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SCIENTIFIC OPINION

Scientific Opinion on Review of the European Union Summary Report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks—Terms of reference 2 to 7[1]

EFSA Panel on Animal Health and Welfare (AHAW)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The Animal Health and Welfare (AHAW) Panel of the European Food Safety Authority (EFSA) has evaluated the European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks by EFSA and ECDC (the report) with regard to data needs and subsequent analyses that will minimise the impact of existing data gaps and inconsistencies. Specific assessments performed for bovine tuberculosis, echinococcosis, Q fever, brucellosis, rabies, cysticercosis and tularaemia show that the report gives an accurate picture of the epidemiological situation for the infections which have an EU harmonised monitoring system. Generally the data analysis is descriptive; further analysis for specific purposes and quantification of the trends should be considered. Specific information for each disease should contain (i) a clear case definition, (ii) a clear description of sampling techniques and diagnostic tests used, (iii) relevant epidemiological characteristics and (iv) relevant control measures or surveillance. Prioritisation of diseases from a public health viewpoint is not in the remit of the AHAW Panel. Proposed criteria to assess the value of including additional diseases in the report are (1) the disease is reported regularly in animals and humans in some EU Member States; (2) the disease is considered a serious public health issue; and (3) monitoring in animals is epidemiologically justifiable. The first two criteria are inclusion criteria; the third is used to prioritise diseases for inclusion in the report. The last section of the opinion addresses the value of the data included in the report for AHAW risk assessment. Their usefulness is often compromised by missing case definition, insufficient metadata or outdated data. It is recommended that data needs are further analysed to improve the preparedness of the AHAW Panel to answer risk questions, via some readily available and stable data as well as good knowledge of ad-hoc data models and sources throughout the EU.

KEY WORDS

Zoonosis, data, risk assessment, animal health and welfare

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[2] Panel members: Edit Authie, Charlotte Berg, Anette Bøtner, Howard Browman, Ilaria Capua, Aline De Koeijer, Klaus Depner, Mariano Domingo, Sandra Edwards, Christine Fourichon, Frank Koenen, Simon More, Mohan Raj, Liisa Sihvonen, Hans Spoolder, Jan Arend Stegeman, Hans-Hermann Thulke, Antonio Velarde, Ivar Vågsholm, Preben Willeberg and Stéphan Zientara. Correspondence: ahaw@efsa.europa.eu

[3] Acknowledgement: the Panel wishes to thank the members of the Working Group on zoonoses review: Aline De Koeijer, Simon More, Mariano Domingo, Mo Salman, Martin Wierup, Mike Sharp and Hans-Hermann Thulke for the preparation of this scientific opinion and Ana Afonso and Franck Boelart for the support provided.

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SUMMARY

The European Food Safety Authority (EFSA) asked the Panel on Animal Health and Welfare (AHAW) to evaluate the European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks by EFSA and European Center for Disease Prevention and Control (ECDC) (hereafter the zoonoses report) with regard to data needs and subsequent analyses that will minimise the impact of existing data gaps and inconsistencies. Further, the AHAW Panel was requested to propose modifications to improve the scientific quality and appropriateness of the data and their usefulness. The first term of reference (TOR) was a direct evaluation of the zoonoses reports of 2009 and 2010, similar to past evaluations. This was addressed separately in a scientific opinion adopted by the AHAW Panel in May 2012 (EFSA Panel on Animal Health and Welfare, 2012). The remaining TORs (2–7) are addressed in this opinion.

TORs 2–5 are addressed in Section 2 separately for specific infections, since the answers can differ according to the epidemiological situation of each. Whether the data presented in the report are giving an accurate picture of the epidemiological situation, this is surely true for those infections which have an EU harmonised monitoring system. This offers a good basis to present a valid, complete and representative picture of the epidemiological situation. Extending this to the other infections will further improve the report.

