

USA Comments

CHAPTER 8.1

ANTHRAX

Article 8.1.1.

Note: US recommendations shown in blue font.

General provisions

This chapter is intended to manage the human and animal health risks associated with the presence *Bacillus anthracis* in commodities and the environment.

There is no evidence that anthrax is transmitted by animals before the onset of clinical and pathological signs. Early detection of *outbreaks*, quarantine of affected premises, destruction of diseased animals and fomites, and implementation of appropriate sanitary procedures at *abattoirs* and dairy factories will ensure the safety of products of animal origin intended for human consumption.

For the purposes of the *Terrestrial Code*, the *incubation period* for anthrax shall be 20 days.

Anthrax should be notifiable in the whole country.

Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

When authorising import or transit of *commodities* listed in this chapter, *Veterinary Authorities* should require the conditions prescribed below.

Article 8.1.1.bis

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any anthrax related conditions:

- a) semen and *in vivo* derived cattle embryos collected and handled in accordance with Chapters 4.5, 4.6., and 4.7., as relevant.

Article 8.1.2.

Recommendations for the importation of ruminants, equines and pigs

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of anthrax on the day of shipment;

AND

2. were kept for the 20 days prior to shipment in an *establishment* where no *case* of anthrax was officially declared during that period; or
3. were vaccinated, not less than 20 days and not more than 6 months prior to shipment in accordance with the *Terrestrial Manual*.

~~Article 8.1.3.~~

~~Recommendations for the importation of products of animal origin (from ruminants, equines and pigs) intended for agricultural or industrial use~~

~~*Veterinary Authorities of importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:~~

- ~~1. originate from animals not showing clinical signs of anthrax; or~~
- ~~2. have been processed to ensure the destruction of both bacillary and spore forms of *Bacillus anthracis*, in conformity with one of the procedures referred to in Chapter X.X. (under study).~~

~~Article 8.1.4.~~

Recommendations for the importation of fresh meat and meat products destined for human consumption

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the products originate from animals which:

1. have shown no sign of anthrax during ante-mortem and post-mortem inspections; and
2. ~~were not immunised against anthrax using live vaccine during the 21 days prior to slaughter; and~~
- 2~~3~~. come from *establishments* which are not placed under quarantine on account of anthrax ~~control and in which~~
 - ~~a) there has been no *case* of anthrax during the 20 days prior to slaughter;~~
 - b) no vaccination against anthrax has been carried out during the 42 days prior to *slaughter*.

Rationale:

As stated by the ad hoc group experts in the preamble of this Code chapter, there is no evidence that anthrax can be transmitted before the onset of clinical or pathological signs. Verification that the animals did not show any signs of anthrax on *ante-mortem* inspection, and the carcass did not show any signs of

anthrax on *post-mortem* inspection provides adequate assurance that the meat or meat product does not pose a risk of transmission of anthrax.

Verification that meat and meat products originate on farms where there has been no case of anthrax for 20 days prior to slaughter is neither practical nor necessary. An animal that is capable of spreading anthrax will not pass *ante-mortem* and *post-mortem* inspection.

In addition, there is no reason to verify that animals have not been vaccinated with attenuated strains of anthrax vaccines. Such a requirement could unnecessarily discourage the use of these safe vaccines. The vaccine that is most commonly utilized worldwide is the Sterne Strain 34F2 of *Bacillus anthracis* (discovered in the 1930s). This vaccine has an excellent safety record due to its naturally deleted pX02 plasmid and consequently has lost its ability to produce a capsule. With the missing plasmid the organism cannot produce all of its virulence factors. Without its capsule, the bacteria can be phagocytized and destroyed. The Sterne strain, therefore, is relatively avirulent, however immunization using the Sterne strain stimulates a protective immune response. It is currently the predominant strain used for immunization of domesticated animals against anthrax worldwide and has been used for this purpose for many decades. No human disease due to anthrax caused by the Sterne strain has been reported.

Article 8.1.5.

