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Training manual

RISK ANALYSIS & QUALITATIVE RISK ASSESSMENT

I. Introduction to risk and risk analysis

What is "RISK" - definitions

OIE, Terrestrial Animal Health Code, 2012:
" the likelihood of the occurrence and the likely magnitude of the biological and economic consequences of an adverse event to animal or human health in the importing country during a specified time period."

WHO:
"The probability that a negative event or condition have to affect an individual in a given time and space. ..."

Last, 1988:
„The probability that an event will occur; the event usually is an unfavourable outcome"

See also: Uncertainty (Vose, 2000):
„The assessor's lack of knowledge (level of ignorance) about the parameters that characterise the physical system that is being modelled".
= indeterminabilty" (= total uncertainty)

The readiness to accept a certain *risk* is determined by the *likelihood* of alternative actions and the assessment of possible *extent* of *consequences*.

Risk is therefore a combination of two factors:

1. the likelihood of a negative event occurring (e.g. a disease or an injury). This is depended on the hazard and the exposure to the hazard. A hazard alone is not sufficient to result in a risk, e.g. a risk cannot occur if there is no exposure to the hazard
2. The consequences of a negative event, including the magnitude of this event

We can therefore express risk as following: Risk = likelihood x magnitude x consequence
If one ore several of the variables are zero, the resulting risk is zero.

Terminology und definitions

SPS agreement

Traditional methods to prevent animal diseases through international animal trade were based on a *zero-risk* approach. This is not acceptable any longer. New agreements are based on an *acceptable-risk* approach. This approach accepts a certain risk The extent of the risk and whether the risk is acceptable requires the agreement of the contract/trade partners.
To achieve these agreements, the risk needs to be assessed based on a methodology which is accepted by all partners: the risk analysis methodology.

The World Trade Organisation (WTO) was founded in 1995 and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) endorsed (see http://www.wto.org.)

Under the SPS Agreement, the WTO regulates member-states' policies relating to food safety (bacterial contaminants, pesticides, inspection and labeling) as well as animal and plant health (phytosanitation) with respect to imported pests and diseases.

Under the SPS Agreement, sanitary or phytosanitary measure are measure including:

(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;

(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;

(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests.

Equivalence: Article 4 states that:

Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection.

The SPS Agreement encourages WTO members to make a wider use of risk assessment: WTO Members shall undertake an assessment of the actual risk involved. WTO members should base their SPS methodologies on agreed standards. Organizations who set standards are World Organization for Animal Health (OIE) for sanitary measures for animals and the FAO/WHO Codex Alimentarius Commission for food safety.

The SPS Agreement therefore recognizes the OIE as the relevant international organization responsible for the development and promotion of international animal health standards, guidelines, and recommendations affecting trade in live animals and animal products.

Appropriate level of protection (ALOP)

The SPS Agreement defines ‘appropriate level of sanitary or phytosanitary protection’ as the level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its

territory. The SPS Agreement notes that many Members also refer to this concept as the 'acceptable level of risk'. In setting their ALOP, Members are to take into account the objective of minimising negative trade effects (Article 5.4).

ALOP:

- determine the level of risk considered to be acceptable, taking into account the country's policies for the protection of animal and human life and health.
- are based on societal expectations
- may vary with time as standards change
- in determining ALOP, costs and benefits must be considered

Determination of a country's ALOP is an issue for government in consultation with the community - it is not a prescription of WTO. ALOP reflects government policy that is affected by community expectations; it is a societal value judgement to which risk assessors contributes by providing technical information and advice. It is important to note that the SPS Agreement does not require a Member to have a scientific basis for its ALOP determination.

ALOP can be illustrated using a risk estimation matrix (Table 1). The cells of this matrix describe the product of likelihood and consequences - termed 'risk'.

Table 1. Risk estimation matrix (adapted from AFFA, 2001)

Likelihood of entry and exposure							
	High likelihood	Negligible risk	Very low risk	Low risk	Moderate risk	High risk	Extreme risk
	Moderate	Negligible risk	Very low risk	Low risk	Moderate risk	High risk	Extreme risk
	Low	Negligible risk	Negligible risk	Very low risk	Low risk	Moderate risk	High risk
	Very low	Negligible risk	Negligible risk	Negligible risk	Very low risk	Low risk	Moderate risk
	Extremely low	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Very low risk	Low risk
	Negligible likelihood	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Very low risk
		Negligible impact	Very low	Low	Moderate	High	Extreme impact
		Consequences of entry and exposure					

When interpreting the risk estimation matrix it should be remembered that although the descriptors for each axis are similar ('low', 'moderate', 'high', etc.), the vertical axis refers to *likelihood* and the horizontal axis refers to *consequences*.

One implication of this is that a 'negligible' probability combined with 'extreme' consequences, is not the same as an 'extreme' probability combined with 'negligible' consequences — that is, that the matrix is *not symmetrical*. Another implication is that 'risk' is expressed in the same units as are used to estimate consequences but risk is *not* a likelihood.

The band of cells in Table 1 marked 'very low risk' may represent a countries accepted level of protection/accepted risk, or tolerance of loss. In the case of e.g. Australia the ALOP might be 'very low'(see example in table 1). This band of cells represents an approximation of a continuous 'iso-risk curve' - a curve that will be asymptotic at the minimum level of consequences considered to be 'acceptable' and at a likelihood that tends toward zero. The principle of an iso-risk curve is illustrated in Figure 1.

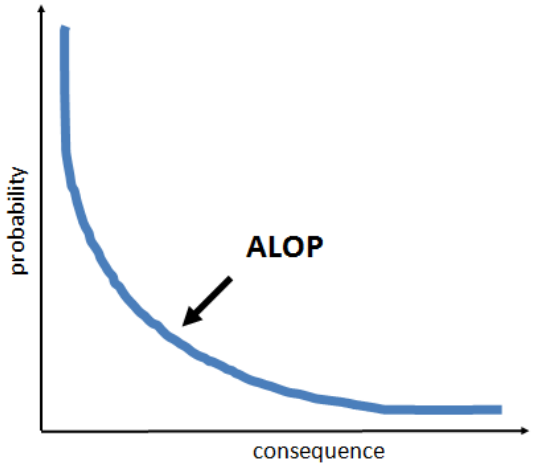

Figure 1. Theoretical iso-risk curve

Concepts of risk analysis

In Veterinary medicine there is a widespread and increasing interest in the evaluation of the risk of adverse events (e.g. disease).The analysis, perception and management of risk have been the focus for the development of formal methods of qualitative and quantitative risk assessment.
Observational studies provide a framework for identifying risk factors for disease occurrence. Another important application of risk analysis is the role in the importation of animals and animal products (import risk analysis). The OIE provides import risk analysis procedure with respect to the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) of the World Trade Organization (WTO).
The principal aim of import risk analysis is to provide importing countries with an objective and defensible method of assessing the disease risks associated with the importation of animals and animal products.

The terminology used during this training mainly follows the Import Risk Analysis chapter 2.1. of the OIE Terrestrial Animal Health Code.

The principal components in risk analysis according to the OIE are:

I Hazard Identification
II Risk assessment
III Risk management
IV Risk communication

These four components of the OIE risk analysis are shown in Fig. 2:

Figure 2. Components of the OIE risk analysis

The ranking of the components under the terms risk analysis and risk assessment varies in the literature. For the practical decision-maker all these elements are considered as management tools complementing each other to reduce and monitor risk.
Hazard identification can be a separate part of the risk analysis (OIE approach) or be part of the risk assessment (Codex alimentarius). In the latter case, risk assessment begins with the identification and clear definition of the hazard.

National requirements for risk analyses could include (examples):

- risk assessments for import
- ad hoc risk assessments for individual animals diseases
- continuous risk assessments for endemic animals diseases

Re. 1.: For import risk assessments it is necessary to check the global and regional epidemiological situation, trade routes and other relevant factors and respond to new developments with new or updated risk analyses.

According to the WTO requirements / SPS agreement, trade barriers must not be imposed but at the same time it is necessary to manage risks connected with international trade of animals and animal products (e.g. RVF, ECF for Ethiopia).

Re. 2.: Ad hoc risk assessments for individual animals diseases are necessary when new diseases occur in a country, already occurring diseases show a new epidemiological pattern or when new disease control strategies are planned to be imposed (e.g. newly emerging FMD strains in Ethiopia).

Re. 3.: Continuous risk assessments for some endemic animals diseases are necessary to monitor the epidemiologoical sitiuation in connection with existing disease control or to improve disease control. (e.g. trypanosomosis, PPR, CBPP, rabies in Ethiopia).

