported cattle, sheep and goat
- imported meat-and-bone meal or greaves;
- imported animal feed and feed ingredients;
- imported products of ruminant origin for human consumption, which may have contained tissues listed in Article 11.4.14. and may have been fed to cattle;
- imported products of ruminant origin intended for *in vivo* use in cattle





CHAPTER 11.4.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 11.4.2

If the entry assessment identifies a risk factor, an exposure assessment should be conducted, consisting of assessing the likelihood of cattle being exposed to the BSE agent, through a

Exposure assessment

- recycling and amplification of the BSE agent through consumption by cattle of meat-and-bone meal or greaves of ruminant origin, or other feed or feed ingredients contaminated with these;
- the use of ruminant carcasses (including from fallen stock), by-products and slaughterhouse/abattoir waste, the parameters of the rendering processes and the methods of animal feed manufacture;
- the feeding or not of ruminants with meat-and-bone meal and greaves derived from ruminants, including measures to prevent cross-contamination of animal feed;
- the level of surveillance for BSE conducted on the cattle population up to that time and the results of that surveillance





1. **Creation of the working experts group**
2. Framing of **risk question** (identify undesirable outcome)
3. Developing of the **risk pathways** to get from hazard of interest to unwanted outcome in the target population
4. **Identifying data and information** needs
5. **Data collection and analysis of necessary data (evidence)** to estimate the probability of each event in the pathway
6. **Risk estimation**
 - *Qualitatively*
7. **Calculation and description of uncertainty;**
8. **Recommendations** for the improving the BSE control system
9. **Preparation of the report**

RESULTS





1. Creation of the working experts group

The experts that would participate in this group should be familiar/involved with:

- control of imported food products, feed and feed additives, meat and bone meal, and live animals,
- BSE monitoring and surveillance,
- control over the activities of slaughterhouses,
- manufacturers of feed and feed additives,
- control of the handling of animal by-products not intended for human consumption,
- control over compliance with the ban on feeding ruminants with feed containing ruminant protein.



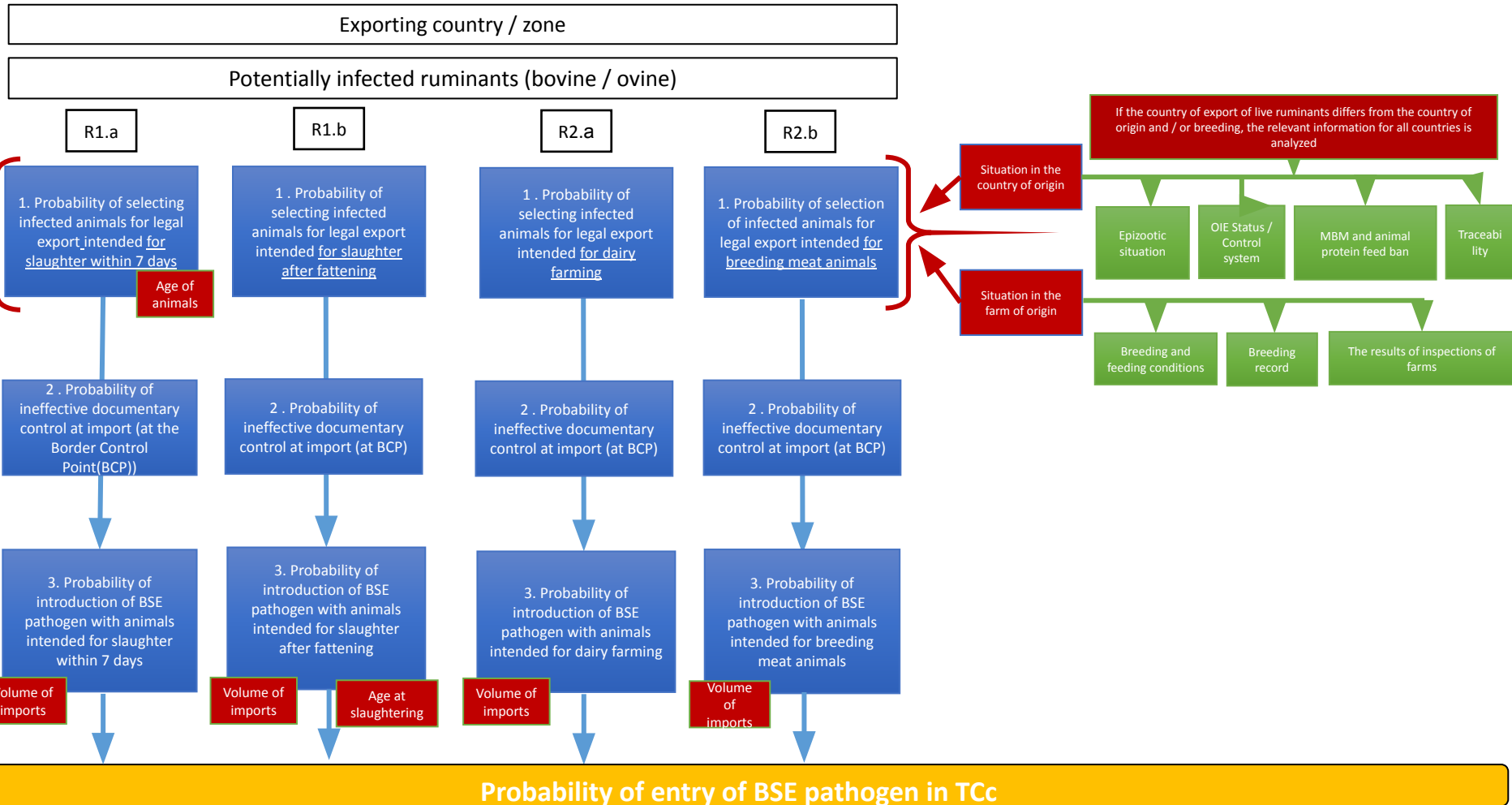
2. Framing of risk question (identify undesirable outcome)

