

REVIEW OF DEFRA'S QUALITATIVE RISK ASSESSMENT METHODOLOGY AND INDIVIDUAL RISK ASSESSMENTS

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TERMS OF REFERENCE

The purpose of the review was to assess the methodology used by the Department of Environment, Food and Rural Affairs (Defra) when performing a qualitative risk assessment following official notification of a new disease incident in a European Union (EU) member state, a country on the border of the EU or one of the United Kingdom's (UK) third country trading partners.

The review team was requested to consider, and in its report make recommendations upon the following:

- Is the approach described sound and fit for the stated purpose?
- Is it successfully applied to the published qualitative risk assessments?
- Are the qualitative risk assessments logically consistent (i.e. are the conclusions supported by the stated facts / assumptions)?
- Do the qualitative risk assessments communicate effectively to a non-specialist audience? In particular, are such terms as 'negligible' well-defined and used correctly?

THE REVIEW PANEL

The review panel comprised:

- Heather Smith (Lecturer in Clinical Epidemiology – Royal Veterinary College)
- Kim Stevens (Clinical Research Assistant – Royal Veterinary College)

DOCUMENTATION

The Review Panel was provided with the following documentation available on Defra's website:

- An introductory webpage on international disease monitoring (<http://www.defra.gov.uk/animalh/diseases/monitoring/>)
- 'Qualitative risk analysis of disease outbreaks in countries outside the UK' - a document detailing the methodology supporting Defra's qualitative risk assessments (<http://www.defra.gov.uk/animalh/diseases/monitoring/pdf/riskplan.pdf>)
- Twenty qualitative risk assessments performed between 14/08/2003 and 10/08/2004 (<http://www.defra.gov.uk/animalh/diseases/monitoring/riskassess.htm>)

The panel also referred to *Handbook on Import Risk Analysis for Animals and Animal Products. Volume 1. Introduction and qualitative risk analysis*, (OIE, 2004) and *Import Risk Analysis Handbook 2003* (http://www.affa.gov.au/corporate_docs/publications/pdf/market_access/biosecurity/bde/ira_handbook_revised.pdf, 1 September 2004).

INTERNATIONAL DISEASE MONITORING WEBPAGE

In general the international disease monitoring webpage was well set out and easy to understand. Links were provided to websites of various national and international animal health organisations providing the reader with a variety of supplementary information, although it was felt that some of the links could be more specific. The link to the Veterinary Laboratory Agency (VLA) takes the reader to the homepage rather than directly to their risk analysis webpage. However, the reviewers are aware that Defra is not responsible for the quality or content of external websites.

At the end of the international disease monitoring webpage the reader is directed to three Defra websites: Biosecurity, Surveillance and Emergency Response. It might be useful to include definitions of these terms on the respective pages as well as providing a general overview of Defra's policy on each topic (e.g. the Emergency Response page could provide a broad outline of how Defra handles a disease outbreak situation rather than detailing Defra's contingency plan for a foot and mouth disease outbreak). Some of the material on these pages could be updated (e.g. the links on the Biosecurity page refer to documents dated July 2003).

QUALITATIVE RISK ASSESSMENT METHODOLOGY

The qualitative risk assessment (QRA) document provides a brief outline of the risk assessment process as undertaken by Defra. The methodology is based upon the general principles of risk analysis as outlined by the OIE (OIE, 2004), which divides the risk assessment process into four main parts - hazard identification, risk assessment (subheadings: release assessment, exposure assessment, consequence assessment, risk estimation), risk management and risk communication. The risk assessment may end at certain points prior to the risk management component, if it is concluded that there is a negligible likelihood of

- the hazard being released
- the commodity being infected or contaminated when imported
- exposure to the pathogenic agent (hazard)
- consequences to exposure, or if consequences are not identified (OIE, 2004)

Defra's QRA methodology document states that detailed exposure assessments are only carried out for certain cases, and consequence assessments are not carried out all. An explanatory statement is required to justify this approach.

The review panel feels that expanding on some of the following, might serve to make the QRA methodology document more complete.

Target audience

The reviewers understand that Defra has chosen as their target audience, the layperson, with the aim of educating the public about the risks associated with the importation of disease. As a result, the methodology document highlights key steps in the risk assessment process without the complications of technical jargon or excessive detail. However, professionals involved in the veterinary and agricultural industry, may require a more detailed document as they will be the ones implementing the recommended risk management policy. In order to satisfy the different needs of these two groups the review panel suggests that it may be better to have two methodology documents available on the website – the current document, which has been drawn up with their target audience in mind, and a second, more detailed document for anyone who may require a more in-depth knowledge of Defra's risk assessment process.