Decisions regarding animal health always include uncertainties because of the complexity of issues. Disease outbreaks are statistically rare events as only few individuals in a population are affected. Sampling strategies and sample size calculations might not reflect this. Useful assessments, prognoses and conclusions are required but information and data for risk assessments are often insufficient or absent. Extensive modelling and simulations might therefore be necessary to improve the quality of forecasts.

Other important terms and definitions:

Acceptable risk: Risk level judged by Member Countries to be compatible with the protection of animal and public health within their country (see ALOP).

Hazard: means a biological, chemical or physical agent in, or a condition of, an animal or animal product with the potential to cause an adverse health effect under certain conditions, e.g., a bus on the road, *Salmonella enteritidis* in a fertilized egg, rabies virus shed by a dog.

Hazard identification: means the process of identifying the pathogenic agents which could potentially be introduced in the *commodity* considered for importation.

Risk analysis: means the process composed of *hazard identification*, *risk assessment*, *risk management* and *risk communication*.

Risk assessment: means the evaluation of the likelihood and the biological and economic consequences of entry, establishment and spread of a *hazard* within the territory of an *importing country*.

Risk communication: is the interactive exchange of information on *risk* among *risk* assessors, *risk* managers and other interested parties.

Risk factor: An attribute or exposure that is associated with an increased probability of a specified outcome, such as the occurrence of a disease; it can be a causal factor for disease (=determinant) or not.

Risk management: means the process of identifying, selecting and implementing measures that can be applied to reduce the level of *risk*.

Uncertainty**:** The lack of precise knowledge of the input values which is due to measurement error or to lack of knowledge of the steps required, and the pathways from hazard to risk, when building the scenario being assessed.

Variability**:** A real-world complexity in which the value of an input is not the same for each case due to natural diversity in a given population.

II. Import risk analysis according to the OIE

0. Introduction:

Steps in the OIE import risk analysis

Import risk analysis for animals and animal products is based on the following procedures:

- Hazard identification
- Risk assessment, incl.
    - entry assessment (formerly release assessment)
    - exposure assessment
    - consequence assessment
    - risk estimation
- Risk management.
- Risk communication

Hazard identification and risk assessment answer three principle questions:

1. What can happen and go wrong?
   = hazard identification, dose response, and exposure conditions
2. How likely is this to happen?
   = frequency/probability
3. What are the consequences?
   = damage and loss quantification

Importing country obligations

Import health measures should:

- comply with the national level of protection chosen for animal and public health (Appropriate level of protection);
- only be for the exclusion of pathogens/diseases:
    - not present in the importing country or if present, are subject to an official control program;
      if pathogens/diseases are subject to an official control programs, no higher level of protection should be required on imports than the protection provided for the same pathogens/diseases within that country;

- which are OIE listed, unless the importing country has identified the pathogen as presenting a significant risk for that country (in an import risk analysis)

Determination of import health measures:

Option 1: Adopt the OIE recommendations/OIE Code (strongly recommended).

Option 2: Where the OIE Code does not make recommendations for a particular commodity, conduct a scientific risk analysis.

Option 3: If the OIE recommendations do not appear to meet the importing country's ALOP, conduct a scientific risk analysis.

Exporting country obligations

- Be prepared to supply to the importing country information relevant to the safety of the traded commodity: e.g. animal health situation, surveillance systems; border control measures; disease reporting procedures; structure of the vet services and the national surveillance system and outcomes of any recent evaluation including OIE PVS Evaluation; risk analyses conducted by other countries; etc.
- Have in place inspection and certification procedures by certifying officials

1. Hazard identification

According to the *OIE Code*, hazard identification should be undertaken as a classification step, to identify pathogenic agents that could be associated with the importation of a commodity. Agents thus classified are termed 'potential hazards'.

Classification of hazards (OIE):

- *'probable hazards'* – pathogens that may be associated with the commodity. Diseases occurs in the exporting country but are absent in the importing country, should therefore probably be considered as hazard in trade;
- *'possible hazards'* – should seek further information which may allow the pathogen to be removed from the list or which may confirm that it's correctly listed. Diseases for which there is no information available either in the exporting country, the importing country, or both. More information is required to determine whether these diseases may be considered as a hazard.
- *'unlikely to be hazards'* – pathogens not associated with the commodity (e.g. bluetongue in meat).
  Diseases that are either absent from both countries, or present in the importing country, and are therefore unlikely to be trade hazards.

To be identified as a hazard a pathogenic agent should comply with *all* of the following criteria:

- the pathogenic agent should be appropriate to the animal species to be imported, or from which the commodity is derived
- the pathogenic agent could produce adverse consequences in the importing country

- the pathogenic agent may be present in the exporting country[1]
- the pathogenic agent should not be present in the importing country. If present, the pathogenic agent should be associated with a notifiable disease, or should be subject to control or eradication measures[2].

Pathogens that are present in both the importing and exporting countries should only be considered if there is an *official control or eradication program in the importing country*. Different strains or serotypes of the same pathogen may be considered to be different hazards.

A risk analysis may be concluded if potential hazards are not identified or if measures recommended in the OIE *Code* can be applied to manage each hazard.

An *importing country* may decide to permit the importation using the appropriate sanitary standards recommended in the *Terrestrial Code*, thus eliminating the need for a *risk assessment*.

The process of hazard identification will begin with an initial list of pathogenic agents. For terrestrial animals, this list might include the causative agents for OIE listed diseases that are relevant to the species to be imported, or from which the commodity is derived.

Hazard identification is a categorisation procedure that may be carried out and reported using a table, with column headings representing the classification criteria described at the start of this section. If reasons for the inclusion or exclusion of particular pathogenic agents are not clearcut, these agents should be retained on the list and examined using a formal risk assessment.

Table 2. Example of hazard identification table (adapted from AFFA, 2001)

Disease agent (disease)	**Susceptible species**	**Distribution**	**Adverse consequences in importing country (Yes / No)**	**Hazard characterisation**	**Reasons for removal**
Disease agent 1 (Disease 1)		Importing country: …….. Exporting country: ……..		(Probable, possible, unlikely to be hazards)	
etc.					

Note that *the risk analysis should halt at the completion of hazard identification* if any of the following conditions apply:

- no potential hazard is identified
- the importing country elects to use risk management measures described in the *OIE Code* for all identified potential hazards
- the importing country decides not to apply risk management measures to hazards not addressed in the *OIE Code*.

2. Risk assessment

Qualitative and quantitative risk assessment

Quantitative risk assessment: relates the resulting numeric value of risk to a defined unit or number of units as a denominator. Since risk includes both the likelihood and

[1] The *OIE Code* states that . ... *the evaluation of the veterinary services, surveillance and control programs and zoning and regionalisation systems are important inputs for assessing the likelihood of hazards being present in the animal population of the importing country* ....

[2] In this context, control or eradication measures. are taken to mean a compulsory control or eradication program.

consequences of a hazard, risk can be expressed in terms of monetary units, lives lost, or epidemiological units affected (e.g. 100 000 persons, meals eaten, animals traded, km² infected, or a whole state). By thus giving weight to the outcome, the term risk is comparable to that used by e.g. insurance companies.

Qualitative risk assessment: compares risks by non-numeric and non-monetary ranking according to opinion and perception.

In a data scarce environment a qualitative risk assessment approach has proved useful for many examples of animal health related questions and provided a useful tool for risk managers to identify ways to mitigate the risk and to communicate their decisions. A qualitative approach is based on subjective evaluation of the risk compared to the quantitative approach where probabilities are used. The main advantages of all qualitative risk assessments are to prevent an overconfident interpretation of outcomes, to understand for a wider public and to be carried out if little or no data are available but opinions from experts and subject matter specialists are required.

Interaction between risk assessment and management

While the functional separation of risk assessment and risk management is a clear priority (see Fig. 3), there is an understanding that the interphase and interaction between these two areas is crucial. The risk assessment is defined by the risk managers in consultation with stakeholders, but risk assessors need to be at the table to advice on the scientific potential. Likewise the development of the risk assessment is the responsibility of the risk assessors, but there has to be ways of consulting with risk managers in relation to potential for redirection of the assessment or more generally to questions on the risk assessment policy (see Fig. 9).