«What is the probability of introduction and spread of the BSE into the northern part of Cyprus?»



3. Developing of risk pathways

Risk Pathways of BSE Entry in TCc during Imports of Live Animals





Risk Pathways of BSE Entry in TCc during Imports of MBM from Ruminants and other animal's species

Exporting country / zone
Meat and bone meal (MBM) from ruminants potentially contaminated with BSE pathogen

R3.a R3.b

Situation in the country of origin of the animals from which the MBM was produced

If the country of export of live ruminants differs from the country of origin and / or breeding, the relevant information for all countries is analyzed

Procedures
Separation of production lines

1. Probability of production of MBM contaminated with BSE

Epizootic situation
OIE Status / Control system
MBM feed ban
Traceability

Killing method
Specific Risk Materials (SRM) removal
SRM disposal

Dead animals' management system

a) From dead ruminants b) From slaughtered ruminants

Storage together with other batches

2. Probability of contamination of MBM with BSE during storage

Procedure and type of packaging

3. Probability of contamination of MBM with BSE during packaging

4. Probability of failure to detect BSE pathogen in MBM during state control over imports

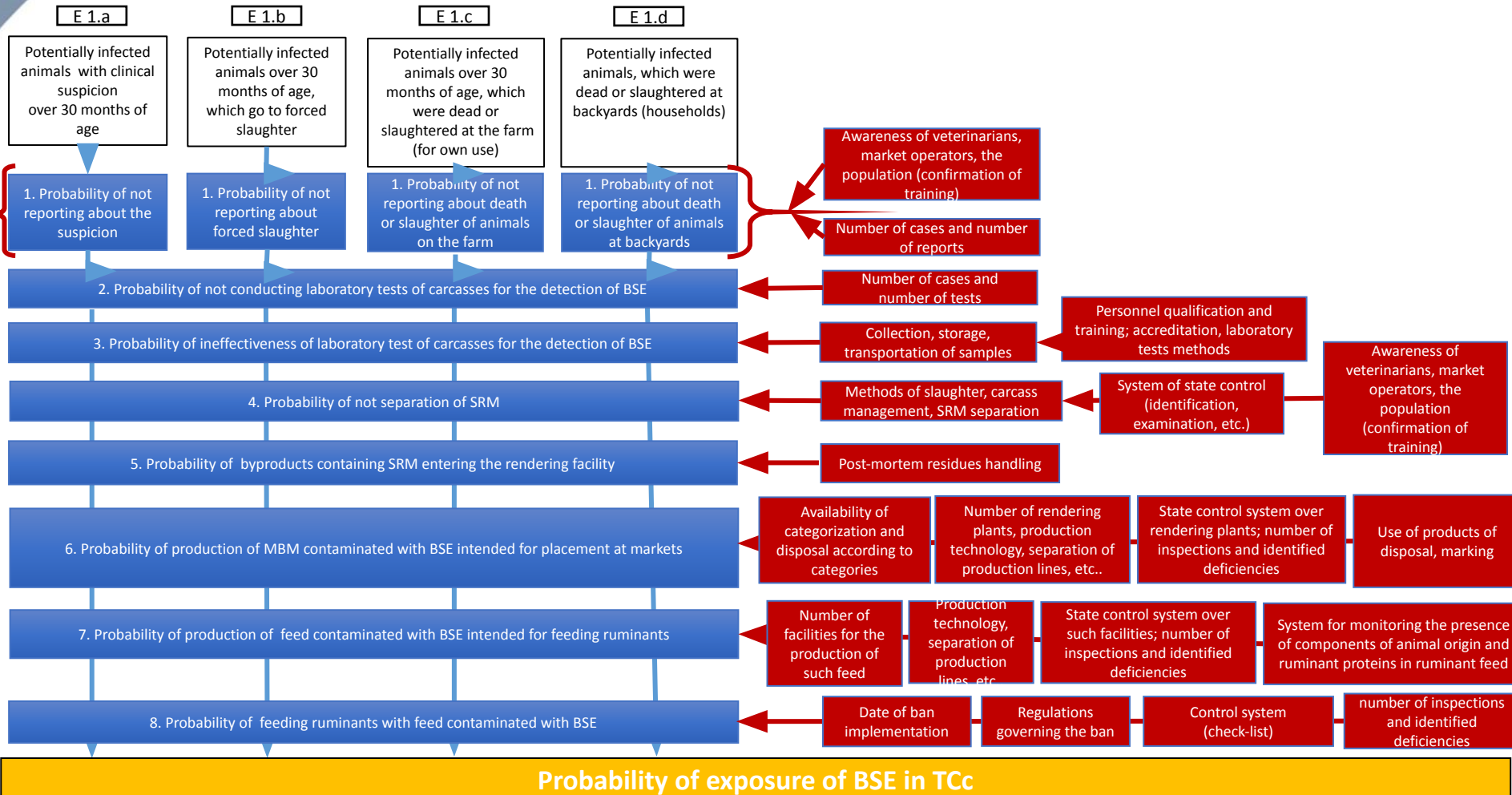
Volume of imports

5. Probability of entry of BSE pathogen during importation of MBM intended for animal feeding

Probability of entry of BSE pathogen in TCc



Risk Pathways of BSE Exposure





Risk Pathways of BSE Exposure

E5.a E5.b E5.c E5.d

Potentially contaminated with BSE imported

MBM from ruminants

Greaves from ruminants

MBM from other species

Greaves from other species

1. Probability of production of feed contaminated with BSE intended for feeding ruminants

2. Probability of ineffectiveness of the system for monitoring the presence of components of animal origin and ruminant proteins in feed for ruminants

3. Probability of feeding ruminants with feed contaminated with BSE

Availability of ingredients on the market

Description of the feed industry, the number of enterprises for the manufacture of such feed, production technology

The system of state and internal control over such enterprises

Monitoring program availability

Number of lab. tests (coverage)

Methods and reliability of lab. tests

Date of ban implementation

Regulations governing the ban

Control system (check-list?)

number of inspections and identified deficiencies

Animal housing system (percentage of farms where cattle are kept with other animals)