With a view to producing a second, more detailed methodology document the reviewers feel that Defra may want to expand on some of the following points:

1. Introductory statement

- As the focus of the QRAs produced by Defra is slightly different to that of other QRAs, Defra may want to highlight this in their introductory statement by expanding on the sentence 'When we are officially notified of a new disease....we carry out a qualitative risk analysis'

2. Risk assessment initiation and follow-up

- By what means is Defra officially notified of a disease outbreak?
- Once a disease outbreak has been identified and assessed, how frequently is the situation re-assessed?
- What happens once the disease outbreak is over?

3. Identifying the hazard

- Because Defra QRAs are principally concerned with OIE list A diseases, the hazard has already been characterized in the title of the document. However, the methodology documents are aimed primarily at people without a veterinary education who will be unaware of the characteristics of these diseases. Bearing in mind the target audience, the reviewers feel that it might be helpful to include a short paragraph summarizing such information as type of disease, how it is transmitted and the population at risk.
- Defra may want to include further information specific to the commodity that is being dealt with such as ease of contamination, effect of processing, and effect of storage and transport on the spread of the disease.
- How is hazard identification handled if the disease under consideration is not a List A disease, or when a disease syndrome is identified but not diagnosed?

4. Risk communication

- Would it be helpful to distribute the QRAs to relevant veterinary and agricultural bodies (e.g. British Equine Veterinary Association (BEVA), British Cattle Veterinary Association (BCVA)) so that they are immediately apprised of the altered situation, rather than the information only being posted on a few central government and general veterinary websites?
- Is the QRA made available to the exporting country so that they are aware of Defra's assessment of the situation?
- Are comments invited from stakeholders before the QRA is made public?

5. Uncertainty and assumptions

- How does Defra assess the validity of the information on which risk assessments are based?
- What is the procedure if insufficient information is available on which to base the risk assessment? Is a provisional assessment made based on available information, and later reviewed as more information becomes available? Is there a specified time limit for the review process (where indicated)?

6. Specific versus general

- Defra may want to look at the wording of certain sentences in the methodology document to ensure that they are sufficiently specific. Statements such as 'Recipients of the report will form a view as to the likely impact of a disease outbreak and respond accordingly', as part of the consequence assessment imply that Defra relies upon all veterinarians and agricultural officers to implement their own risk strategies.

Presentation

The reviewers feel that altering the formatting of the QRA methodology document slightly might make it easier to assimilate. This could include numbering headings and subheadings and using paragraphs of more than two or three lines to improve readability. All abbreviations should be written in full the first time they are used, even such well known ones as EU and OIE, and proof-reading all documents before publishing on the website would help to eliminate minor errors.

INDIVIDUAL RISK ASSESSMENTS

Layout

If Defra wanted to tailor their individual QRAs closer to OIE guidelines the reviewers suggest that use of standard OIE headings such as 'Release Assessment' instead of 'Trade Information' and 'Risk Estimation' rather than 'Hazard Assessment' would allow people to orientate themselves more easily within the document.

Terminology

Of prime importance in the risk analysis process is the use of appropriate terminology to describe or estimate disease risk posed by a hazard (e.g. likelihood, probability, likely) and adjectives to qualify the likelihood estimates (e.g. low negligible, significant). At present, terminology definitions are provided in only 3 of the 20 published risk assessments, although some definitions are provided in the QRA methodology document. Terminology definitions should be included in all QRAs, as it cannot be assumed that the reader will refer to the QRA methodology document.

Although the definitions are those used by the OIE in their risk analysis guidelines, Defra may feel that they can improve upon them so that they have more relevance within the context of their QRAs. The reviewers suggest that uncommon words which are specific to individual reports (e.g. ratites) should be included in the terminology definitions.

Individual sections of the QRAs

Summary

The summaries currently contain descriptions of the disease outbreak, conclusions and recommendations of the risk analysis. A link to the QRA methodology document for details of the risk assessment process would be helpful.

Disease Report

The disease reports provide varying levels of detail regarding the disease outbreak. A clear statement is required in each QRA to identify the hazard and the specific population at risk in the UK should also be identified. References in this section of the report tend to be limited or absent. Although some risk assessments include an appendix of references, with a predominance of websites, these are not always referenced in the text of the document. A wider range of information sources, referenced in the text, would give more authority to the information presented.