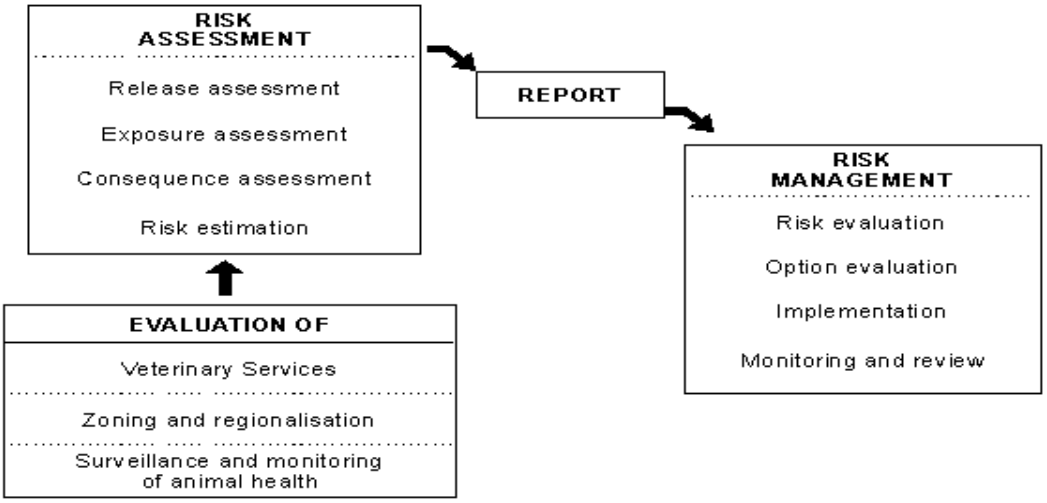

Figure 3: The relationship between risk assessment and risk management processes (FAO: Risk Analysis and OIE)

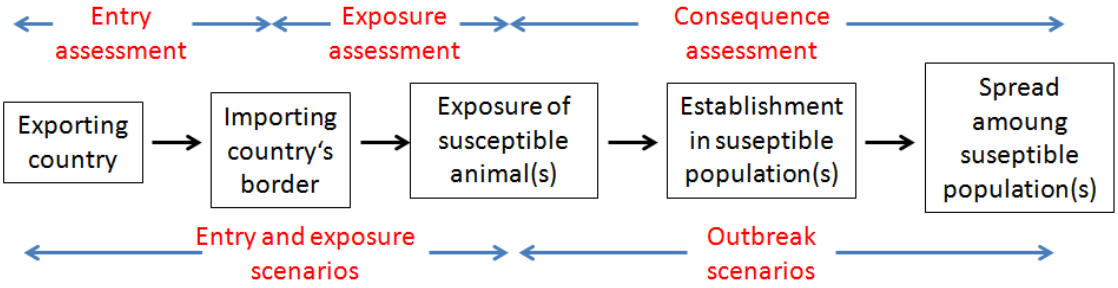

Figure 4. The components of risk assessment (adapted from AFFA, 2001)

2.1. Entry assessment

Entry assessment (formerly release assessment, OIE) comprises two distinct procedures

- description of scenarios
- evaluation of likelihoods

Description of scenarios

In the context of import risk analysis, a 'scenario' represents the ordered sequence of steps that lead to a particular outcome, or 'event', and should have a carefully stated 'initiating step' and 'end point'.

The initiating step for a entry scenario will vary among commodities, but will generally be the first discrete process associated with a commodity's production or selection for export. The end point of a entry/release scenario will be the initiating event of the subsequent exposure scenario, in either case defined as 'the arrival in the importing country of an infected or contaminated commodity' (see Fig. 4). The initiating step and end point of a entry scenario are illustrated in Figure 5.

After the initiating event and the end point of a entry scenario have been defined, the 'steps' that connect the two need to be identified. The level of detail required will vary among assessments, although the governing principle should be to represent adequately any relevant processes that may affect the likelihood of entry.

The *OIE Code* provides a list of factors or considerations that should be taken into account when identifying and describing the steps in a entry scenario. These factors should also be considered when assigning likelihoods to the component steps, as will be described in the following section.

Factors contributing to entry scenarios (OIE, 2012)

a) Biological factors

- species, age and breed of animals
- agent predilection sites
- vaccination, testing, treatment and quarantine.

b) Country factors

- incidence or prevalence
- evaluation of Veterinary Services, surveillance and control programmes and zoning and compartmentalisation systems of the exporting country.

c) Commodity factors

- quantity of commodity to be imported
- ease of contamination
- effect of processing
- effect of storage and transport.

If the entry assessment demonstrates no significant risk, the *risk assessment* does not need to continue.

A hypothetical example of a entry scenario is provided below. In this example, the release scenario describes a series of four events (with likelihoods L1–L4) that *must* occur in order for contaminated semen to enter the importing country. The initiating step is the selection of stud herds from which the donor will be sourced, whereas the end point is, as always, the arrival in the importing country of the contaminated commodity — in this case, semen.

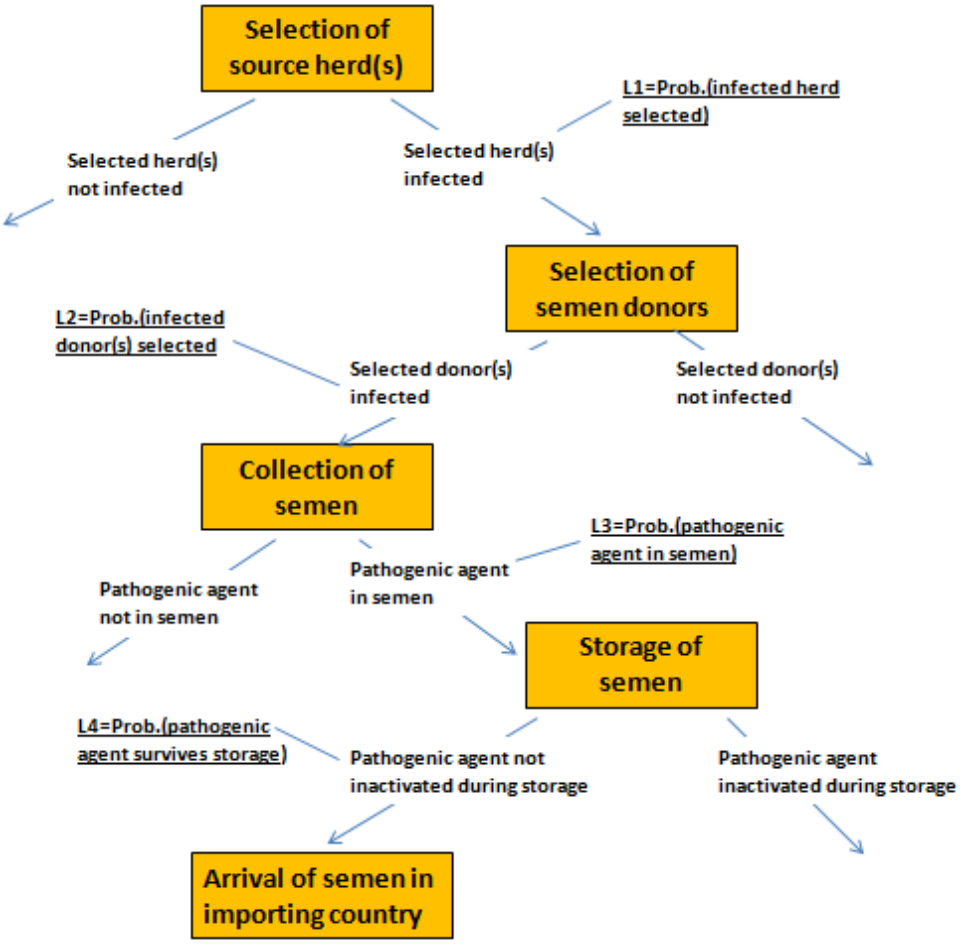

Fig. 5. Entry scenario, an example for the importation of semen

Evaluation of likelihood

In the second phase of the entry assessment, likelihoods are ascribed to each of the identified steps in the scenario. In some situations, it may subsequently be useful to combine these step-level likelihoods to estimate the overall likelihood of entry. Alternatively, it may be more appropriate to assign the likelihoods and to calculate the

overall likelihood of entry *and* exposure at the close of the risk assessment (see, Risk Estimation). The method adopted will generally be determined by the inherent complexity of the release and exposure scenarios, and by the decision to carry out the release and exposure assessments 'qualitatively', 'semi-quantitatively', 'quantitatively' or using a mixture of these approaches.

Table 2. Likelihood categories

Likelihood	Descriptive definition, OIE 2004 & EFSA 2010	Descriptive definition, AFFA 2001	Numeric definitions (range; probability of event per year), FAO/WHO (2009)
Certain			1
Very high			$> 10^{-1}$, not 1
High	occurrence of event is clearly a possibility	The event would be very likely to occur	10^{-1} to 10^{-2}
Moderate	occurrence of event is a possibility	The event would occur with an even probability	10^{-2} to 10^{-3}
Low	occurrence of event is a possibility in some cases	The event would be unlikely to occur	10^{-3} to 10^{-4}
Very low		The event would be very unlikely to occur	$< 10^{-4}$, except 0
Extremely low		The event would be extremely unlikely to occur	
Negligible	probability of event sufficiently low to be ignored or event only possible in exceptional circumstances	The event would almost certainly not occur	indistinguishable from 0

Qualitative likelihoods can be assigned to individual steps in scenarios, or to the probability that the entire scenario will occur.

