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Identifying, selecting and  
implementing sanitary  
measures to mitigate risk



**Regional training course (Africa)  
Import risk analysis for African swine fever  
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# Topics for discussions

- the steps involved in risk management
- the role that risk management plays in facilitating safe international trade
- An example of the application of risk management for African Horse Sickness virus

# Risk management is the process of ...

... identifying, selecting and implementing sanitary measures to effectively mitigate against the risks posed by the hazard(s) associated with the commodity under consideration

- it is not acceptable to simply identify a range of measures that might reduce the risk
- there must be a rational relationship between the measure(s) and the risk assessment so that the results of the risk assessment support the measure(s)

The objective is to manage risks effectively and reasonably to ...

- minimise the likelihood of disease incursions
- participate fairly in international trade
- fulfil obligations under international trade agreements

## Four steps are involved ...

- risk evaluation
- option evaluation
- implementation
- monitoring and review

# Step 1: Risk evaluation

- The risk estimate is compared to a country's ALOP
  - ALOP = appropriate level of protection
    - also known as the acceptable level of risk (ALR)
    - embedded in the WTO SPS Agreement

# ALOP ...

- is the level of risk considered to be compatible with protecting public and animal health
- reflects the balance a country wishes to achieve between its desire to participate in international trade and the associated disease risks
- it is a societal or political judgement
- it is the right of each country to set its own ALOP
- there is no unique or defined level
- it is actually a concept that demands consistency in the application of sanitary measures for the various hazards associated with the full spectrum of imported commodities

## Under the provisions of the *WTO SPS Agreement* ...

- ... there should not be any restrictions on international trade in animals and animal products unless it is likely that a disease may enter, establish or spread and lead to unacceptable biological and economic consequences
- if the risk estimate is greater than the importing country's ALOP, sanitary measures may be justified
  - pragmatically, if the risk estimate is greater than negligible, sanitary measures can be justified
- it is essential that risks be assessed in a consistent and transparent manner



## Step 2: Option evaluation

- sanitary measures are identified, evaluated and selected to effectively manage the risks
- it is not acceptable to simply identify a range of measures that might reduce the risk
- there must be a rational relationship between the measure(s) and the risk assessment so that the results of the risk assessment support the measure(s)

# Sanitary measures should be ...

- technically, operationally and economically feasible
- implemented to the extent that is reasonably necessary to protect human or animal health
- consistent with obligations as members of WTO and OIE
- applied consistently across a range of commodities likely to contain the same or similar hazards to avoid situations where different levels of protection arise

# OIE standards are the preferred choice

- where OIE standards do not exist, or
- where the proposed measure(s) result in a higher level of protection than that provided by an OIE standard
- the measures must be supported by a risk analysis

# To assist in identifying appropriate option(s) ...

- formulate an objective, which clearly states the intended outcome of the sanitary measure(s)
  - take account of the risk pathways leading from the likelihood of introducing the hazard, the exposure of susceptible animals and/or humans and of significant consequences arising
- should be quite specific, for example
  - to effectively manage the risks associated with AHS virus, sanitary measures should ensure that imported horses are not viraemic

# Select an option or combination of options that will achieve the ALOP ...

- ensure that the *Code*'s sanitary measures are considered
  - if there is scientific justification that the *Code*'s measure(s) will not effectively achieve the ALOP, measures that result in a higher level of protection may be applied
  - less stringent measures than those recommended in the *Code* may be applied where there is sufficient justification that the risks can be effectively managed using those measures

Ensure that option(s) are not chosen or applied arbitrarily ...

