AN ANIMAL HEALTH IMPORT RISK ANALYSIS TEMPLATE

Summary Box

Steps involved in an animal health import risk analysis:

1. determining the scope of the risk analysis
2. stating the purpose of the risk analysis clearly
3. developing a risk communication strategy
4. identifying sources of information for the risk analysis
5. identifying the hazards likely to be associated with the commodity under consideration
6. determining whether or not the *Code* provides sanitary measures for the hazard in the commodity under consideration
7. conducting a *risk assessment* for each hazard
  - **7.1** identifying the populations of interest
  - **7.2** drawing a scenario tree to identify the various biological (risk) pathways leading the commodity harbouring the hazard when imported; susceptible animals and/or being exposed; and, potential "outbreak" scenarios
  - **7.3** conducting an *entry assessment* to estimate the likelihood of the commodity introducing the hazard into the country
  - **7.4** conducting an *exposure assessment* to estimate the likelihood of susceptible animals and/or humans being exposed to the hazard
  - **7.5** conducting a *consequence assessment* to estimate the likely magnitude of potential biological, environmental and economic consequences associated with the entry establishment or spread of the hazard and the likelihood of their occurrence
  - **7.6** summarising the conclusions of the entry, exposure and consequence assessments to provide an overall estimate of the risk (*risk estimation*)
8. determining whether sanitary measures are warranted (*risk management*)
  - **8.1** evaluating the risk to determine if the risk estimate is greater than the county's *acceptable risk*
  - **8.2** evaluating sanitary options to effectively manage the risks posed by each hazard as well as ensuring that the options chosen are consistent with obligations under the *SPS Agreement*
  - **8.3** implement the sanitary options by undertaking a scientific peer review of the risk analysis, notifying the WTO as appropriate and making a final decision on the measures selected
  - **8.4** monitoring and reviewing factors that could impact on the conclusions of the risk analysis and/or the implementation of the sanitary measure

Reference: Appendix 1, Handbook on Import Risk Analysis for Animal and Animal Products, Volume 1, 2nd Edition, 2010. Introduction and qualitative analysis. World Organisation for Animal Health (OIE).

1. Determine the scope of the risk analysis

Define as precisely as possible the animals or animal products which are the subject of the risk analysis by taking account of:

- the nature, source(s) (including country) and intended use(s) of the animals or animal products
- the scientific names when describing the animal species or disease agents
- the relevant methods of production, manufacturing, processing or testing that are normally applied as well as quality assurance programmes (such as HACCP) and how they are verified
- the likely annual volume of trade (if possible)

Draft a suitable title for the risk analysis (based on the above).

2. State the purpose of the risk analysis clearly

The purpose of the risk analysis should be stated in an appropriate form, for example:

- To identify and assess the likelihood of (*the hazard(s)*) being introduced and spreading or becoming established in (*your country*) together with the likelihood of and the likely magnitude of their potential consequences for animal or human health as a result of importing (*the commodity*) for *(intended use)*.
- To recommend sanitary measures, if appropriate.

3. Develop a risk communication strategy

The risk communication strategy should:

- identify interested parties
- determine the most appropriate times to communicate with them
- determine the appropriate means of communication

4. Identify sources of information for the risk analysis

Information to assist in identifying hazards, assessing risks and exploring options to manage risk can be found in a variety of sources including:

- OIE website
- Import risk analyses carried out in other countries
- scientific journals and textbooks
- websites devoted to diseases of livestock, aquatic animals, wildlife and zoo animals
- the Competent Authority in the exporting country

Assistance and advice can also be sought from a variety of specialists including epidemiologists, veterinary pathologists, virologists, microbiologists, parasitologists, laboratory diagnosticians, wildlife specialists, biologists, ecologists, risk analysts, biostatisticians, livestock industry specialists, agricultural economists, field veterinarians and product specialists.

5. Identify the hazards likely to be associated with the commodity

Draw up a list of the pathogens associated with the species from which the commodity is derived and, based on the following criteria, determine whether or not they can be classified as a hazard for further consideration in a risk assessment:

5.1 Taking account of the methods of production, manufacturing or processing is the commodity under consideration a potential vehicle for the pathogenic agent?

- If the answer is YES proceed to step 5.2, otherwise the pathogenic agent is not a hazard.