Recommendations for the importation of hides, skins and hair (from ruminants, equines and pigs)

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products originate from animals which:

~~1. have shown no sign of anthrax during ante-mortem and post-mortem inspections; and~~

~~2. come from establishments which are not placed under quarantine on account of anthrax control.~~

Rationale: As stated by the OIE in the preamble of this chapter, there is no evidence that anthrax can be transmitted before the onset of clinical or pathological signs. This requirement would have the unintended effect of unnecessarily impeding trade. A large amount of hides are traded from animals that are not necessarily subjected to *ante* and *post mortem* inspection. Further, hides are commonly separated from the carcass prior to the carcass being subjected to *post-mortem* examination. Zero risk should not be the goal. Verification that the hides do not originate in establishments under quarantine for anthrax assures minimal risk of exposure without seriously disrupting trade.

Article 8.1.6.

Recommendations for the importation of wool

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the products:

~~1. originate from animals showing no clinical signs of anthrax at the time of shearing; and~~

21. come from *establishments* which are not placed under quarantine on account of anthrax control. ~~originate from establishments where no case of anthrax has been reported since the previous shearing of all animals;~~

OR

2. have been treated in accordance with the recommendations in Article 8.1.11. Veterinary Authorities should not require certification that wool from establishments not placed under quarantine on account of anthrax control be treated in accordance with the recommendations in Article 8.1.11.

Rationale: In general, the chapter refers to the absence of quarantine as opposed to verification that no case of anthrax has been reported. Consistent language should be utilized throughout the chapter.

As stated in the preamble, there is no evidence that anthrax can be transmitted before the onset of clinical or pathological signs. Wool is generally collected outside of government supervision. The treatments described in Article 8.1.11 cannot easily be applied by industry to all wool. The United States is concerned that the changes to Article 8.1.6 as drafted could be interpreted by some countries as requiring that all wool collected outside of the direct supervision of the government would have to be subjected to treatment in accordance with the recommendations in Article 8.1.11 which would unnecessarily impede trade.

Article 8.1.7.

Recommendations for the importation of milk and milk products intended for human consumption

Veterinary Authorities of importing countries should require the presentation of an *international veterinary certificate* attesting that the products:

1. originate from animals showing no clinical signs of anthrax at the time of milking ~~or~~
- ~~2. were processed using a heat treatment of 120 °C for 106 seconds at least equivalent to pasteurisation (under study).~~

Rationale: The United States again is concerned that the changes as drafted could be interpreted by some trading partners to mean that milk should be processed for 120C for 16 seconds unless the milk is collected under the direct supervision of a government official. Verification that the source animals showed no clinical signs of anthrax is sufficient to ensure that milk products do not pose any risk of anthrax transmission. Processing milk products to 120 C for 16 seconds is not generally practical, and as stated in the preamble, there is no evidence that anthrax can be transmitted before the onset of clinical or pathological signs.

Reference

Sa Xu, Theodore P. Labuza, and Francisco Diez-Gonzalez (2006). Thermal Inactivation of *Bacillus anthracis* Spores in Cow's Milk. *Applied and Environmental Microbiology*, June 2006, Vol. 72, No. 6: p. 4479–4483.

Article 8.1.8.

Recommendations for the importation of bristles (from pigs)

Veterinary Authorities of importing countries should require the presentation of an international veterinary certificate attesting that the products originate from animals which:

1. have shown no clinical signs of anthrax during ante-mortem and post-mortem inspections; and
2. come from establishments which are not placed under quarantine on account of anthrax control;

OR

3. have been processed to ensure the destruction of *B. anthracis* by:

a) boiling for 60 minutes; and

b) drying in hot air.

c) immersion for 24 hours in a 2% solution of formaldehyde at >20 °C.

Rationale: Bristles are normally separated from the pig prior to *post-mortem* inspection. As stated in the preamble, there is no evidence that anthrax can be transmitted before the onset of clinical or pathological signs. Managed rather than zero risk should be the goal. Verification that the bristles originate from pigs showing no clinical signs of anthrax and from establishments not under quarantine for anthrax control is sufficient to mitigate risk of anthrax transmission. The United States has been exporting pig bristles using these verification approaches for decades without incident.

References

- Böhm, Reinhard. Institut für Umwelt-und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Personal communication to Dr Wolf-Arno Valder, OIE Terrestrial Animal Health Standards Commission.
- Spotts Whitney, EA, Beatty, ME, Taylor, TH, Weyant, R, Sobel, J, Arduino, MJ, Ashford, DA. (2003) Inactivation of *Bacillus anthracis* spores. *Emerging Infectious Diseases* 9(6): 623-627.