Generally the data analysis applied in the zoonoses report is restricted to descriptive and summarising methods. Further analyses could be valuable for specific purposes, but are mostly not relevant within the scope of the zoonoses report, i.e., reporting on trends and sources. Further quantification of the trends could be considered, where changes in the trend are observed.

The collection of sample-based data instead of aggregated (population) data could potentially improve the quality and value of the report, but only if the background information and metadata are sufficiently clear. In general, specific information for each zoonosis should contain (i) a clear and agreed case definition, (ii) a clear description of sampling techniques and tests used, (iii) relevant epidemiological characteristics and (iv) relevant control measures or surveillance.

In Section 3, this opinion considers if the data collection should be extended to additional zoonoses, or zoonotic agents, such as vector-borne zoonoses. Prioritisation regarding infections, especially regarding the importance of the disease in humans, is not considered within the remit of the AHAW Panel. Thus we propose a list of criteria, to assess the value of adding a specific infection to the report, while leaving the proposal of naming diseases or infections to other authorities. Three criteria are proposed: (1) the disease or infection is reported regularly in animals and humans in one or more MS; (2) the zoonoses must be considered a serious human disease problem; and (3) monitoring in animals must be epidemiologically justifiable. The first two criteria are proposed as inclusion criteria while the third could be used to prioritise the diseases for inclusion in the report.

In Section 4, possible improvements to the data collection and presentation of the data in the zoonoses report were addressed by evaluating the value of the data in the report for AHAW mandates, while keeping the purpose of the report in mind. In the past, data in the zoonoses report have been of limited value in supporting the AHAW risk assessment process. The usefulness of the data is often compromised by a missing case definition or insufficient metadata. Furthermore, the most recent report is already outdated, with respect to the AHAW risk questions addressed, especially when infections with fast spread or an epidemic behaviour are addressed. Data collections for risk assessment in animal health and welfare should best be driven by the risk question, which makes the zoonoses report (and data libraries in general) a less suitable data source. However, background data which are stable over time, such as information on national surveillance systems and local-level population density data, could be regularly collected, to prevent losing time in a crisis situation, eg evaluating a fast spreading epidemic in Europe. This does not typically fit within the zoonoses report or lead to improvement, but could be taken up separately aiming at increased preparedness of EFSA.

Efforts should continue to improve and develop the zoonoses report, aiming at making the data presented as valid, complete and representative as possible.

Duplications between data collection and reporting exercises should be avoided. Any proposed change in the data collection, analysis and reporting should be shared, discussed and agreed with all interested parties.

The AHAW Panel proposes that inclusion of new diseases in the zoonoses report should start with a list of infections proposed from public health viewpoint, subsequently to be evaluated for inclusion in the zoonoses report by using criteria based on the principles explained in Section 3. A periodical repetition of such an exercise will be important.

It is recommended that data needs are analysed further to help improving the AHAW preparedness to answer risk assessment questions in the form of some readily available more stable data and good knowledge of ad-hoc data sources throughout the EU.

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BACKGROUND AS PROVIDED BY EFSA

The Directive 2003/99/EC establishes the system on EU-wide data collection for zoonoses, zoonotic agents, antimicrobial resistance and food-borne outbreaks. The Directive assigns EFSA the tasks analysing the data and publishing in collaboration with ECDC annual EU Summary Reports on trends and sources zoonoses, zoonotic agents and food-borne outbreaks.

Each year substantial quantities of data are received from the Member States and part of this data monitoring and reporting is harmonised by EU legislation or by EFSA specifications. The analyses of the data at supra-national EU level is challenging due to different epidemiological situations in the Member States and the fact that the data are not always directly comparable between the countries and years.

The scientific panels of Biological Hazards (BIOHAZ) and Animal Health and Welfare (AHAW) have been in the past consulted about the Community Summary reports from years 2004 and 2005, and two opinions from the panels have been issued on this review (EFSA Journal (2006) 403, 1-62 and EFSA Journal (2007) 600, 1-32). It would be appropriate to repeat this review of the EU summary report in order to further improve the scientific quality of the reports, the data collected and the analyses carried out.