Likelihood estimates of dependent steps

If qualitative likelihoods have been assigned to individual steps along the risk pathway, then some form of 'combination rule' will be needed for calculating the probability that the entire scenario will occur. Rules can be displayed in various formats, but the most intuitive is a two-by-two tabular matrix, such as shown in the table below. The rules in this matrix are, by definition, arbitrary.

Table 3. Combination matrix for combining descriptive likelihoods along the risk pathway (AFFA, 2001)

	High	**Moderate**	**Low**	**Very low**	**Extremely low**	**Negligible**
High	High	Moderate	Low	Very low	E. low	Negligible
Moderate		Low	Low	Very low	E. low	Negligible
Low			Very low	Very low	E. low	Negligible
Very low				E. low	E. low	Negligible
Extremely low					Negligible	Negligible
Negligible						Negligible

The procedure can be illustrated using the hypothetical semen example above. In this example, each of the four steps has been assigned a likelihood. These likelihoods were subsequently combined using the 'rules' provided in the table above.

Table 4. Qualitative evaluation of the importation-of-semen scenario

Step	**Qualitative descriptor**	**Product of likelihoods**
L1: Selection of an infected herd	Low	
L2: Selection of an infected semen donor	Moderate …….. →	Low
L3: Pathogenic agent present in semen	High …….. →	Low
L4: Pathogenic agent survives storage and transport	V. low …….. →	V. low

The result of the procedure is an estimate of the probability that the complete chain of events will occur - that is, 'the probability that imported semen will be infected on arrival'. In this hypothetical example, the probability that imported semen is infected is estimated to be 'very low'. Alternatively, it could be stated that it is 'very unlikely' that imported semen will be infected. The calculation of this probability would conclude a qualitative release assessment, if this is consistent with the countries' ALOP.

The *advantage* of this matrix-based qualitative approach is that a release scenario can be broken into its component steps and a descriptive likelihood assigned to each. This provides a simple means by which to improve the transparency of an assessment. The principal *disadvantage* is that the assessment will often lead to a conservative overestimate of the likelihood that would have been obtained had the scenario been evaluated using a quantitative or semi-quantitative approach.

This is because the repeated application of any one of the rules in the matrix (table above) will lead to the same likelihood. For example, if two steps in a scenario were considered to have a 'low' likelihood of occurrence, then the product of these, as determined using the matrix, would be 'very low'. Unfortunately, the same result would be obtained if there were three, four, five, etc., steps with a 'low' likelihood, and yet clearly the overall likelihood should be progressively lower in each case.

Where the problem is considered to be severe, a practical 'solution' may be to assign a single likelihood to the entire release scenario, to do the same for the exposure scenario(s) (see Exposure Assessment), and to subsequently combine these using a *single* application of the qualitative combination rules (see combination matrix table). The disadvantage of this approach is that the transparency afforded by the scenariobased assessment will, at least in part, be lost.

A similar approach with a less conservative matrix was proposed and used by EFSA (2010). Pairs of steps in the risk pathway that described an exclusive cascade of events were assessed (e.g. "presence of disease" followed by "non-efficient response measures" leads into "disease endemicity"). Table 5 provides the matrix applied to combine risk estimates of such cascading, or dependent, steps. Also with this matrix, increase of risk along a pathway is not possible. To maintain the "High" risk estimate of the first step, the second step estimate must also be "High". All other estimates will decrease the combined risk estimate.

Table 5. Combination matrix to evaluate two risk estimates based on the assumption that the second event is conditioned on the first event and/or an increase of risk is not meaningful; EFSA 2010

Event 2 / Event 1	Negligible	Low	Moderate	High
Negligible	Negligible	Negligible	Negligible	Negligible
Low	Negligible	Low	Low	Low
Moderate	Low	Low	Moderate	Moderate
High	Low	Moderate	Moderate	High

Application: if event 1 has an estimate "Low" and event 2 has "Moderate", the combined estimate of the sequence event1 and event 2 will be "Low".

Combination of likelihood estimates of non-dependent steps

Another approach considers the combination of risk estimates downstream from the steps of the risk pathway describing independent events ("disease endemic" and "further spread despite mitigation", either leads into "spread into unaffected areas").

The table below provides the matrix applied to combine risk estimates of such non-dependent steps. With this matrix an increase of risk along a pathway becomes possible. If the risk estimate of one step is "Low" but the second step is "High" the combined risk will be "Moderate". Hence, the overall risk is assumed to be between "Low" and "High". The matrix principle transfers the average of independent probabilities to combinations of qualitative risk levels.

Table 6. Combination matrix for descriptive likelihoods to evaluate two risk estimates which are independent of each other and/or an increase of risk is meaningful (for the training purpose: "combination matrix 2") , EFSA 2010

Event 2 / Event 1	Negligible	Low	Moderate	High
Negligible	Negligible	Low	Low	Moderate
Low	Low	Low	Moderate	Moderate
Moderate	Low	Moderate	Moderate	High
High	Moderate	Moderate	High	High

Application: if event 1 has estimate "Low" and event 2 has "Moderate", the combined estimate of event 1 or event 2 worsening the situation, will be "Moderate"

An important consideration in carrying out an entry assessment is how each likelihood may be influenced by the volume of trade during a specified period. This issue is difficult to incorporate into a qualitative framework, because numeric manipulation of descriptive adjectives (at least beyond that used as the basis for combination rules) is likely to be criticised.

One solution may be to state at the start of the risk assessment that *all* likelihoods have been assigned or derived under the implicit assumption that they refer to the volume of commodity likely to be imported in a given period.

Another solution for this problem is to provide a quantitative or semi-quantitative assessment.
Besides estimating the likelihoods, for each factor an estimate for uncertainty should be given to increase the transparency, and prevent misinterpretation and overconfidence in the outcomes of the risk assessment and to highlight areas with extremely poor data quality or disagreement between experts.
Definitions of uncertainty categories are presented in the table below.

Table 7. Uncertainty categories, EFSA 2010

Uncertainty category	*Interpretation*
Low	Solid and complete data available; strong evidence provided in multiple references; authors report similar conclusions
Medium	Some but no complete data available; evidence provided in small number of references; authors report conclusions that vary from one another
High	Scarce or no data available; evidence is not provided in references but rather in unpublished reports, based on observations, or personal communication; authors report conclusions that vary considerably between them

Further examples of risk pathways:
Example 1 (Duarte et al. 2008):

