USA Comments – noted in blue font

CHAPTER 2.X.

CRITERIA APPLIED BY THE OIE FOR ASSESSING THE SAFETY OF COMMODITIES

Article 2.X.1.

Assessing the safety of animal products from a country or zone not free from a specific listed disease

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

Rationale: As referenced in draft Article 2.x.2(1), it is not the total absence of the agent in the commodity, but rather the absence of an “amount able to cause infection in a human or animal by a natural exposure route” that should be mitigated by the recommendations of the Terrestrial Animal Health Code. Indeed, referencing “absence” without this additional text could increase the likelihood of importing countries insisting upon “zero risk” with is not consistent with the SPS Agreement nor is it sound scientific reasoning.

The assessment of the safety of the animal products 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 pathogen 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 sanitary way which prevents commingling of the processed/treated commodity with other unprocessed/untreated animal-origin materials of concern 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: 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 the level of processing. Indeed higher quality products often are processed to a lesser degree (for example high levels of processing will denature proteins and decrease nutrition value or taste). In addition, “good manufacturing practices” vary dramatically depending upon the commodity. For example, good manufacturing practices for a product for human consumption could be very different than those for the manufacture of leather. The use of the term “good manufacturing practices” could result in countries insisting upon certification of ambiguous “good manufacturing practices” unrelated
to the prevention of the spread of pathogens of concern. This requirement would be inconsistent with Article 5.1.1 of the Code which indicates that “Certificates should be exact and concise”. The United States, therefore, recommends that the wording instead address the pertinent criteria – and that is that the processed/treated product not be commingled with other potential sources of the infectious agent such as raw materials or other commodities not included in the list of commodities that can be traded safely.

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 at a concentration/dose 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 animal product commodity to be traded, while not being specifically directed at this pathogenic agent, inactivates the pathogen 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

or

c) biological (e.g. fermentation);

or

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

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