5.2 Is the pathogenic agent present in the exporting country?

- If the answer is YES proceed to step 5.3.
- If the answer is NO, is there sufficient confidence in the capacity and capability of the exporting country's *Competent Authority* to satisfactorily substantiate a claim that the pathogenic agent is absent?[1]
  - If the answer is YES the pathogenic agent is not a hazard.
  - If the answer is NO, contact the *Competent Authority* to seek additional information or clarification and proceed to step 5.4, assuming that, until otherwise demonstrated, the pathogenic agent is likely to be present in the exporting country.

5.3 Are there *zones* or *compartments* from which the commodity will be derived within the exporting country that are free of the pathogenic agent?

- If the answer is YES, is there sufficient confidence in the capacity and capability of the exporting country's *Competent Authority* to satisfactorily substantiate a claim that the pathogenic agent is absent from and ensure that the commodity is only derived from these zones or compartments?[1]
  - If the answer is YES the pathogenic agent is not a hazard.
  - If the answer is NO, contact the *Competent Authority* to seek additional information or clarification and proceed to step 5.4, assuming that, until otherwise demonstrated, either the pathogenic agent is likely to be present in these zones or compartments or that the commodity is likely to be derived from other areas in the exporting country.
- If the answer is NO proceed to step 5.4.

5.4 Is the pathogenic agent present in the importing country?

- If the answer is YES proceed to step 5.5.
- If the answer is NO, is the *Competent Authority* of in the importing country able to satisfactorily substantiate a claim that it is absent?
  - If the answer is YES the pathogenic agent is classified as a hazard.
  - If the answer is NO, proceed to step 5.5 assuming it is present and explore options within a reasonable period of time to ascertain its presence or absence with a sufficient level of confidence.

5.5 For a pathogenic agent reported in both the exporting and the importing country, if

- it subject to an *Official control programme* in the importing country, OR
- there are *zones* or *compartments* of different animal health status, OR
- local strains are likely to be less virulent than those reported internationally or in the exporting country
- THEN pathogenic agent may be classified as a hazard. Proceed to step 6.

A risk analysis may be concluded at this stage if none of the pathogenic agents considered are classified as potential hazards.

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[1] The evaluation of the Veterinary Services, the identification and traceability of animals and/or animal products, surveillance, Official control programmes and management and husbandry practices related to biosecurity are important inputs for assessing the likelihood of pathogenic agents being present in, or absent from the animal population of the exporting country or subpopulations within zones or compartments.

6. Does the *Code* provide sanitary measures for the hazard in the commodity under consideration?

- If the answer is YES
  - Is it requirement by legislation, policy or other considerations within the country to undertake a complete risk analysis?
    - If the answer is YES, proceed to step 7 and conduct a risk assessment.
    - If the answer is NO, consider applying the sanitary measures prescribed in the *Code* as a risk assessment to fulfil WTO obligations is not necessary.
- If the answer is NO or it is decided to adopt a higher level of protection than that provided by the measures in the *Code*, proceed to step 7 and conduct a risk assessment.

7. Conduct a risk assessment for each hazard

7.1 Identify the populations of interest:

- potentially susceptible species need to be identified to ensure that all the appropriate biological pathways are considered in the risk assessment. Susceptible species include terrestrial and aquatic animals that are reared on farm or in captivity or are in the wild, as well as humans if the hazard has zoonotic potential.

7.2 Draw a scenario tree to identify the various biological (risk) pathways leading to:

- the commodity harbouring the hazard when imported
- susceptible animals and/or humans being exposed
- potential "outbreak" scenarios

7.3 Conduct an entry assessment to estimate the likelihood of the commodity introducing the hazard into your country

- list the relevant biological, country and commodity factors considered in each step
- Is the likelihood negligible that the commodity is carrying the hazard when imported?
  - If the answer is:
    - YES the risk estimate (step 7.6) is classified as *negligible* and the risk analysis may be concluded at this point
    - NO proceed to step 7.4

7.4 Conduct an exposure assessment to estimate the likelihood of susceptible animals and/or humans being exposed to the hazard

- list the relevant biological, country and commodity factors considered in each step
- Is the likelihood negligible of susceptible animals and/or humans being exposed to the hazard via each and every exposure pathway?
  - If the answer is:
    - YES the risk estimate (step 7.6) is classified as *negligible* and the risk analysis may be concluded at this point
    - NO proceed to step 7.5