Cross-contamination during transportation, storage and feeding of ruminant

Probability of exposure of BSE in TCc



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RESULTS





4. Identifying **data** and **information** needs

- A risk assessment requires lots of data: the data required to assess the **likelihood of occurrence** of each step of the pathway must be identified
- How to determine **which data** precisely?
 - The data should help to answer the risk question
 - The risk pathway helps to determine what kind of data you need



Risk Pathways of BSE Entry in TCc during Imports of MBM from Ruminants and other animal's species

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Volume of imports

5. Probability of entry of BSE pathogen during importation of MBM intended for animal feeding

Probability of entry of BSE pathogen in TCc



4. Identifying data and information needs

Entry assessment

The potential for the entry of the BSE agent through the **importation of meat-and-bone meal or greaves** (Article 11.4.24, edition 2022)

- Documentation to support claims that meat-and-bone meal, greaves or feedstuffs containing either meat-and-bone meal or greaves have not been imported, OR
- Where meat-and-bone meal, greaves or feedstuffs containing them have been imported, documentation of country of origin and, if different, the country of export.
- Documentation on annual volume, by country of origin, of meat, greaves or feedstuffs containing them imported during the past eight years.
- Documentation describing the composition (on a species and class of stock basis) of the imported meat-and-bone meal, greaves or feedstuffs containing them.
- Documentation, from the country of production, supporting why the rendering processes used to produce meat-and-bone meal, greaves or feedstuffs containing them would have inactivated, or significantly reduced the titre of BSE agent, should it be present.
- Documentation describing the fate of imported meat-and-bone meal and greaves.



4. Identifying data and information needs

Entry assessment

The potential for the entry of the BSE agent through the importation **of live animals potentially infected with BSE** (Article 11.4.25, edition 2022)

- Documentation on the country of origin of imports. This should identify the country of breeding of animals, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing origins, species and volume of imports.
- Documentation describing the fate of imported animals, including their age at slaughter.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.



4. Identifying data and information needs

Entry assessment

The potential for the entry of the BSE agent through the **importation of products of animal origin potentially infected with BSE** (Article 11.4.26, edition 2022)

- Documentation on the country of origin of imports. This should identify the country of breeding of animals, the length of time they lived in that country and of any other country in which they have resided during their lifetime.
- Documentation describing origins, species and volume of imports.
- Documentation describing the end use of imported animal products, and the disposal of waste.
- Documentation demonstrating that risks are periodically reviewed in light of evolving knowledge on the BSE status of the country of origin.



4. Identifying data and information needs

Exposure assessment

The potential for the exposure of cattle to the BSE agent through consumption of meat-and-bone meal or greaves of ruminant origin (Article 11.4.27, edition 2022)

- Evidence that cattle have not been fed products of animal origin (other than milk or blood) potentially containing meat-and-bone meal or greaves of ruminant origin within the past eight years.



4. Identifying data and information needs

Exposure assessment

The origin of animal waste, the parameters of the rendering processes and the methods of animal feed production (Article 11.4.28, edition 2022)

- Documentation describing the collection and disposal of fallen stock and materials condemned as unfit for human consumption.
- Documentation describing the definition and disposal of specified risk material, if any.
- Documentation describing the rendering process and parameters used to produce meat-and-bone meal and greaves.
- Documentation describing methods of animal feed production, including details of ingredients used, the extent of use of meat-and-bone meal in any livestock feed, and measures that prevent cross-contamination of cattle feed with ingredients used in monogastric feed.
- Documentation describing monitoring and enforcement of the above.



5. Collecting data and information to estimate the probability of each event in the pathway

- The collected data are analyzed and described by experts with clear references to their sources or annexes.

2.4 Epidemiology

The transmission between animals through direct contact is inefficient according to experimental and field evidence. However, experimental intravenous transmission was successful, what indicates that the natural cases of LSDV are probably spread by blood-sucking arthropods (2,21).

In a study assessing outbreak dynamics and risks factors by analyzing a dataset collected during a LSD Outbreak in 2006 in Israel, three transmission modes were mathematically modelled: Indirect contact within groups within a herd, direct contact or contact via common drinking water within the groups and transmission by contact during milking procedures. The overall effect of indirect contact was assessed to be five times larger than any other way. It is concluded that direct contact is hardly responsible for LSDV transmission and that it occurs probably mostly by flying, blood-sucking insects (22) (23).