Article 8.1.9.

Recommendations for importation of Procedures for the inactivation of *B. anthracis* spores in skins and trophies from wild animals

Veterinary Authorities or other Competent Authority should require the presentation of an international veterinary certificate attesting that these products have been processed to ensure the destruction of *B. anthracis* by one of the following methods:

In situations in which skins and trophies from wild animals are known to ~~may~~ be contaminated with *B. anthracis* spores, the following disinfection procedure is recommended if the hides and trophies are not destroyed:

1. fumigation with ethylene oxide 500 mg/L, at relative humidity 20-40%, at 55 °C for 30 minutes; or
2. fumigation with formaldehyde 400 mg/m³, at relative humidity 30%, at >15 °C for 4 hours; or
3. fumigation with methylene bromide 3.4-3.9 g/L, in the presence of moisture, at room temperature for 24 hours; or
4. gamma irradiation with a dose of 40 kGy.

Note: Veterinary Authorities should not routinely require anthrax related certification for the import of skins or trophies of wild animals.

Rationale: Veterinary authorities will not generally be able to provide certification regarding the clinical signs demonstrated by wild animals prior to death. The United States is concerned that this article could be interpreted to indicate that veterinary authorities should require certification that skins and trophies are either from animals slaughtered under government inspection or processed using one of the above treatment methods. Authorities could interpret this to apply even to finished game trophies. These interpretations could disrupt large amounts of trade, as game trophies and skins are not necessarily processed using one of the above listed methods.

References

- Böhm, Reinhard. Institut für Umwelt-und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Personal communication to Dr Wolf-Arno Valder, OIE Terrestrial Animal Health Standards Commission.
- Turnbull P., Cosivi O. (2008) Anthrax in humans and animals, 4th Edition, WHO/FAO/OIE
- Spotts Whitney, EA, Beatty, ME, Taylor, TH, Weyant, R, Sobel, J, Arduino, MJ, Ashford, DA. (2003) Inactivation of *Bacillus anthracis* spores. *Emerging Infectious Diseases* 9(6): 623-627.

Article 8.1.10.

Procedures for the inactivation of *B. anthracis* spores in bone meal and meat and bone meal

The following procedure should be used to inactivate any *B. anthracis* spores which may be present during the production of bone meal or meat and bone meal from ruminants, equines and pigs:

1. the raw material should be reduced to a maximum particle size of 50 mm before heating; and
2. the raw material should be heated under saturated steam conditions to a temperature of not less than 133°C for a minimum of 20 minutes at an absolute pressure of 3 bar.

Rationale: The United States is concerned that the article as drafted could be interpreted to mean that MBM cannot be produced from carcasses that are not from animals that were subjected to and passed *ante* and *post mortem* inspection. This requirement is not consistent with

industry practices, and could halt most trade in MBM, significantly impacting worldwide food production.

References

- Böhm, Reinhard. Institut für Umwelt-und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Personal communication to Dr Wolf-Arno Valder, OIE Terrestrial Animal Health Standards Commission.
- Turnbull P., Cosivi O. (2008) Anthrax in humans and animals, 4th Edition, WHO/FAO/OIE

Article 8.1.11.

Procedures for the inactivation of *B. anthracis* spores in wool and hair

In situations in which wool or hair may be contaminated with *B. anthracis* spores, the following five-step disinfection procedure is recommended:

1. immersion in 0.25-0.3% soda liquor for 10 minutes at 450.5 °C;
2. immersion in soap liquor for 10 minutes at 450.5 °C;
3. immersion in 2% formaldehyde solution for 10 minutes at 450.5 °C;
4. a second immersion in 2% formaldehyde solution for 10 minutes at 450.5 °C;
5. rinsing on cold water followed by drying in hot air.

References

- Böhm, Reinhard. Institut für Umwelt-und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Personal communication to Dr Wolf-Arno Valder, OIE Terrestrial Animal Health Standards Commission.
- Turnbull P., Cosivi O. (2008) Anthrax in humans and animals, 4th Edition, WHO/FAO/OIE

Article 8.1.12.