In some assessments, it is reported that epidemiological investigations have been undertaken. However, no further information is given as to which authority may be conducting the investigation, or what the investigation may involve (e.g. Newcastle disease in Norway). Details of authorities are lacking in the majority of reports, with their being named by country only. Naming the authority body would increase confidence in the report and would increase transparency of the risk assessment process. If information is not available or is limited, this should be stated and a follow-up report published at a later date.

Legal trade and related sections

A list of commodities that may be affected by the hazard is currently given under the heading of Legal Trade, although in the context of the OIE framework, it would be more appropriate to use the heading Release Assessment.

Additional channels by which the hazard may enter the UK (e.g. illegal trade, fomites, migratory birds) are considered in some risk assessments, although their ordering is not consistent. Where pathways other than legal trade are not assessed, this should be stated and justified.

There are many examples where reference is made to 'EU rules' with regard to the treatment of commodities in legal trade. However, detailed information regarding these rules is infrequently provided or referenced. It is recognised that the EU documentation may be vast, but an attempt should be made to refer to specific rules or directives in both the text and reference list wherever possible.

Useful information regarding disease control measures in the host country is provided in some assessments. Where this information is given, it is recommended that such terms as protection zone, surveillance zone, restricted zone and affected zone are clearly defined with respect to geographical area and size, in order to prevent confusion or ambiguity. As previously stated, reference to the state authority responsible for the control of the outbreak and knowledge of the material used to support the control measures implemented, is recommended.

The OIE recommends that all data sources are referenced. The use of phrases such as 'electronic data' or 'electronic records' does not provide transparency. The reviewers recognise that there may be issues of confidentiality surrounding the naming of data sources, but this should not prohibit sufficient detail being provided to ensure transparency of the QRA process. Where data sources cannot be named, out of respect for the trading partner and to encourage the mutual exchange of confidential information between the UK and her trading partners, a statement should be included to justify the exclusion of such information.

Assessment of risk to UK animal health

This section of the QRA appears to fall under the OIE category of "Risk Estimation". In a number of instances conclusions regarding the likelihood of introduction of the hazard are supported by statements referring to 'EU rules'. As previously stated, referencing of specific EU rules, would improve transparency, and identification of the data sources used to provide information for the risk estimation process is also recommended.

The QRA conclusions for the hazard associated with legal trade are clearly stated in all assessments using the terminology outlined in the QRA methodology document. However, the role of illegal trade is addressed to varying degrees. Some ambiguity remains in the description of risk for other potential pathways of hazard introduction into the UK. In particular, "background risk" and "unquantifiable" risk are regularly referred to with respect to migrating birds, and in some cases this risk is stated as being "unchanged" or "marginally increased". Care should be taken with the use of such terminology as 'a marginal increase' is difficult to quantify especially if no baseline description of risk has been given. Supportive evidence for these statements tends to be lacking, with limited references being included.

General

References must be accurate and appear in both the text and reference list (e.g. classical swine fever, Slovakia – reference in list but not in text).

It is clearly stated in some QRAs that they have been updated. However, others indicate that availability of information was limited at the time of assessment, yet no update has been published. The OIE recommends that when information is limited, 'additional information should be sought to allow a more objective risk assessment within a reasonable period of time' (OIE, 2004).

CONCLUSION

In conclusion, the Defra International Disease Monitoring introductory website provides adequate general information for the target audience. The QRA methodology document is currently brief and targeted at the layperson and the reviewers suggest that a second, more detailed document, be made available for those who require a more in-depth explanation of Defra's risk assessment process. Although the individual QRAs follow a general template their depth and quality of content is variable. The reviewers recognise that there are time constraints for the production of such documents, but would suggest that assessments are regularly reviewed to ensure consistency of presentation and content.

REFERENCES

Murray, N. (2004) *Handbook on Import Risk Analysis for Animals and Animal Products. Volume 1. Introduction and qualitative risk analysis*, OIE, Paris, pp 1-55,

Import Risk Analysis Handbook 2003, downloadable as a .pdf document from the Australian government's Department of Agriculture, Fisheries and Forestry website (<http://www.affa.gov.au/content/publications.cfm?ObjectID=D667DCE6-A412-4673-A6B49B7579CF4AD7>).