- Risk assessment should be based on the most reliable information.



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RESULTS





6. Risk estimation

Entry assessment

What is the probability of introduction of the BSE into the northern part of Cyprus with the...

- imported cattle, sheep and goat
- imported meat-and-bone meal or greaves;
- imported animal feed and feed ingredients;
- imported products of ruminant origin for human consumption



6. Risk estimation

Exposure assessment

What is the probability of spread of the BSE in the northern part of Cyprus from the...

- potentially infected animals older than 30 months with clinical suspicion?
- potentially infected animals older than 30 months, which are going to forced slaughter?
- potentially infected animals older than 30 months, that died or were slaughtered on the farm (for their own needs)?
- potentially infected animals that died or were slaughtered in the yard (private sector)?
- potentially infected animals older than 36 months that are intended for scheduled slaughter?
- potentially infected imported live animals?

6. Risk estimation

Experts qualitatively evaluate each risk pathway using different methodologies (for example expert knowledge elicitation process)

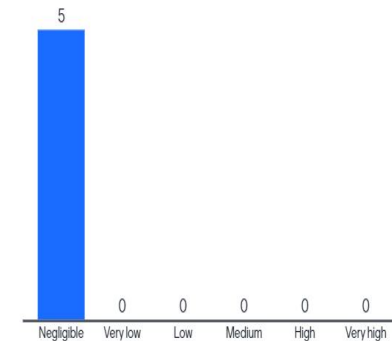
For example: combination of the Sheffield protocol (interaction between experts) and Delphi (the expert has access to the opinions of other participants)

1. Presentation of collected data on each step of the risk pathway
2. Conduct individual evaluations without prior discussion (first round)
3. The result will be presented to the group for discussion.
4. The second round of individual evaluations -> MODA will be accepted as the final result.

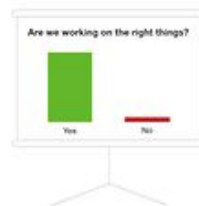
Перейдіть на [mentimeter.com](https://www.mentimeter.com) та використайте код 3160 8171

Mentimeter

R 3. What are the probability of introducing BSE with import of MBM?



Create question
Use example



1 Create a question

Start by creating a question. You can start from scratch and create your own question, or use one of our best practice examples.

2 Vote on the question

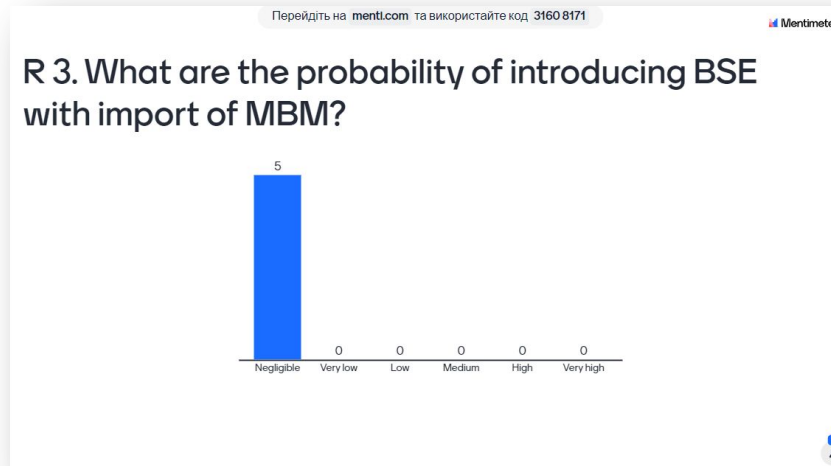
Your audience goes to the voting web-site, enters the code for your presentation and votes. No installation or setup needed.

3 See the result in real-time

The result will be displayed in real-time as the votes drop in. Of course you can also hide the results until everybody is finished.