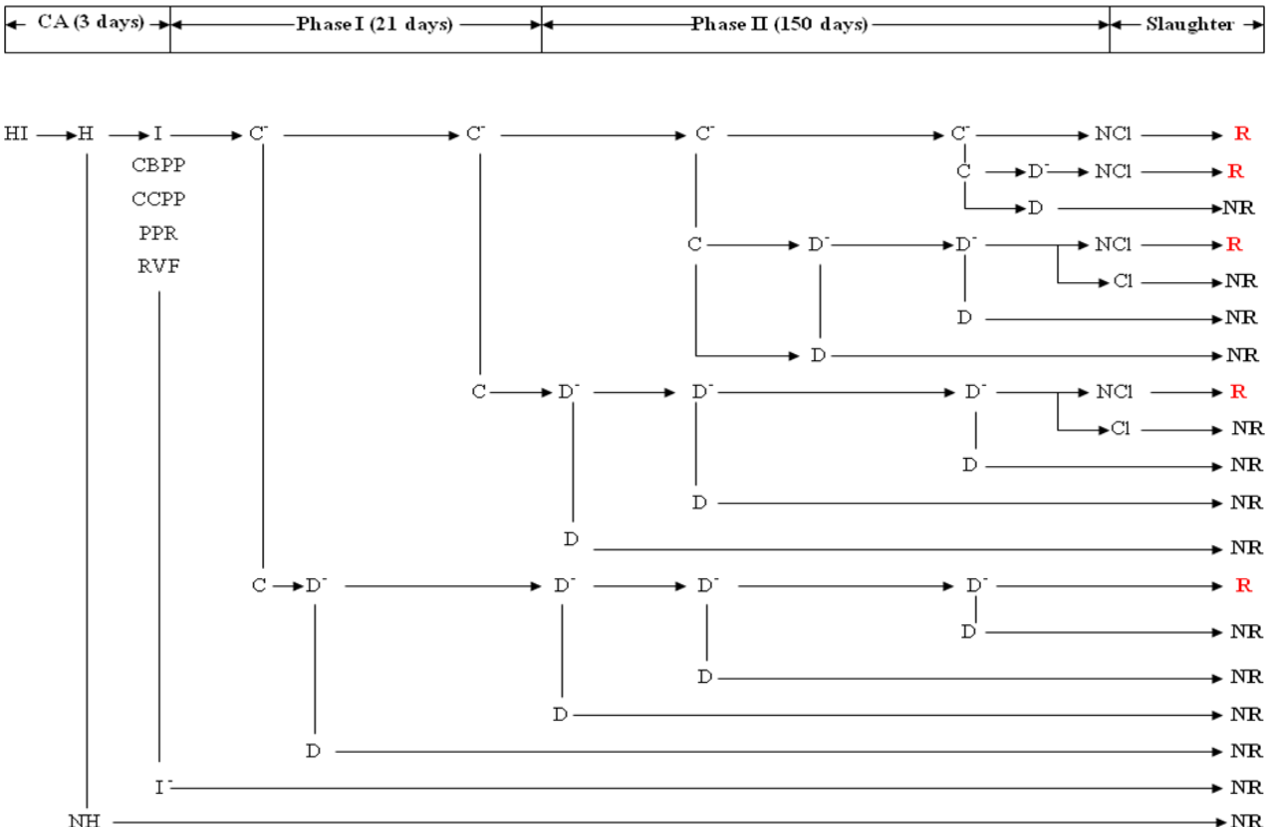

Figure5: General pathway diagram for the release of an animal infected with CBPP, CCPP, PPR or RVF from the proposed system, Duarte et al. 2008
CA: Collection area; HI: Health inspection; H: Healthy; NH: Not healthy; I: Infected; I-: Not infected; C: Clinical case; C-: Non-clinical case; Cl: agent cleared; NCl: agent not cleared; R: Infected animal released; NR: Infected animal not released; D-: Non-detected; D: Detected;
CBPP: contagious bovine pleuropneumonia; CCPP: contagious caprine pleuropneumonia; PPR: Peste des petits ruminants; RVF: Rift Valley fever

Example 2 (EFSA 2010): also including likelihood and uncertainty

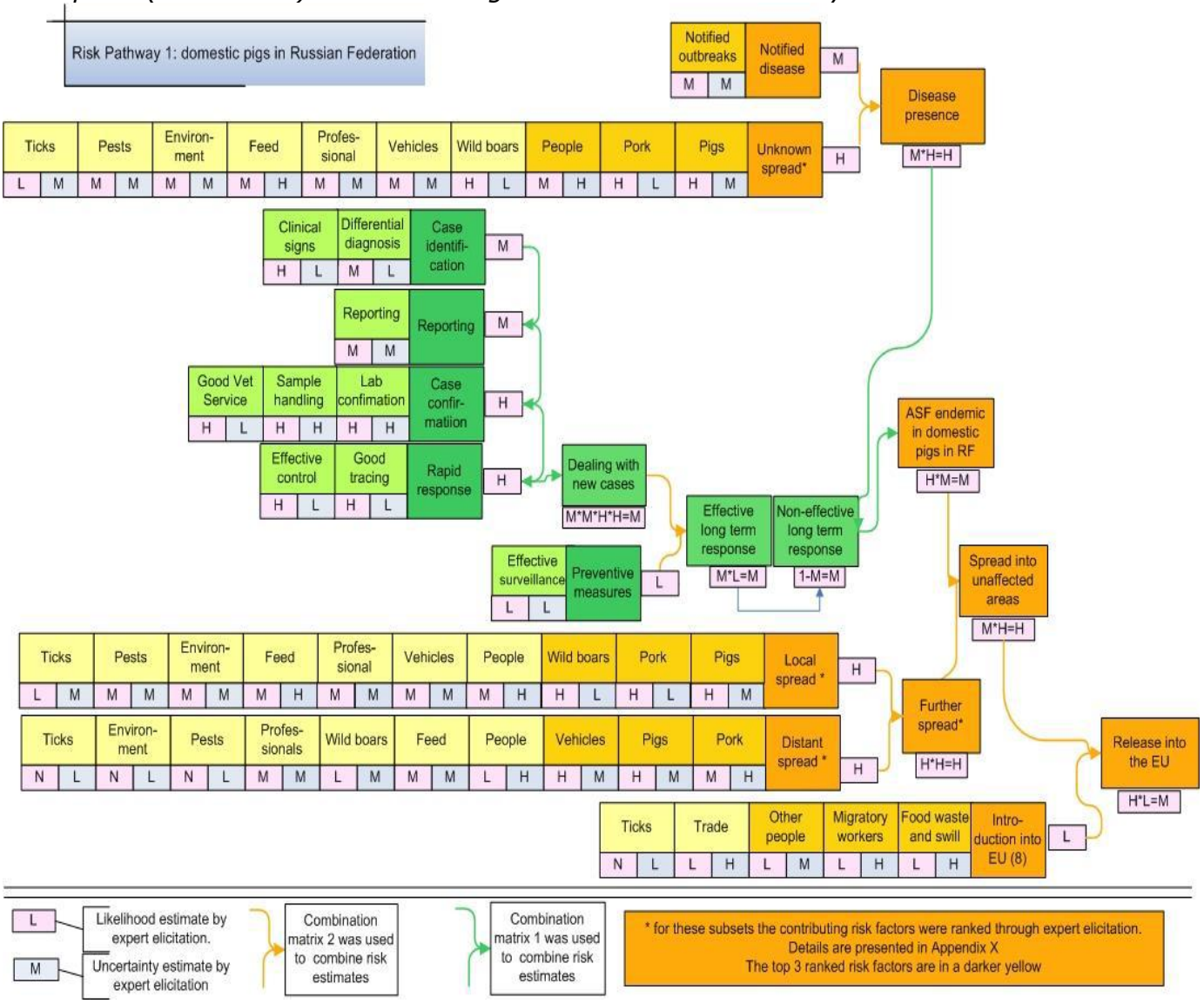

Figure 6. Risk pathways for the entry of ASF virus from domestic pigs in to Russian Federation into the EU, brown: risk factors, green: mitigation measures; EFSA 2010

For this risk pathway three components had to be defined:

1. Deriving total likelihood estimates of steps influenced by multiple factors*;
2. Combining likelihood estimates of dependent steps (see matrix Table 5);
3. Combining likelihood estimates of non-dependent steps (see matrix Table 6)

*If several factors contribute to the risk estimate of a certain step, the factor with the worst likelihood estimate of the step is used in the downstream calculations.
Example: factor1 = moderate; factor 2 = high; factor 3 =moderate; combined result: high likelihood

2.2. Exposure assessment

Exposure assessment comprise two distinct procedures

- description of scenarios
- evaluation of likelihoods

Description of scenarios

As was the case for release scenarios, exposure scenarios are based on initiation points, end points and the steps that link these 'events'. The initiation point for an exposure scenario will be the end point for the corresponding release scenario — that is, 'the arrival in the importing country of an infected or contaminated commodity'. The end point, or end points, will represent 'the exposure of susceptible animals in the importing country (see Fig. 4).

The principal difference between release and exposure assessments is that exposure assessments are frequently more complicated. In general, exposure assessments will follow one of the three configurations shown below:

- a single exposure pathway leading to a single end point — as described for the entry scenario in the example with the import of semen, Fig. 5.
- multiple exposure pathways leading to a single end point
- multiple exposure pathways leading to multiple end points.

The first configuration is the simplest and structurally identical to the hypothetical release scenario of infected semen described above. An example might be the importation of production animal semen, where the commodity is implanted directly into the recipient animal in the importing country. Here it is clear that the exposure scenario will be limited to the steps or procedures associated with the storage and transport of semen in the importing country, any further processing, and the ability of the agent to infect the recipient.

The second configuration — multiple pathways leading to the same end point — is more complex and might be illustrated by the importation of live production animals (cattle, sheep, pigs, etc.). Here, for example, susceptible animals in the importing country could be exposed through direct contact with infected imported animals or indirectly through a vector, fomites, contaminated feed, etc. Each of these two alternatives would constitute a 'pathway', and should be considered as such in the assessment.

Finally, and most difficult to model, is the situation where there are several distinct groups, or species, of exposed animals. An example of this situation might be the importation of a meat product for human consumption, where discrete populations (e.g. domestic, feral or wild animals) could be exposed. The difference between this scenario and that described above is that the separate pathways lead to separate end points.

Once the initiation point and end point(s) of an exposure scenario(s) has been defined, it remains to identify the connecting 'steps'. The level of detail required at this stage will vary amongst assessments, although the governing principle should be to adequately represent processes that may affect the likelihood of exposure.

