



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

**Consultation exercise
on `official` recognition of risk status for BSE**

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- aspects of the BSE control system that must be implemented based on EU Regulation and Terrestrial Animal Health Code to obtain the BSE risk status of the cattle population;
- consultation how to prepare the application for `official` recognition of BSE risk status.



Aspects of the BSE control system that must be implemented based on EU Regulation and Terrestrial Animal Health Code to obtain the BSE risk status of the cattle population



Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

02001R0999 — EN — 19.11.2020 — 055.001 — 1

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► **B** REGULATION (EC) No 999/2001 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 22 May 2001
laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies
(OJ L 147, 31.5.2001, p. 1)

Amended by:

		Official Journal		
		No	page	date
► M1	Commission Regulation (EC) No 1248/2001 of 22 June 2001	L 173	12	27.6.2001
► M2	Commission Regulation (EC) No 1326/2001 of 29 June 2001	L 177	60	30.6.2001
► M3	Commission Regulation (EC) No 270/2002 of 14 February 2002	L 45	4	15.2.2002
► M4	Commission Regulation (EC) No 1494/2002 of 21 August 2002	L 225	3	22.8.2002

According to Article 1 of that Regulation it applies to the production and placing on the market of live animals and products of animal origin. For that purpose, **the bovine spongiform encephalopathy (BSE) status of Member States or third countries or regions thereof (countries or regions) is to be determined by classification into one of three categories depending on the BSE risk as laid down in Article 5(1) of that Regulation.**



2007/453/EC:
Commission Decision of
29 June 2007
establishing the BSE
status of Member
States or third
countries or regions
thereof according to
their BSE risk (notified
under document
number C(2007) 3114)
(Text with EEA
relevance)

02007D0453 — EN — 01.01.2021 — 014.001 — 1

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► **B** COMMISSION DECISION
of 29 June 2007
establishing the BSE status of Member States or third countries or regions thereof according to
their BSE risk
(notified under document number C(2007) 3114)
(Text with EEA relevance)
(2007/453/EC)
(OJ L 172, 30.6.2007, p. 84)

Amended by:

		Official Journal		
		No	page	date
► M1	Commission Decision 2008/829/EC of 30 October 2008	L 294	14	1.11.2008
► M2	Commission Decision 2009/830/EC of 11 November 2009	L 295	11	12.11.2009
► M3	Commission Decision 2010/749/EU of 2 December 2010	L 318	47	4.12.2010



The **objective of categorizing countries or regions according to their BSE risk is to establish trade rules** for each BSE risk category in order to provide the necessary guarantees for protecting animal and public health.

The WOAHP plays a leading role in the categorization of countries or regions according to their BSE risk



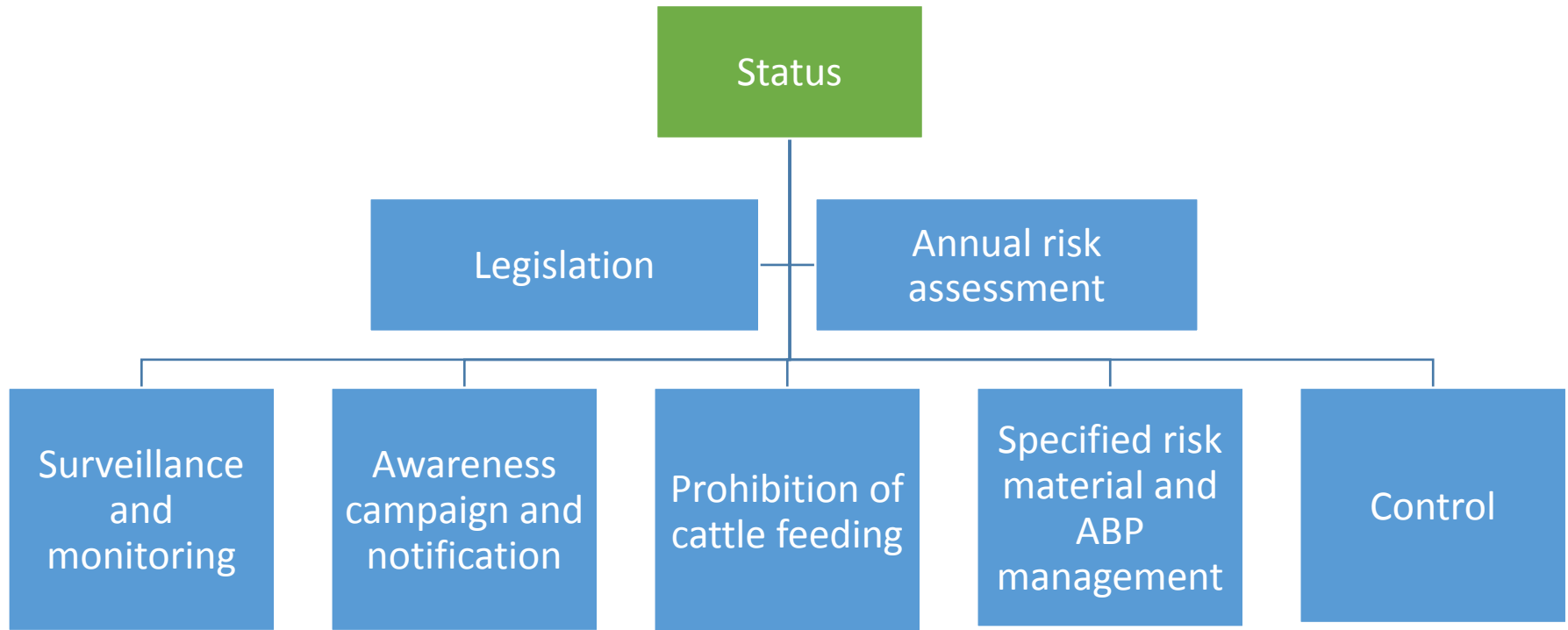
Classical BSE is a disease for which the WOAHP has established official recognition of sanitary risk status in countries in their entirety or in defined zones, through a transparent, science-based and impartial procedure.