... but that they are based on scientific principles, which are best elaborated in 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 according to the option(s) that might be applied

# Ensure that negative trade effects are minimised ...

- the option(s) should be
  - technically, operationally and economically feasible
  - only applied to the extent that is necessary to protect human or animal health

## Avoid situations where some parts of a risk pathway are over managed ...

- consider each option from the perspective of the entire risk pathway, not in isolation
- if the contribution of a particular option to the overall reduction in risk is insignificant or negligible, it is effectively redundant and should not be included
  - it could create unnecessary and unjustifiable technical and/or operational challenges as well as an unwarranted inflation in costs
  - in most, if not all situations, it is not necessary to apply a measure at each and every step in the risk pathway



## Ensure that option(s) do not result in ...

- discrimination between an importing and exporting country where similar conditions exist\*, or
- preferential treatment being granted to one exporting country over another where similar conditions exist\*

\*disease status, control or eradication programs, sanitary measures, etc.

Ensure that measures chosen are applied consistently ...

... across a range of commodities likely to contain the same or similar hazards to avoid situations where different levels of protection arise

# Step 3: Implementation

- the focus is on reaching a final decision on the sanitary measures to be adopted
  - a risk analysis provides recommendations on whether or not the measures can be justified and, if they are, the type of measures required
  - other factors may be taken into account in reaching a final decision
    - What are they?
    - Are non-disease associated effects considered? How are they taken into account?

# Clarify who makes the decision ...

- the CVO?
- another official from the *Competent Authority*?
- the political level?
- ...

# Decision makers should ...

... transparently document the rationale for any decisions that are not based on or supported by the risk analysis

# WTO members have an obligation to ...

- ... notify other Members through the SPS Secretariat of measures that
  - are new or changed
  - are not based on an existing international standard or where a relevant international standard does not exist
  - are likely to have a significant effect on trade
- except in urgent circumstances, 60 days should be allowed for comments to be taken into account, amendments to be introduced and exporters to adapt

# Where circumstances are urgent ...

- the proposed measure(s) must still be notified with a brief indication of the objective and rationale of the measure(s), including the nature of the urgency
- Members must be extended the opportunity to comment, and their comments should be taken into account.

## Step 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



## Steps identified in the risk assessment ...

... which have the greatest impact on the risk estimate, particularly those with the greatest uncertainty, should be identified and updated as new information becomes available

Risk factors are dynamic and could be adversely affected by ...

- changes in the animal disease status of the exporting country, neighbouring countries, or regions
- major political changes or social instability
- natural disasters
- significant changes in economic circumstances
- ...

# A risk management example

African Horse Sickness virus

# Step 1: Risk evaluation

- Since the risk estimate for AHS virus is greater than negligible, sanitary measure(s) need to be employed to achieve New Zealand's ALOP.

## Step 2: Option evaluation

- Objective
  - To effectively manage the risks associated with AHS, sanitary measures should ensure that imported horses are not viraemic.

# Sanitary options available

- Considerations
  - since commercial vaccines are unlikely to prevent viraemia, the only means available to ensure that imported horses are not viraemic is to ensure they are either resident in a free country or free or seasonally free zone, or protected from insect vectors for a period equal to the maximum duration of viraemia plus the incubation period
  - since the incubation period may be up to 14 days and viraemia may last up to 21 days, horses would need to be protected from insect vectors for up to 35 days
  - the duration of viraemia following vaccination with a live vaccine is likely to be similar to that resulting from a natural challenge

# Sanitary options available in the OIE Code (1)

- standards for a defining a free country or free or seasonally free zone and importing horses from them
  - not vaccinated within the last 40 days, and
  - kept in a free country or zone for at least 40 days, or
  - kept in a seasonally free zone during the seasonally free period for at least 40 days

# Sanitary options available in the OIE Code (2)

- standards for importing horses from an infected country or zone
  - not vaccinated within the last 40 days, and
  - held in isolation in an establishment protected from vectors
    - for at least 28 days with a negative serological test after 28 days, or
    - for at least 40 days with a serological test demonstrating no significant rise in titre (first test at least 7 days after being introduced into the establishment followed by a second test at least 21 days later), or
    - for at least 14 days with a negative agent identification test at least 14 days after being introduced into the establishment



# OIE standards ...

... are consistent with the objective of ensuring that imported horses are not viraemic

- provide appropriate measures to mitigate against the risks associated with AHS virus for horses imported from
  - a free country or free or seasonally free zone, or
  - an infected country or zone



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