CHAPTER AS ADOPTED MAY 2017 – USA COMMENTS FOLLOWING THE USA INTERVENTION ON BEHALF OF THE 29 COUNTRIES OF THE AMERICAS

CHAPTER 2.X.

CRITERIA APPLIED BY THE OIE FOR ASSESSING THE SAFETY OF COMMODITIES

Note: the United States, on behalf of the 39 Member countries of the Americas, supported the adoption of this new chapter; however, intervened to:

- ask that language found in Article 2.X.2, for purposes of consistency and clarity, also be added to Article 2.X.1 under General Provisions. This comment was made before and is again reflected below;

- recommend that the wording “accordance with Good Manufacturing Practices” be deleted because such reference to GMPs addresses the quality of the product and not its safety (The OIE definition for GMPs refers to quality). Therefore, to maintain the intent of this point, which is to address the safety of the product, the alternate text is proposed.

Article 2.X.1.

General provisions

For the purposes of this chapter the word ‘safety’ is applied only to animal and human health considerations for listed diseases.

In many disease-specific chapters, Article X.X.2, lists commodities that can be traded from a country or zone regardless of its status with respect to the specific listed disease. The criteria for their inclusion in the list of safe commodities are based on the absence of the pathogenic agent or is not present in an amount able to cause infection in a human or animal by a natural exposure route in the traded commodity, either due to its absence in the tissues from which the commodity is derived or to its inactivation by the processing or treatment that the animal/products have undergone.

Rationale: wording already used in Article 2.X.2 Point 1) is added here for consistency and clarity.

The assessment of the safety of the commodities using the criteria relating to processing or treatment can only be undertaken when processing or treatments are well defined. It may not be necessary to take into account the entire process or treatment, so long as the steps critical for the inactivation of the pathogenic agent of concern are considered.

It is expected that processing or treatment (i) uses standardised protocols, which include the steps considered critical in the inactivation of the pathogenic agent of concern; (ii) is conducted in a way which maintains the integrity of the treatment process, accordance with Good Manufacturing Practices; and (iii) that any other steps in the treatment, processing and subsequent handling of the animal product do not jeopardise its safety.

- Rationale: As previously noted in comments that were submitted, the
glossary of the Terrestrial Animal Health Code defines “Good manufacturing practice” as “a production and testing practice recognised by the Competent Authority to ensure the quality of a product.” The “quality” of a product generally has to do with the economic value and not with its inherent safety or animal or human health safety. Indeed, higher quality products often are processed to a lesser degree. Therefore, deleting this reference removes any reference to quality, and the suggested new text maintains the intent of ensuring the safety of the commodity from a pathogen risk perspective.

Article 2.X.2.

Criteria

For an animal product to be considered a safe commodity for international trade, it should comply with the following criteria:

1) There is strong evidence that the pathogenic agent is not present in the tissues from which the animal product is derived in an amount able to cause infection in a human or animal by a natural exposure route. This evidence is based on the known distribution of the pathogenic agent in an infected animal, whether or not it shows clinical signs of disease.

OR

2) If the pathogenic agent may be present in, or may contaminate, the tissues from which the animal product is derived, the standard processing or treatment normally applied to produce the commodity to be traded, while not being specifically directed at this pathogenic agent, inactivates it to the extent that possible infection of a human or animal is prevented through its action, which is:

a) physical (e.g. temperature, drying, irradiation);

or

b) chemical (e.g. iodine, pH, salt, smoke); or

c) biological (e.g. fermentation);

or

d) a combination of a) to c) above.