TERMS OF REFERENCE AS PROVIDED BY EFSA

The AHAW panel is asked to:

1. review the European Union Summary Report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2009 and 2010. This review should in particular focus on data related to bovine tuberculosis, *Echinococcus,* Q fever, brucellosis, and non-food-borne zoonoses including the current analyses of the available data;
2. evaluate the appropriateness of the data collected at EU level;
3. consider what data are needed at EU level to provide an accurate picture of the epidemiological situation in the EU and the Member States;
4. assess if the analysis methods used in the report are appropriate;
5. consider if the collection of sample based data for the report's aim instead of aggregated data would improve the quality and analyses of data at EU level;
6. consider if the data collection should be extended to additional zoonoses, or zoonotic agents, such as vector-borne zoonoses; and
7. propose any improvements to the data collection, the presentation of the data and their analyses, as appropriate.

ASSESSMENT

1. Introduction and Background

The purpose of the European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks by EFSA and ECDC (hereafter the zoonoses report) is the identification and reporting of trends and sources of specified zoonoses on an annual basis. Previous scientific opinions of the Animal Health and Welfare (AHAW) Panel reviewing these zoonoses reports have drawn attention to the current gaps and inconsistencies that exist in the collection of data on the specified zoonoses that were submitted to EFSA (EFSA, 2006, 2007). The type and quality of these data varied between the zoonoses and among EU Member States (MSs), which has compromised accurate assessments of trends and sources for some diseases. Therefore, EFSA has tasked the AHAW Panel to evaluate the zoonoses report as was done in the past. In addition, the Panel was also asked to evaluate the report with regard to data needs and subsequent analyses that would minimise the impact of existing data gaps and inconsistencies. Further, the Panel was requested to propose modifications that would improve the scientific quality and appropriateness of the data and their usefulness or value for MSs, EFSA and ECDC.

The first term of reference requesting a direct evaluation of the zoonoses report has been addressed in a scientific opinion adopted by the AHAW Panel in May 2012 (EFSA Panel on Animal Health and Welfare, 2012). The remaining terms of reference (2–7) are addressed in this opinion.

EU Directive 2003/99/EC on the monitoring of zoonoses and zoonotic agents attributes to EFSA the responsibility to examine data provided by the MSs and the publication of an annual summary report focusing on the trends and sources of zoonoses. Owing to the report's focus on trends and sources, the current data contents are not expected to be exhaustive with regards to other purposes. Further, although there might be additional and potentially helpful data to be collected and presented in a report on zoonoses, only a limited number of these data would be relevant for the purpose of the zoonoses report.

The data that are used for the zoonoses report were assessed by the AHAW Panel from a biological and epidemiological perspective. It is not within the scope of this opinion to address tasks regarding harmonisation of data collection between MSs, standardisation of the data formats or the linkages to these records from different providers. This opinion provides indications on how to improve the completeness, representativeness and validity of reported data. It is also not the purpose of this opinion to address or elaborate on methods of data cleaning, record matching and data validation, even though it is recognised that issues related to data standardisation or data validations are becoming increasingly important in science.

The terms of reference 2 to 5 are addressed jointly in Section 2 of this opinion, by evaluating specific zoonoses: bovine tuberculosis, echinococcosis, Q fever, brucellosis, rabies, cysticercosis and tularaemia. This approach of specific evaluation was chosen because optimal treatment of data can differ between the different diseases, as a result of their specific characteristics.

Term of reference 6 is not answered directly since prioritisation and selection of relevant infections should first take into account the public health impact of zoonotic agents under consideration. Once additional zoonoses are proposed by the public health competent authorities for future inclusion in the zoonoses report, the relevance of data in terms of trends and sources should be assessed. Section 3 of this opinion provides a set of criteria to be fulfilled to select diseases relevant for the zoonoses report. The criteria were applied to a shortlist of diseases as an illustration of their potential. The intention is not to suggest a shortlist of diseases but rather to propose a proof of concept.