6. Risk estimation



Step of risk pathway	Probability	Justification
R3. What are the probability of introducing BSE with import of MBM?	Negligible	Since MBM from ruminant animals are not imported into the country, and the current system of control over the import of MBM from other types of animals guarantees the prevention of their contamination with ruminant tissues, the risk of introduction of BSE through the import of MBM is negligible



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RESULTS





7. Calculation and description of uncertainty

Calculate the level of uncertainty

Uncertainty -> reflects the lack of knowledge about the likelihood of risk

Calculation:

The level of disagreement between different experts will be recorded through an individual voting process and will be used as an indicator of the level of uncertainty.

The distribution of marks for a specific question will be evaluated by:

- a) converting the qualitative risk assessment into a quantitative assessment (negligible = 1, very high = 6), and then
- b) the average value of the absolute difference of individual risk estimates and mode (AVDIF-MODE) will be calculated



7. Calculation and description of uncertainty

1							
2	Entry	Life animal	MBM RUM	MBM OA	food	feed	food without bones
3							
4		R 1-2	R 3	R 5	R 10	R 7	R 11
5	Expert 1	1	1	1	1	2	1
6	Expert 2	2	1	1	1	2	1
7	Expert 3	2	1	1	1	2	1
8	Expert 4	2	1	1	1	2	1
9	Expert 5	2	1	1	1	3	1
10							
11							
12	Average	1,80	1,00	1,00	1,00	2,20	1,00
13	AveDev	0,32	0	0	0,00	0,32	0,00
14	Mode	2	1	1	1	2	1
15	Min	1	1	1	1	2	1
16	Max	2	1	1	1	3	1
17	Range (Min-Max)	1	0	0	0	1	0
18	Average range						
19	AveDevMode	0,20	0,00	0,00	0,00	0,20	0,00
20	Uncertainty (percentiles)						
21	AveDev	low	low	low	low	low	low
22	AveDevMode	High	low	low	low	High	low
23	negligible (1), count:	1	5	5	5	0	5
24	very low (2), count:	4	0	0	0	4	0
25	low (3), count:	0	0	0	0	1	0
26	medium (4), count:	0	0	0	0	0	0
27	high (5), count:	0	0	0	0	0	0
28	very high (6), count:	0	0	0	0	0	0
29							
30	Mode in Words:	very low	negligible	negligible	negligible	very low	negligible
31							
32							

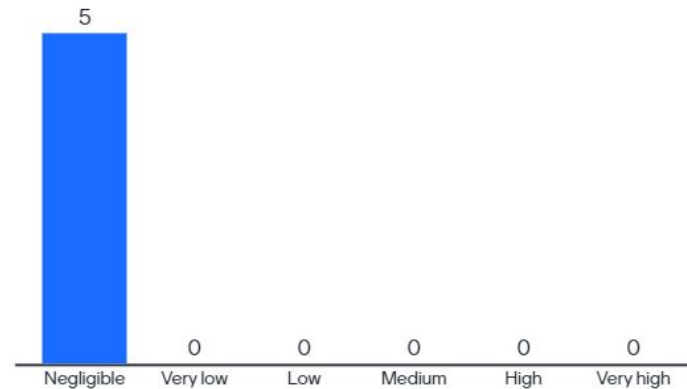


7. Calculation and description of uncertainty

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Mentimeter

R 3. What are the probability of introducing BSE with import of MBM?



Step of risk pathway	Probability	Uncertainty
R3. What are the probability of introducing BSE with import of MBM?	Negligible	Low



Example: Table for the results of the entry risk assessment

Step of risk pathway	Probability	Uncertainty	Justification
R1. What are the probability of introducing BSE with import of live cattle ?			
R2. What are the probability of introducing BSE with import of live sheep and goat ?			
R3. What are the probability of introducing BSE with import of MBM ?			
R4. What are the probability of introducing BSE with import of animal feed and feed ingredients ?			
R5. What are the probability of introducing BSE with import of products of ruminant origin for human consumption ?			
R6. What are the probability of introducing BSE with import of products of ruminant origin intended for <i>in vivo</i> use in cattle ?			