Status`s classification

- negligible BSE risk
- controlled BSE risk
- undetermined BSE risk



The criteria for determination of official status of BSE



NB: The criteria excludes 'atypical BSE' as a condition believed to occur spontaneously in all cattle populations at a very low rate



Surveillance

- **passive surveillance:** the reporting of all animals suspected of being infected by a TSE and, where TSE cannot be excluded by clinical investigation, the laboratory testing of such animals;
- **active surveillance:** the testing of animals not reported as suspected of being infected by a TSE, such as emergency slaughtered animals, animals with observations at ante mortem inspection, fallen stock, healthy slaughtered animals and animals culled in connection with a TSE case, in particular in order to determine the evolution and prevalence of TSE in a country or region thereof



Monitoring

- Each Member State shall carry out an annual monitoring programme for TSEs based on active and passive surveillance
- The monitoring programme provides a reliable insight into the prevalence and evolution of TSEs in the MS and at the same time ensures that no BSE cases are not being slaughtered for human consumption.
- BSE in bovine
 - all animals of 24 months which are at risk (48 for some MS, Decision 2009/719)
 - testing of healthy animals over 30 months,
- More details are in Annex III of the Regulation (EC) No 999/2001



Awareness campaign

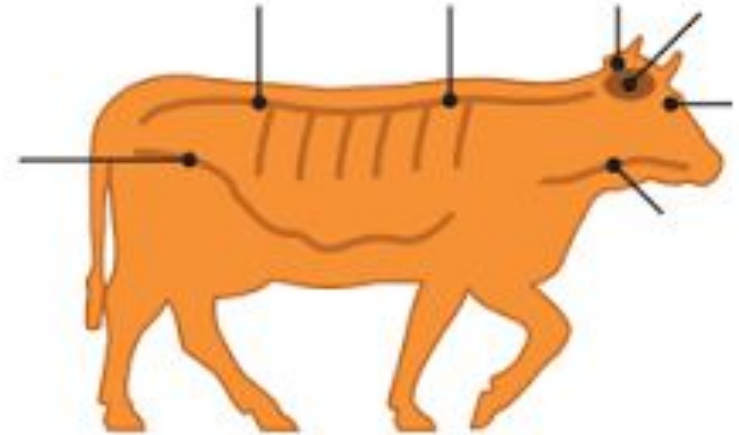
Member States shall ensure that staff of the competent authority, of diagnostic laboratories and colleges of agriculture and veterinary medicine, official veterinarians, veterinary practitioners, slaughterhouse personnel and animal breeders, keepers and handlers have been given training in the clinical signs, epidemiology and, in the case of staff responsible for carrying out checks, in interpreting laboratory findings relating to TSEs.