Factors contributing to exposure scenarios (OIE, 2012)

The probability of exposure to the identified *hazards* is estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure, such as ingestion, inhalation or insect bite, and the number, species and other characteristics of the animal and human populations exposed.

The *OIE Code* provides a list of factors that may be considered when identifying or describing the steps in exposure scenarios. These factors are not steps as such, but considerations that should be borne in mind when identifying and describing the scenarios. These factors should also be considered when assigning likelihoods to the component steps.

Examples of the kind of inputs that may be required in the exposure assessment are:

a) Biological factors

– properties of the agent.

b) Country factors

– presence of potential *vectors*
– human and animal demographics
– customs and cultural practices
– geographical and environmental characteristics.

c) Commodity factors

– quantity of *commodity* to be imported
– intended use of the imported *animals* or products
– disposal practices.

If the exposure assessment demonstrates no significant risk, the *risk assessment* may conclude at this step.

As for release assessments, scenario diagrams or 'trees' should be constructed to illustrate scenarios and to communicate the process of likelihood evaluation. The principle behind this form of representation is that 'events' are described in boxes or 'nodes', whereas the probability or likelihood to be described to each event is associated with the arrows coming from its respective node.

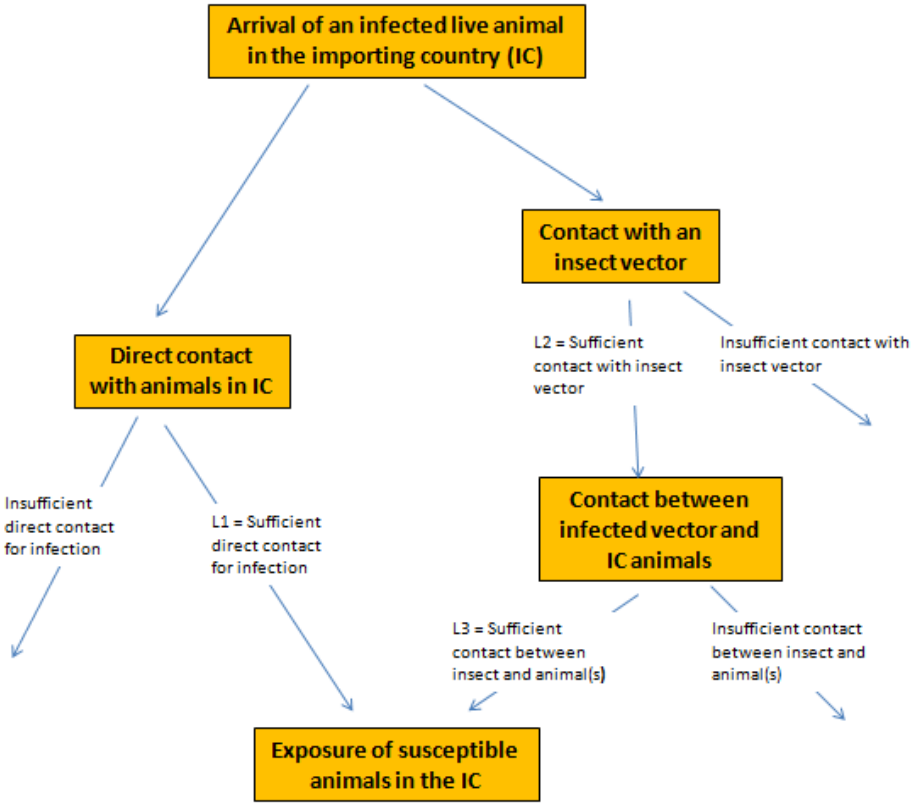

Figure 7. Exposure scenarios for the importation of live animals (example: multiple exposure pathways leading to a single end point)

Evaluation of likelihood

In the second phase of the exposure assessment, likelihoods are ascribed to the steps in each identified exposure scenario. In some situations, it may subsequently be useful to combine these step-level likelihoods to estimate the overall likelihood of exposure. Alternatively, it may be more appropriate to assign the likelihoods to steps in scenarios, but to calculate the overall likelihood of entry *and* exposure at the close of the risk assessment (see, Risk Estimation).

In the example of multiple scenarios / single end point (importation of live animals), as shown in the exposure scenario above, the challenge is to combine likelihoods ascribed to the separate steps in such a way as to convey the relative importance of each branch of the scenario diagram.

Two factors may influence the relative importance of a particular branch of the exposure scenario diagram. The first factor affecting the importance of a branch will be the likelihoods assigned to individual steps. Examples of this might be the likelihood that unsuitable vectors in the importing country would adapt to become competent hosts for an introduced agent, or the likelihood that a live zoo animal would escape and come into contact with susceptible domestic species. Either of these likelihoods might lead to the given path being considered relatively unimportant.

Secondly, it may be relevant to consider the relative 'volume' of commodity physically distributed to that pathway. For example, if the branch described direct contact between imported live animals and susceptible animals in the importing country, then the proportion of live animals that would be distributed directly to recipient herds should be considered.

The principles described in the section evaluation of likelihoods of the entry/release assessment also apply for the exposure assessment.

It is also possible to determine 'partial likelihood of exposure' of each branch of a scenario diagram and calculate the overall likelihood of exposure. The result of this procedure will be a qualitative estimate for '*the likelihood that exposure of susceptible animals will occur by at least one of the branches or pathways described in the exposure scenario diagram*'. For further reading refer to AFFA, 2001.

This document is intended to provide 'guidelines', and not a definitive description of all possible forms of exposure assessment. It may, for example, be appropriate to construct an exposure scenario in which one of the more complicated configurations is 'nested' within the other. Where complications arise, it will be necessary to break the scenario down into its fundamental components and address each using the principles described in this document.

2.3. Consequence assessment

Consequence assessment consists of describing the relationship between specified exposures to a biological agent and the consequences of those exposures. A causal process should exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences.

A consequence assessment should include:

- an assessment of the criteria upon which a disease may impact
- an evaluation of the likely magnitude of consequences, and the likelihood that they will occur at any given magnitude.

Therefore, consequence assessment should incorporate:

- the likelihood of the hazard establishing and spreading
- the estimation of biological, environmental and economic consequences

This may be difficult in a country in which the hazard has never been present.

Consequences not related to a hazard, e.g. the impact of competition from cheaper imported goods, are not considered as relevant according to the SPS Agreement.

Potential consequences may be 'direct' or 'indirect':

Direct consequences:

- on domestic animals
  - ✓ morbidity and mortality
  - ✓ production losses
- on public health (zoonotic diseases, food borne diseases)
- on the environment
  - ✓ physical environment e.g. 'side effects' of control measures (adverse effects of pesticides etc..)
  - ✓ biodiversity, endangered species

Indirect consequences:

- economic
  - ✓ control / eradication costs; compensation programmes
  - ✓ surveillance / monitoring costs
  - ✓ domestic effects (changes in consumer demand, effects on related industries)
  - ✓ potential trade losses (sanctions, lost market opportunities, costs of additional requirements to meet existing markets)
- environmental
  - ✓ reduced social amenity, tourism etc

Usually, a limited number of likely 'outbreak scenarios' are used to estimate the relative likelihood that each scenario will occur (the likelihood of establishment and spread[3]), and the likely magnitude of the consequences in each case.

Direct and indirect consequences are estimated at each of four levels — local, district, regional and national:

Local: an aggregate of households or enterprises — e.g. a rural community, a town or a local government area

District: a geographically or administratively associated collection of aggregates, e.g. a wereda in Ethiopia

Region: a geographically or administratively associated collection of districts, e.g. a region in Ethiopia

National: nation-wide

[3] In the context of import risk analysis, establishment. is taken to mean the establishment of a pathogenic agent within the exposed population/sub-population, whereas .spread. implies the subsequent spread of the agent to other susceptible populations/sub-populations.

At each level, the quantum of impact is described as 'unlikely to be discernible', of 'minor significance', 'significant' or 'highly significant':

- an '*unlikely to be discernible*' impact is not usually distinguishable from normal day-to-day variation in the criterion
- an impact of '*minor significance*' is not expected to threaten economic viability, but would lead to a minor increase in mortality/morbidity or a minor decrease in production. For non-commercial factors (e.g. biodiversity, public health), the impact is not expected to threaten the intrinsic 'value' of the criterion — though the value of the criterion would be considered as 'disturbed'. Effects would generally be reversible.
- a '*significant*' impact would threaten economic viability through a moderate increase in mortality/morbidity, or a moderate decrease in production. For non-commercial factors, the intrinsic 'value' of the criterion would be considered as significantly diminished or threatened. Effects may not be reversible.
- a '*highly significant*' impact would threaten economic viability through a large increase in mortality/morbidity, or a large decrease in production. For non-commercial factors, the intrinsic 'value' of the criterion would be considered as severely or irreversibly damaged.