Procedures for the inactivation of *B. anthracis* spores in manure, dung and bedding

In situations in which manure, dung or bedding may be contaminated with *B. anthracis* spores, the following are recommended:

1. small volumes by incineration; or
2. chemothermal treatment by composting with quicklime as follows:

- a) mix the manure with granulated quicklime at a rate of 100 kg quicklime per m³ and spray with water;
- b) turn the material after 5 weeks;
- c) leave for a further 5 weeks.

Note: spontaneous combustion of the composting pile is possible.

References

- Böhm, Reinhard. Institut für Umwelt-und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Personal communication to Dr Wolf-Arno Valder, OIE Terrestrial Animal Health Standards Commission.

Article 8.1.13.

Procedures for the inactivation of *B. anthracis* spores in liquid manure (slurry)

In situations in which liquid manure (slurry) may be contaminated with *B. anthracis* spores, the following is recommended:

1. disinfection with formalin (35% aqueous solution of formaldehyde) with stirring one hour stirring daily;
 - a) for slurry up to 5% dry matter, 50 kg formalin per m³ for 4 days;
 - b) for slurry >5% and <10% dry matter, 100 kg formalin per m³ for 4 days.

References

- Böhm Reinhard. Institut für Umwelt-und Tierhygiene Sowie Tiermedizin mit Tierklinik, Universität Hohenheim. Personal communication to Dr Wolf-Arno Valder, OIE Terrestrial Animal Health Standards Commission.
- Turnbull P., Cosivi O. (2008) Anthrax in humans and animals, 4th Edition, WHO/FAO/OIE

Article 8.1.14.

Procedures for the disinfection of surfaces in animal houses, buildings contaminated with *B. anthracis*

In situations in which surfaces in animal houses, stables, *vehicles*, etc. may be contaminated with *B. anthracis* spores, the following three-step approach is recommended:

1. a preliminary disinfection should be carried out using one of the following disinfectants at a rate of 1-1.5 L/m³ for 2 hours;
 - a) 10% formaldehyde (approximately 30% formalin); or
 - b) 4% glutaraldehyde (pH 8.0-8.5);

2. all surfaces should be washed and scrubbed using ample hot water and, when cleaned and waste water is free from dirt particles, dried;
3. a final disinfection step should be carried out using one of the following disinfectants applied at a rate of 0.4 L/m³ for 2 hours;
 - a) 10% formaldehyde (approximately 30% formalin), repeated after one hour; or
 - b) 4% glutaraldehyde (pH 8.0-8.5), repeated after one hour; or
 - c) 3% hydrogen peroxide; or
 - d) 1% peracetic acid, repeated after one hour.

Note: Formaldehyde and glutaraldehyde should not be used at temperatures below 10 °C. Hydrogen peroxide and peracetic acid are not suitable in the presence of blood.

References

- Turnbull P., Cosivi O. (2008) Anthrax in humans and animals, 4th Edition, WHO/FAO/OIE
- Spotts Whitney, EA, Beatty, ME, Taylor, TH, Weyant, R, Sobel, J, Arduino, MJ, Ashford, DA. (2003) Inactivation of *Bacillus anthracis* spores. *Emerging Infectious Diseases* 9(6): 623-627.

Article 8.1.15.

Procedures for the fumigation of rooms contaminated with *B. anthracis*

Contaminated rooms which cannot be cleared before cleaning and disinfection can be fumigated to eliminate *B. anthracis* spores. The following procedure is recommended:

1. all windows, doors and vents to the outside should be sealed with heavy adhesive tape; and
2. for rooms up to 30 m³, 4 L of water containing 400 ml of concentrated formalin (37% w/v formaldehyde) in an electric kettle (with a timing switch to turn it off) should be boiled away and the room left overnight. Room temperature should be >15 °C.

Note: Formaldehyde fumigation is hazardous and proper respirators should be on hand for operator safety. The effectiveness of the fumigation process should be verified by exposing dried discs of filter paper which have been dipped in a suspension of spores of *B. subtilis* var *globigii* or *B. cereus* or Sterne vaccine strain of *B. anthracis* and placed in the room before fumigation is started. At the end of fumigation, the discs should be placed on nutrient agar plates containing 0.1% histidine and incubated overnight at 37 °C. If fumigation has been effective, there will be no bacterial growth.

References

- Turnbull P., Cosivi O. (2008) Anthrax in humans and animals, 4th Edition, WHO/FAO/OIE