Notification

Member States shall ensure that **any animal suspected** of being infected by a BSE is notified immediately to the competent authorities

Specified risk material

- The specified risk material (SRM) shall be removed and disposed of in accordance with the Regulation (EC) No 999/2001 and Regulation 2009/1069 on ABP



Products of animal origin

- PAO listed in Annex VI of the Regulation (EC) No 999/2001 should be obtained by using the approved processes
- Bones of bovine, ovine and caprine animals from countries or regions with a controlled or undetermined BSE risk shall not be used for the production of mechanically separated meat (MSM)

Prohibition of animal feeding

- The feeding to ruminants of protein derived from animals shall be **prohibited**
- Prohibition is extended to animals other than ruminants and restricted, as regards the feeding of those animals with products of animal origin
- Undetermined BSE risk are not permitted to export except for feed for dogs, cats and fur animals





Annual risk assessment

- A **BSE risk assessment**, in accordance with the provisions of the 'Application for official recognition by WOAHP of risk status for bovine spongiform encephalopathy' that evaluates the risk of the classical BSE agent being recycled within the bovine population by **identifying all potential factors associated with the occurrence of BSE and their historic perspective. Member Countries should review the risk assessment annually to determine whether the situation has changed.**
- The risk assessment for the purpose of BSE, based on the framework provided by Article 2.1.4



Terrestrial Code Online Access

Terrestrial Animal Health Code

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PDF

CHAPTER 11.4.

BOVINE SPONGIFORM ENCEPHALOPATHY

TOPIC	RELEVANT ARTICLES OF THE TERRESTRIAL CODE (edition 2023)
BSE risk status (country, zone or compartment)	Article 11.4.3.
Negligible BSE risk status	Article 11.4.4.
Controlled BSE risk status	Article 11.4.5.
Surveillance	Articles 11.4.20.



Negligible BSE risk

The BSE risk of a country or zone can be considered to be negligible if all the following conditions for the bovine population are met for **at least the preceding 8 years**:

1. A **risk assessment** has identified all potential risk factors associated with classical BSE has been conducted, and the Member Country has demonstrated through documented evidence that any **identified risk factors have been adequately managed** and that the risk of the classical BSE agent being recycled within the bovine population has been negligible as a result of:
 - EITHER
 - **livestock industry practices ensuring that protein meal derived from ruminants has not been fed to ruminants;**
 - OR
 - **effective and continuous mitigation of each identified risk ensuring that protein meal derived from ruminants has not been fed to ruminants.**



Negligible BSE risk

2. The surveillance provisions have been implemented.

EITHER:

- there has been no case of BSE or, if there has been a case, each case of BSE has been demonstrated to have been imported;

OR

- if there has been an indigenous case of BSE:

either:

- all cases were born before the date from which the risk of BSE agents being recycled within the bovine population has been negligible;

or

- where a case was born after that date, subsequent investigations have confirmed that any identified source of infection has been controlled and the risk of BSE agents being recycled within the bovine population has continued to be negligible.

3. Any cases of BSE or any bovines affected by atypical BSE that have been detected have been completely destroyed or disposed of to ensure that they do not enter the feed or food chain.



Controlled BSE risk

The BSE risk of a country or zone can be considered to be controlled provided all of the conditions of Article 11.4.4. are met, but **one or more of these conditions has not been met for the preceding eight years.**

Undetermined BSE risk

The BSE risk of a country or zone is considered to be undetermined if **it cannot be demonstrated that it meets the requirements for negligible or controlled BSE risk.**