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8. Recommendations for the improving the BSE control system

Negligible	1	The event is so rare that it does not merit to be considered
Very low	2	The event is rare but cannot be excluded
Low	3	The event is rare but does occur
Medium	4	The event occurs regularly
High	5	The event occurs very often
Very high	6	The event occurs almost certainly

If the results of the assessment are from 'very low' to 'very high' the recommendations should be formulated



8. Recommendations

Example of the chapter:

Based on the conducted risk assessment the experts have prepared a range of key recommendations aimed at the improvement of BSE control system:

- introduce regular and uniform reporting for imported MBM;
- introduce regular (inclusive of 8-year keeping period) and uniform reporting on the imported feed and feed ingredients for ruminants;
- introduce 100% analysis of animals with BSE suspicion (including those that are tested in the event of rabies suspicion);
- develop a fully-fledged feed monitoring programme in terms of ruminant protein content and ensure its implementation;
- implement an efficient control and supervision system for holdings in the areas of activity related to processing/destruction of animal by-products not intended for human consumption as well as production, mixing and preparation of feed additives, premixtures and feeding stuffs;
- introduce separate reporting on BSE as regards the implementation of controls of the compliance with legislation on animal by-products and feed;
- develop and introduce reporting forms to ensure transparency and consistency of receiving data from territorial bodies in accordance with the programme for obtaining BSE status, having regard to recommendations provided in this report



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RESULTS



9. Preparation of the report

Example of the report structure:

Contents

ABSTRACT

LIST OF ABBREVIATIONS AND ACRONYMS

BACKGROUND

(contains the composition of the working group of experts involved in the risk assessment, a description of the terms of reference for the risk assessment and the prerequisites for the risk assessment)

1. HAZARD IDENTIFICATION

1.1 Etiology

1.2 Epidemiology

1.3 Statuses on BSE in accordance with WHO

1.3.1 Statuses on BSE in the world

1.3.2 Statuses on BSE in the northern part of Cyprus



9. Preparation of the report

Example of the report structure:

2. ANALYSIS OF THE CURRENT SYSTEM OF BSE CONTROL IN THE NORTHERN PART OF CYPRUS

2.1 Legal texts

2.2 Structure and responsibilities of 'veterinary department'

2.3 Control of the importation into the territory of the northern part of Cyprus of objects which present a risk of introducing the BSE (live animals, MBM, food, feed, etc.)

2.4 Current BSE control system in the northern part of Cyprus

2.4.1 Overview of cattle movements

2.4.2 Animal identification/registration system and control system over compliance with requirements for animal identification

2.4.3 Approach of cattle feeding, requirement to prohibit the feeding of cattle with MBM obtained from ruminants and control system over this requirement

2.4.4 Cattle slaughter

2.4.5 Laboratory diagnostics

2.4.5 Categorization/handling of by-products and control system over the circulation and utilization of animal by-products of animal origin

2.4.7 Control over the prevention of cross-contamination in the production MBM

2.4.8 Surveillance and monitoring of BSE

2.4.9 Feed monitoring



9. Preparation of the report

Example of the report structure:

3. MATERIALS AND METHODS

- 3.1 Qualitative risk assessment framework
- 3.2 Risk questions
- 3.3 Risk pathways
- 3.4 Data collection
- 3.5 Expert knowledge elicitation
- 3.6 Uncertainty assessment

4. RESULTS

- 4.1 Entry assessment of BSE into the northern part of Cyprus
- 4.2 Exposure assessment of BSE into the northern part of Cyprus

5. CONCLUSIONS

6. RECOMMENDATIONS

REFERENCES



The results of the risk assessment and recommendations should be presented to risk managers