When considering the extent of consequences of a disease, it will also be important to consider the persistence of its effects. In general, where the effect is prolonged, as may be the case if it persists for several production cycles for production animals, or if regeneration of an ecosystem would take several generations, the consequences are considered to be greater. If the effect is not prolonged, then consequences are likely to be less serious. In either case, it may be necessary to place the disease into the next higher or lower level for that consequence criterion.

Table 8. Assessment of local, district, regional and national consequences; AFFA, 2001

Impact score	**F**				H. significant
	E			H. significant	Significant
	D		H. significant	Significant	Minor
	C	H. significant	Significant	Minor	Unlikely. to be discernible
	B	Significant	Minor	Unlikely. to be discernible	Unlikely. to be discernible
	A	Minor	Unlikely. to be discernible	Unlikely. to be discernible	Unlikely. to be discernible
		Local	**District**	**Regional**	**National**
		Level			

After obtaining a measure of individual direct and indirect consequences of a disease, these need to be combined to estimate the overall consequences associated with an outbreak scenario.

Intuitively, individual effects on each direct and indirect criterion should be summed, because these outcomes will be 'additive'. However, because the system is qualitative, true summation is not possible and the following rules have been developed to provide an approximate solution.

The rules are mutually exclusive, and should be addressed in the order that they appear in the list. For example, *if the first set of conditions does not apply, the second set should be considered. If the second set does not apply, the third set should be considered* ..., and so forth until one of the rules applies:

1. Where any direct or indirect effect is 'F', the overall consequences associated with the outbreak scenario are considered to be 'extreme'.
2. Where more than one direct or indirect effect is 'E', the overall consequences associated with the outbreak scenario are considered to be 'extreme'.
3. Where a single direct or indirect effect is 'E' and each remaining direct or indirect effect is 'D', the overall consequences associated with the outbreak scenario are considered to be 'extreme'.
4. Where a single direct or indirect effect is 'E' and remaining direct and indirect effects are not unanimously 'D', the overall consequences associated with the outbreak scenario are considered to be 'high'.
5. Where all direct and indirect effects are 'D', the overall consequences associated with the outbreak scenario are considered to be 'high'.
6. Where one or more direct or indirect effect is 'D', the overall consequences associated with the outbreak scenario are considered to be 'moderate'.
7. Where all direct and indirect effects are 'C', the overall consequences associated with the outbreak scenario are considered to be 'moderate'.
8. Where one or more direct or indirect effect is 'C', the overall consequences associated with the outbreak scenario are considered to be 'low'.
9. Where all direct and indirect effects are 'B', the overall consequences associated with the outbreak scenario are considered to be 'low'.
10. Where one or more direct or indirect effect is 'B', the overall consequences associated with the outbreak scenario are considered to be 'very low'.
11. Where all direct and indirect effects are 'A', the overall consequences associated with the outbreak scenario are considered to be 'negligible'.

Having obtained an estimate of the consequences associated with each outbreak scenario, it remains to combine this with the likelihood that the scenario will occur and thus derive a scenariospecific measure of 'likely consequences', or 'risk'.

Table 9. Likely consequences: a combination of the likelihood of establishment

Likelihood of establishment & spread						
High	Negligible	Very low	Low	Moderate	High	Extreme
Moderate	Negligible	Very low	Low	Moderate	High	Extreme
Low	Negligible	Negligible	Very low	Low	Moderate	High
Very low	Negligible	Negligible	Negligible	Very low	Low	Moderate
Extremely low	Negligible	Negligible	Negligible	Negligible	Very low	Low
Negligible	Negligible	Negligible	Negligible	Negligible	Negligible	Very low
	Negligible	*Very low*	*Low*	*Moderate*	*High*	*Extreme*
	Consequences of entry and exposure					

For combined consequence assessments with one or more groups of exposed leading to several outbreak scenarios refer to AFFA, 2001.

2.4. Risk estimation

Risk estimation consists of integrating the results from

- release assessment,
- exposure assessment
- consequence assessment

Risk estimation includes the integration of likelihood evaluation and consequence assessment, with the objective of deriving a measure of the 'risk' associated with each pathogenic agent. The procedure used to integrate the various components of the risk assessment will depend upon several factors, including:

- whether each component was obtained using a qualitative, semi-quantitative or quantitative approach
- whether one or more than one group of exposed animals was identified
- the manner in which the volume of trade during a specified period is to be included in the assessment.

  Although it is generally accepted that the volume of trade during a given period may have a marked effect on various likelihoods calculated or derived during a risk assessment, this aspect of import risk analysis remains relatively experimental. The trade volume can be incorporated in semi-quantitative or quantitative approaches.

Risk estimation with a single identified exposure group

The risk estimation matrix shown in Table 10 provides one means by which decision rules can be intuitively displayed. The cells in the matrix represent 'expected loss' — that is, the combination of a measure of consequences and a measure of likelihood. Accordingly, risk will always be expressed in the same 'units' as consequences, and must be less than or equal to the original estimate of consequences.

Table 10. Risk estimation matrix (adapted from AFFA, 2001)

Likelihood of entry and exposure							
	High likelihood	Negligible risk	Very low risk	Low risk	Moderate risk	High risk	Extreme risk
	Moderate	Negligible risk	Very low risk	Low risk	Moderate risk	High risk	Extreme risk
	Low	Negligible risk	Negligible risk	Very low risk	Low risk	Moderate risk	High risk
	Very low	Negligible risk	Negligible risk	Negligible risk	Very low risk	Low risk	Moderate risk
	Extremely low	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Very low risk	Low risk
	Negligible likelihood	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Very low risk
		Negligible impact	*Very low*	*Low*	*Moderate*	*High*	*Extreme impact*

Likely consequences of entry and exposure (s. Tab. 9)

Risk estimation with more than one exposure group (multiple exposure groups)

The partial risk associated with each exposure group will be evaluated in essentially the same manner as described in the discussion of simple exposure pathways, the only difference being the replacement of the 'likelihood of exposure' with the 'partial likelihood of exposure'.

Given this, the release assessment and each partial likelihood of exposure can be combined as described above, and the result modified to incorporate an estimate of the annual volume of trade. This likelihood can then be combined with the assessment of consequences to give the 'partial risk' associated with each exposure group. The process can be undertaken using the risk estimation matrix (Table above).

After a partial risk estimate has been obtained for each of the identified groups of exposed animals, these can be combined to give an overall estimate of annual risk. Where at least one component is qualitative or semi-quantitative, and the qualitative or semi-quantitative terminology described throughout this document has been adopted, partial risks can be combined by applying the eleven decision rules shown below. These rules are mutually exclusive, and should therefore be addressed in the order that they appear in the list. For example, *if the first set of conditions does not apply, the second set should be considered. If the second set does not apply, the third set should be considered* ..., and so forth until one of the rules applies.

1. Where any one partial risk is 'extreme', the overall risk is also considered to be 'extreme'.
2. Where more than one partial risk is 'high', the overall risk is considered to be 'extreme'.
3. Where any one partial risk is 'high' and each remaining partial risk is 'moderate', the overall risk is considered to be 'extreme'.
4. Where a single partial risk is 'high' and the remaining partial risks are not unanimously 'high', the overall risk is considered to be 'high'.
5. Where all partial risks are 'moderate', the overall risk is considered to be 'high'.
6. Where one or more partial risks are 'moderate', the overall risk is considered to be 'moderate'.
7. Where all partial risks are 'low', the overall risk is considered to be 'moderate'.
8. Where one or more partial risks are 'low', the overall risk is considered to be 'low'.
9. Where all partial risks are 'very low', the overall risk is considered to be 'low'.
10. Where one or more partial risks are 'very low', the overall risk is considered to be 'very low'.
11. Where all partial risks are 'negligible', the overall risk is considered to be 'negligible'.

3. Risk management

The OIE Code states in articles 2.1.5 and 2.1.6:

Principles of risk management

1) *Risk management* is the process of deciding upon and implementing measures to achieve the Member's appropriate level of protection, whilst at the same time ensuring

that negative effects on trade are minimized. The objective is to manage *risk* appropriately to ensure that a balance is achieved between a country's desire to minimize the likelihood or frequency of *disease* incursions and their consequences and its desire to import *commodities* and fulfil its obligations under *international trade* agreements.

2) The international standards of the OIE are the preferred choice of *sanitary measures* for *risk management*. The application of these *sanitary measures* should be in accordance with the intentions in the standards.

Risk management components

1) Risk evaluation - the process of comparing the *risk* estimated in the *risk assessment* with the Member's appropriate level of protection.