7.5 Conduct a consequence assessment to estimate the likely magnitude of potential biological, environmental and economic consequences associated with the entry establishment or spread of the hazard and the likelihood of their occurrence

- list the relevant direct and indirect consequences considered
- Is the likelihood of each and every significant biological, environmental or economic consequence associated with the hazard negligible?
  - If the answer is:
    - YES the risk estimate (step 7.6) is classified as *negligible* and the risk analysis may be concluded at this point
    - NO proceed to the step 7.6

7.6 Risk estimation: summarise the results and/or conclusions arising from the entry, exposure and consequence assessments and proceed to step 8

8. Risk Management

8.1 Risk evaluation:

- Is the risk estimate greater than the country's *acceptable risk*
  - If the answer is:
    - YES proceed to the step 8.2
    - NO the sanitary options cannot be justified and the risk analysis may be concluded at this point

8.2 Option evaluation:

- formulate an objective which clearly states the intended outcome of the sanitary measure(s) by taking into account the risk pathways leading from the likelihood of introducing the hazard, the exposure of susceptible animals and/or humans and of significant consequences arising
- identify possible sanitary measures, including those in the *Code*
  - if there is a scientific justification that the *Code*'s measure(s) will not achieve the *acceptable risk* of the importing country, measures that result in a higher level of protection may be applied provided they are based on a risk assessment
  - less stringent measures than those recommended in the *Code* may be applied where there is sufficient justification that they will achieve the importing country's *acceptable risk*
- select an option or combination of options that will achieve the *acceptable risk* of the importing country by ensuring that:
  - option(s) are not chosen or applied arbitrarily but are based on scientific principles and a risk analysis
    - evaluate the likelihood of the entry, exposure, establishment or spread of the hazard together with an estimate of the likely magnitude and likelihood of occurrence of biological, environmental and economic consequences <u>according to the option(s)</u> that might be applied
  - minimise negative trade effects
    - choose measures that are technically, operationally and economically feasible
    - apply measures only to the extent that is necessary to protect human or animal life or health
    - avoid situations where some parts of a risk pathway are over managed
    - consider each measure from the overall perspective of the entire risk pathway, not in isolation
    - if the contribution of a particular measure to the overall reduction in risk is insignificant or negligible, it is effectively redundant and should not be included
    - apart from not being a defensible measure, its inclusion could create unnecessary and unjustifiable technical and/or operational challenges as well as an unwarranted inflation in costs
    - it is unlikely to be necessary to apply a sanitary measure at each and every step in the risk pathway in order to achieve the *acceptable risk* for an importing country.
    - ensure that the option(s) do not result in either discrimination between an importing and exporting country or preferential treatment being granted to one exporting country over another where similar conditions, such as disease status or control programmes are known to exist

8.3 implementation

- undertake a scientific peer review to ensure that the risk analysis is technically robust and that the sanitary measures chosen are appropriate to the circumstances and consistent with international obligations under the *SPS Agreement*
- notify the WTO of measure(s)
  - where an international standard, guideline or recommendation does not exist
  - that are not substantially the same as an international standard, guideline or recommendation and that may have a significant effect on the trade of other WTO Members.
- make the final decision and implement the sanitary measure(s)

8.4 monitoring and review

- sanitary measures are audited to ensure that they are achieving the results intended
  - e.g. the evaluation of compliance with certification requirements through an onsite inspection visit
- monitor factors that may have an immediate impact on the risk , for example
  - changes in the animal disease status of the exporting or importing country, neighbouring countries, or regions
  - major political changes or social instability
  - natural disasters
  - significant changes in economic circumstances
- monitor factors associated with each risk analysis that may need to be reviewed and periodically updated as new information becomes available, for example
  - those steps in the importation process, which incorporate the greatest uncertainty or have the greatest impact on the risk estimate
  - the volume of commodity imported, particularly where a threshold has been established, that, if exceeded could impact on the *acceptable risk* of the importing country
- monitor the implementation of sanitary measures, especially if they are new, or required a change in a normal production or trade process within the exporting or importing country to ensure they are achieving the results intended through
  - periodic audits of the *veterinary service*, disease control programs, production and processing practices, certification requirements and so on.