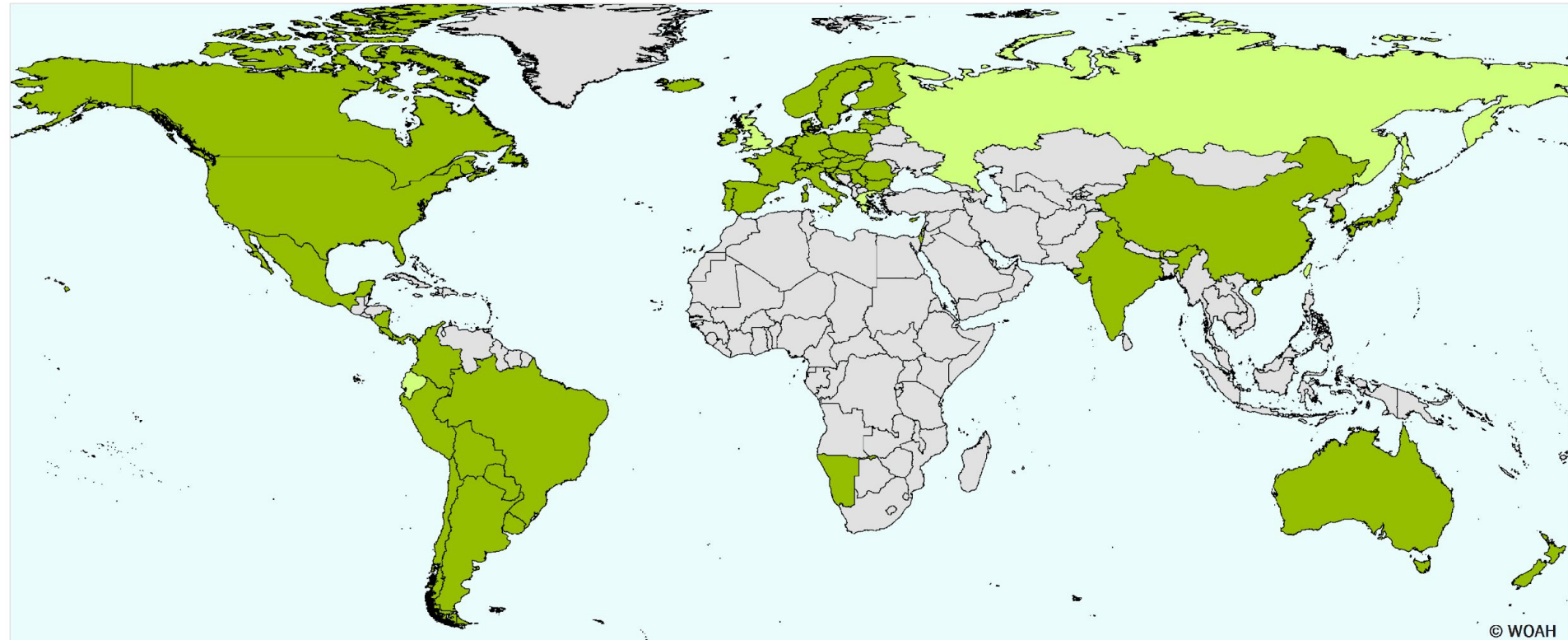





Important aspects

- ✓ Applicant should compliance with the questionnaire in Chapter 1.8. of the Terrestrial Code (edition 2022)
- ✓ The country or the zone will be included in the list of countries or zones posing a controlled risk for BSE in accordance with Chapter 1.6.
- ✓ Retention on the list **requires annual confirmation of the conditions** in points 1 to 4 of Article 11.4.4. Documented evidence should be resubmitted annually for points 1 to 4 of Article 11.4.4.
- ✓ Any **changes in the epidemiological situation or other significant events should be notified to WOA**H in accordance with Chapter 1.1.