2) Option evaluation - the process of identifying, evaluating the efficacy and feasibility of, and selecting measures to reduce the *risk* associated with an importation in order to bring it into line with the Members appropriate level of protection. The efficacy is the degree to which an option reduces the likelihood or magnitude of adverse health and economic consequences. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the *risk assessment* and then comparing the resulting level of *risk* with that considered acceptable. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the *risk management* options.

3) Implementation - the process of following through with the *risk management* decision and ensuring that the *risk management* measures are in place.

4) Monitoring and review - the ongoing process by which the *risk management* measures are continuously audited to ensure that they are achieving the results intended.

4. Risk communication

Principles according to the OIE Code (2012):

1) *Risk communication* is the process by which information and opinions regarding *hazards* and *risks* are gathered from potentially affected and interested parties during a *risk analysis*, and by which the results of the *risk assessment* and proposed *risk management* measures are communicated to the decision-makers and interested parties in the *importing* and *exporting countries*. It is a multidimensional and iterative process and should ideally begin at the start of the *risk analysis* process and continue throughout.

2) A *risk communication* strategy should be put in place at the start of each *risk analysis*.

3) The *communication of the risk* should be an open, interactive, iterative and transparent exchange of information that may continue after the decision on importation.

4) The principal participants in *risk communication* include the authorities in the *exporting country* and other stakeholders such as domestic and foreign industry groups, domestic livestock producers and consumer groups.

5) The assumptions and uncertainty in the model, model inputs and the *risk* estimates of the *risk assessment* should be communicated.

III. Practical Risk Analysis

Workflow in risk assessment - 5 steps

1. Phrasing the right risk questions

The correct formulation of the objectives of the risk assessment (risk questions or terms of reference) is essential!

Comparing risk questions A and B:

Risk question A	Risk question B
Risk caused by all imports for the national livestock population	Annual risk because of an infection of the national livestock population caused by the import of a specific subpopulation
Risk of infections with any infectious agent	Risk of infections with FMD virus
Risk of any animal in the national livestock population	Method of selection of animals for import? Randomly selected or other selection criteria?

2. Identification of potential hazards

List all potential hazards which are associated with the risk question and rank them according to their importance for the risk assessment. In the example above, for risk question A the list will be long, and for question B contains only FMD virus.

3. Develop the risk pathway/event tree

4. Collect the necessary data and information

5. Estimate the risk

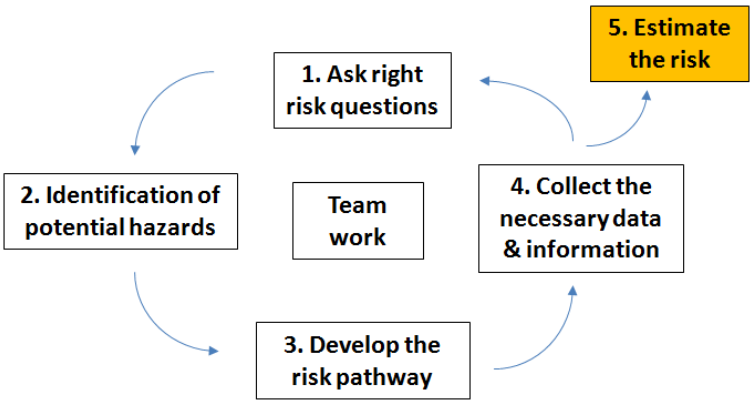

Figure 8. Summary of the 5 steps in risk assessment

Risk analysis often requires the constant co-action between the risk analysts and risk managers. This is illustrated in Fig. below.

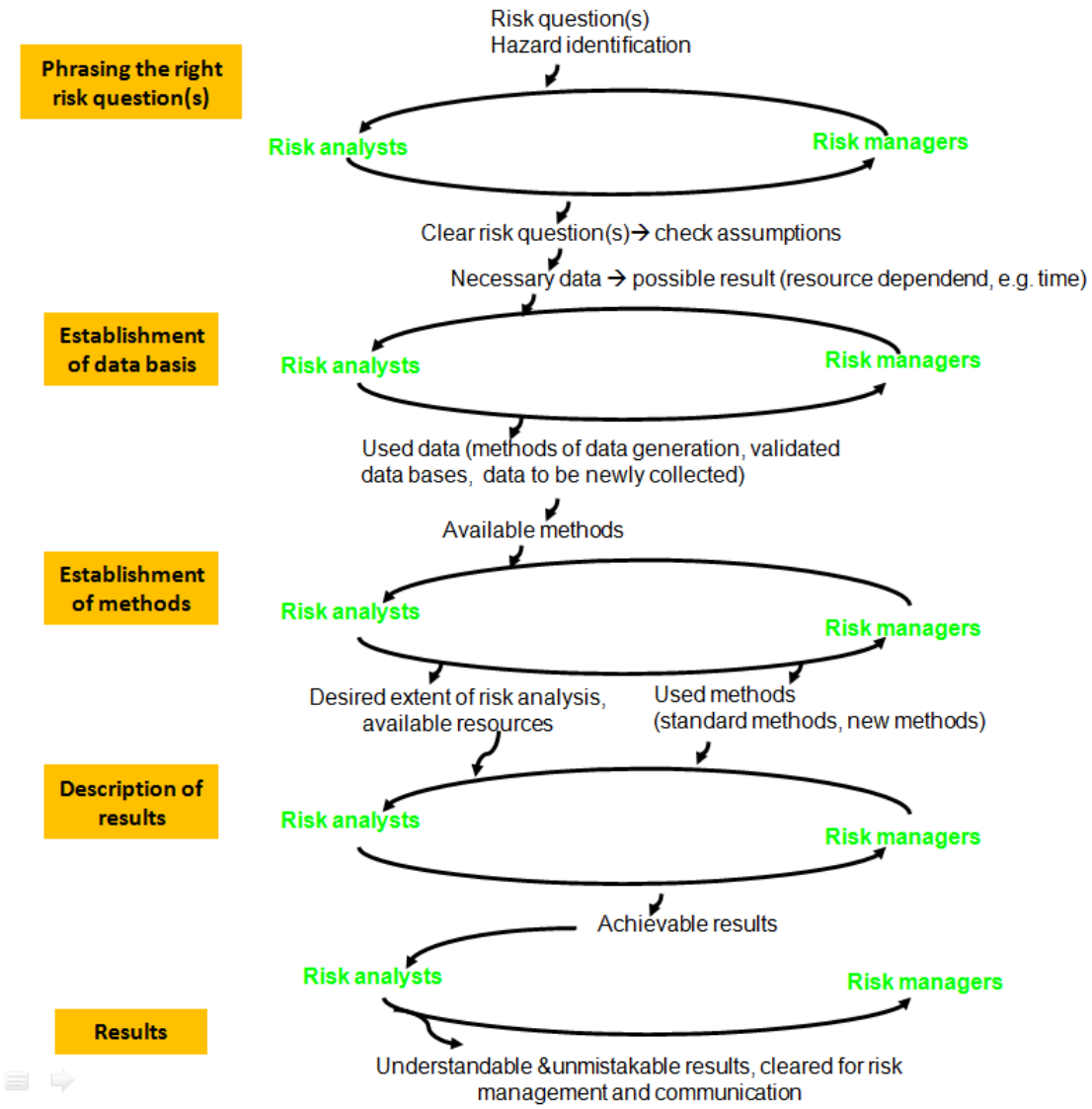

Figure 9. Co-action between risk analysts and risk managers in risk assessment

Exercises

QUESTION 1: Is it true that any dog in a rabies-infected country is a hazard as a potential transmitter of the infection?

ANSWER: This question is incorrectly formulated for a risk assessment. To avoid later confusion in risk assessment and communication, first clarify whether all dogs, or all nonvaccinated dogs or stray dogs, or only rabies-infected dogs, are defined as a hazard in a particular risk assessment. A non-vaccinated dog may be easy to characterize but difficult to identify in a given situation. The applicability of the chosen definition is of great importance.

Hazard characterization includes a number of other conditions concerning virus, host, and environment which determine the likelihood of the event. The term hazard needs to be specified concerning the transmission of the infection to another dog, to wildlife, or to a person.

Moreover, it is unclear whether "hazard" refers only to stray dogs or also to dogs correctly vaccinated and kept under strict supervision, and whether the rabies reservoir is in dogs, terrestrial wildlife, or bats.

<u>QUESTION 2:</u> Where, when, and how does the risk of human infection by Crimean-Congo hemorrhagic fever in Ethiopia exist?

ANSWER: This question is correctly formulated since it leaves space for the definition of the hazard and the scenario. The risk of CCHF infection depends on factors like local ecological conditions and human factors. The question permits the specification of the scenarios.

Further reading:

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