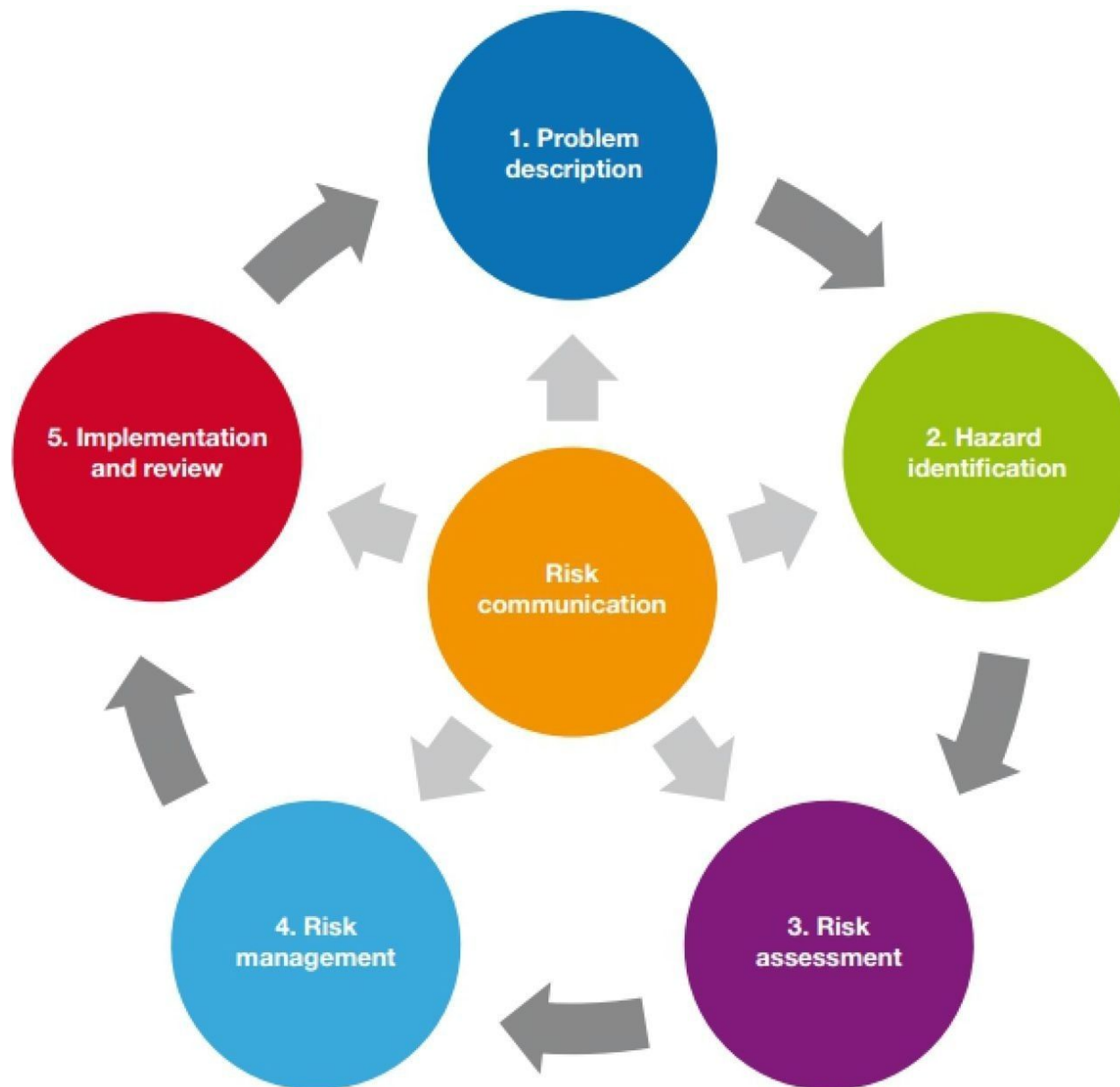
Based on the report and recommendations **managers should conduct risk management** and prepare a `road map` with clear list of activities (corrective measures) and responsible persons for improving the BSE control system



Example of the 'road map':

Recommendation	Activity	Responsible person(s) at central level	Support (Projects)	Responsible person(s) for the implementation at regional level	Deadline	Statuses
Corrective measures to prevent introduction of BSE						
Introduce regular unified reporting of imported meat and bone meal	Development of an order on approving the procedure for informing about the import of meat and bone meal	Department of the State Control at the Border	FSP Project	Regional units	October 2023	

Process of the risk analysis:





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THANK YOU FOR YOUR ATTENTION

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