WOAH Members' official BSE risk status map

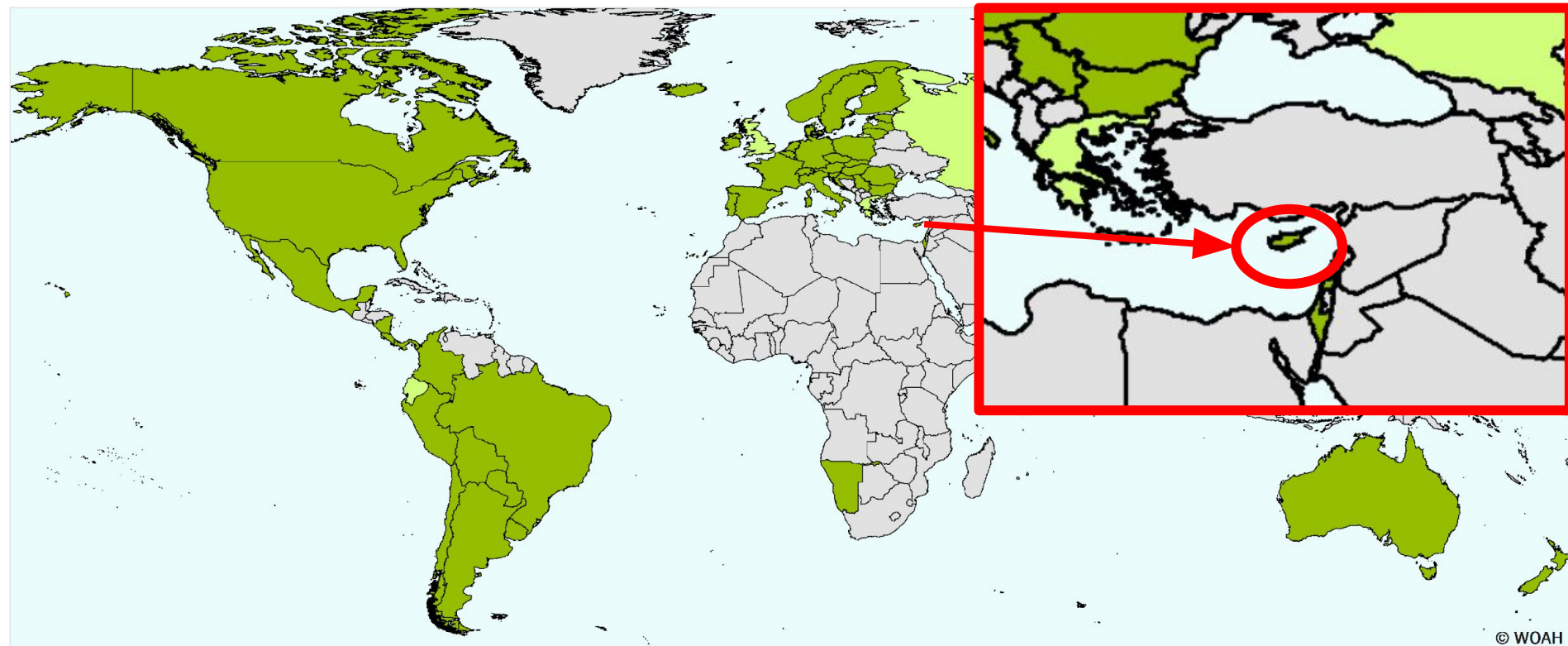
Last update May 2023






-  Members and zones recognised as having a negligible BSE risk status
-  Members and zones recognised as having a controlled BSE risk status
-  Countries and zones without an official BSE risk status

WOAH Members' official BSE risk status map

Last update May 2023



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-  Members and zones recognised as having a negligible BSE risk status
-  Members and zones recognised as having a controlled BSE risk status
-  Countries and zones without an official BSE risk status



**Consultation how to prepare the
application (dossier) to WOH
for `official` recognition of BSE risk status**



The dossier should comply with the questionnaire in [Chapter 1.8. of the Terrestrial Code \(edition 2022\)](#) and should contain:

- A **letter signed** by the Delegate requesting the evaluation of the dossier.
- A **one-page executive summary** stating clearly:

What the Member or third country is applying for:

- official BSE status recognition;
 - whether the dossier relates to the whole country or to one or more zones;
 - for which status it is applying:
i.e., a Member or third country without a recognized risk status should indicate whether it is applying for “negligible risk” or “controlled risk” categories or for both risk categories (in this case, WOAHP evaluates the dossier for both);
- How it has addressed the various requirements set out in the Terrestrial Animal Health Code (Terrestrial Code);
- The type of information provided in the dossier.

- **A core document, with possible relevant appendices.**
- **The contact details**
- **A proof of payment of application fees**



- The Delegate submitting documentation of the legislation under which the Veterinary Services are mandated should provide a **description of the content of the relevant legal texts** (in one of the three official languages of WOA), as well as the dates of official publication and implementation.
- Legal texts may be referred to and **annexed as appropriate in one of the WOA official languages**. Weblinks to supporting documents in one of the official languages of the WOA may also be provided, where they exist.
- The dossier provided to the WOA should address concisely all the topics under the headings provided to describe the **actual situation in the country and the procedures currently applied**, explaining how these comply with the *Terrestrial Code*.
- The Delegate applying for official recognition of BSE risk status **must submit documentary evidence that the provisions of Article 11.4.2., 11.4.3, 11.4.4. have been properly implemented and supervised**.
- The **terminology** defined in the *Terrestrial Code* and *Terrestrial Manual* should be referred to and used in compiling the dossier.



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- **PART A: Background and key facts**
- **PART B: Step by step preparation of dossier (Learning by doing approach)**
 - The text in the Part B is just an example giving direction of what should be described under each point and therefore should be adapted according to the existing practices, legal texts and data available



- A core document should not be voluminous, but should contain a **specific description of the procedures, regulatory documents that will be annexed**;
- It is necessary to **describe everything in reality, and not just make a description of the instructions or normative documents**, because every description must be accompanied by evidence of the implementation of what is described;
- **Size:** a core document of no more than **50 pages** in A4 format, using Times New Roman font size 10pt **+ unlimited number of the Annexes**



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THANK YOU FOR YOUR ATTENTION

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