The Japan Food Safety Commission's Comment on EFSA's Revision of the Geographical BSE Risk Assessment (GBR) Methodology

The Japan Food Safety Commission (FSC) would like to express its profound esteem for and appreciation of the praiseworthy efforts EFSA has made to release a draft opinion of the Scientific Panel on the revision of the Geographical BSE Risk Assessment (GBR) methodology. It is a more flexible methodology based on latest scientific knowledge, and is drastically improved from the previous one.

Specifically, the FSC deems the revised methodology worthy of the following special mention:

1. Details on the BSE transmission mechanism have been discussed from multidisciplinary perspectives by the working group, comprised of members who have various expertise, including epidemiology and prion diseases;

2. The revised methodology meets the objectives set as the reason to replace SSC GBR with EFSA GBR;

3. The revised methodology has the advantage that it can:
   (1) indicate changes over time;
   (2) express quantitatively increased/decreased risk;
   (3) determine major risk factors by comparing risk scale in three categories, i.e. challenge, stability and their mutual interactions ;
   (4) provide understandable diagrammatic representation of rules;
   (5) provide easy-to-guess calculation flow without complex equations so that scientists and consumers without expertise in statistics may comprehend the process.

The FSC regards the revised methodology as a great help in developing its ongoing preliminary discussion over risk assessment of beef imported from abroad. In this regard, we would like to take this opportunity to submit the following questions. Any information from you will be highly appreciated.

Questions:

1. Line 257 (4.2 Assumptions on transmission of BSE and origin of the BSE epidemic)

- On what knowledge are you basing this, and how did you conduct an assessment to conclude the statement: “The recent results of large scale BSE-testing in combination with reports on feed controls have further substantiated the opinion of the SSC that any cross contamination of cattle feed with bovine MBM, even below 0.5%, represents a risk of transmitting the disease”?
- Do you suppose this (“any cross contamination of cattle feed with bovine MBM, even below 0.5%, represents a risk of transmitting the disease”) holds true of countries other than EU member states and of any feed regulation conditions?

2. Line 293 (4.4 External challenge) and line 571 (4.5 Stability assessment)

- How did you take into consideration the fact that the bovine animals born after the total feed ban in 2001, or “Barbs,” are found infected with BSE, in assessing the external challenge of imported cattle and the stability? For those countries that confirmed BSE in Barbs, for example, will their compliance with feed regulation be rated insufficient?

3. Lines 321- (4.4 External challenge)

- It reads that imported live animals or MBM may be excluded from external challenge if they are exported subsequently; however, how can you tell whether imported animals/MBM were originally produced in a particular exporting country? (In the real world, it is likely that animals/MBM are imported to a third nation from the U.K. via a non-risk country.)

4. Line 360 (Age of animals at slaughter)

- The reason why “Imported calves that are slaughtered before 2.5 years (30 months) can be assumed to represent no external challenge” is based on the assumption that “Imported animals slaughtered young (*i.e.* below 30 months of age) can only carry a very small fraction of the infectivity, even if infected prior to export.” However, given the fact that BSE clinical cases have been confirmed among young animals below 30 months of age and that the infectivity has been confirmed in the distal ileum of infected animals early in the incubation period, is it not more rational to regard such animals below 30 months as representing an external challenge to a reduced extent, instead of excluding them uniformly from the external challenge?

5. Line 604 (4.5.1 SRM-removal)

- “The removal involves SRM from all bovine animals that leave the population (healthy and casualty slaughtered animals, clinical suspect animals, fallen stock).” Should this statement be construed to involve SRM of every animal in every country, regardless of age and presence or absence of BSE occurrence in each nation?

6. Lines 631- (4.6 Methodology for assessing stability)

- The introduction of weighting factor values is understandable so as to differentiate reduction effectiveness depending upon control measures in place during individual processes of SRM removal, rendering, and feed regulation. But on what basis did you allocate different weighting factors to the reduction effectiveness of individual processes?

7. Lines 705-712 (4.6.2 Assessing the impact of rendering)

- The maximum reduction factor of 0.001 is applied if no rendering exists, which is the same value as given to systems where rendering is provided according to 133/20/3. Should no-rendering be assessed as more effective than all other rendering systems?

8. Lines 859- (4.7.3 Rules for assessing the interaction between challenge and stability)

- Challenge levels are differentiated depending on the sizes of cattle populations. What are the grounds for defining “large cattle population” as more than 20 million cattle?

9. Line 901 (Table 5: Equivalence between the overall challenge and the new different GBR categorization)

- How do you calculate the “estimated number of risk units” that categorizes the “level of overall challenge” in Table 5? (We presume the calculation is based on the unit of external challenge multiplied by stability; we kindly request a more specific method, if one exists.)
- In addition, provided that the “EFSA GBR” has two categories—“likely” and “unlikely,” based on the likelihood of cattle being infected with BSE (lines 229 and 230)—how should the “estimated number of risk units” be construed? (If the “estimated number of risk units” is less than 20, will the likelihood of a BSE case then be categorized as “unlikely” anyway?)

10. ANNEX II (Comparison of GBR method and OIE method assessing geographical risk for BSE in a country)

- The revised GBR recommends it be compatible with the OIE standard wherever possible. However, GBR adopts “unlikely,” “likely and decreasing” and “likely and increasing,” whereas OIE uses the three categories known as “negligible,” “controlled” and “unknown.” We kindly request your future plan to improve the compatibility and information on clear-cut role sharing between risk assessment and risk management bodies (e.g. which organization determines risk categories among “unlikely,” “likely and decreasing” and “likely and increasing”?)

We found the following corrections in the documents and corrigenda:

- Line 902; Last line in Table 5, “Very Low” -> “Extremely low”
- Annex I, line 82; Title “3. Consideration of…” -> “C. Consideration of…”
- Annex V, line 38; ”the USA” -> “this country”
- Annex V, line 73; “low＋1 level upgrade” -> “very low + 1 level upgrade”
- Annex V, line 85; “moderate” -> “high”
- Annex V, line 91; “moderate” -> “very high”