The last term of reference (TOR 7) is not addressed in the context of the zoonoses report alone. Section 4 addresses the question from the AHAW Panel perspective. This section provides an

overview of the data needs and assesses the value of the zoonoses report with respect to these needs, and its value for responding to the AHAW risk questions. While Section 2 of the opinion deals with improvements to the zoonoses report for the purpose of assessing trends and sources, Section 4 only addresses its value as a source of data to respond AHAW risk questions.

2. Principles for presenting trends and sources

This section addresses terms of reference 2 to 5 and provides a specific evaluation of the sections of the zoonoses report for bovine tuberculosis, echinococcosis, Q fever, brucellosis, rabies, cysticercosis, and tularaemia. The questions posed are answered by addressing the relevant issues per infection and no specific answers to the TORs are generated.

Three fundamental questions will be considered to evaluate the routinely collected data in the EFSA Zoonoses database, using guidelines as formulated by Martin et al. (1993):

- *Is it valid* (i.e., do the reported data provide an accurate picture of reality)?
- *Is it complete* (i.e., have all the relevant data been captured)?
- *Is it representative* (i.e., do the reported data provide an unbiased snapshot of the broader population in question)?

To address these three questions, specific data should include:

a. a clear case definition including the causative agent and hosts affected, as well as providing specific features of what constitutes a suspect or confirmed case. An agreement on the case definition should be established with the data providers.

b. the sampling techniques (i.e., random vs 'diagnostic' vs convenience vs risk-based sampling). The collection of disease cases should be related to the populations in which cases occur. Passive, versus active, collection of cases should also be indicated in the report.

c. any relevant epidemiological information on related factors, particularly spatio-temporal occurrence, prevalence and incidence, herd vs individual. Characteristics of the reported cases in terms of host demographics, host environments, time of the events and geographical location should be indicated in the report.

d. any relevant control measures or surveillance. Methods and policy for the surveillance of the disease under consideration should be indicated in the report since they can influence reporting bias.

While some of the zoonoses included in the report are already highly regulated and notifiable in the context of animal diseases surveillance (e.g., brucellosis, tuberculosis, rabies), issues had been identified with their reporting (EFSA, 2006, 2007), and it was agreed to evaluate them again in this opinion.

2.1. Disease-specific requirements

2.1.1. Brucellosis

2.1.1.1. Validity

Brucellosis is notifiable in all MSs for both animals and humans. Thus, MSs are expected to provide valid records and relevant information. However, the variations in the diagnostic methods used (particularly in animals) make the compiling or comparing of data difficult. Furthermore, the variety of host species (bovine, ovine, caprine, etc.) can be another complication for compiling or comparing data.

Future reporting would be improved by the following suggestions in terms of the data validity:

- There is a need for a clear and agreed case definition. The case definition should include:
    - brucellosis seropositivity specifying the surveillance system in place, the host species and the testing protocol;
    - brucellosis bacteriological testing (if conducted) specifying the identification of the *Brucella* species and subspecies, which is important epidemiological information in regard to trends and sources.
- Herd/flock-level prevalence should be presented with denominator data in relation to geographical distribution and structure of the animal population.

The case definition for human cases should also specify the diagnostic tests and bacterial species involved. Data on human cases should provide information on whether diagnostic was completed through serological testing or a combination of different serological tests, on the bacterial identification, and on clinical signs. This type of information will support the validity of the data in regard to trends and sources.

2.1.1.2. Completeness

The key epidemiological objective is to identify the source of human infection, particularly regarding the type of exposure to animals or animal products. The relative impact of different sources of infection will determine the value of the surveillance and control measures applied in animal populations.

The following suggestions could improve the completeness of the synthesis and presentation of the relevant data:

- Comprehensive description of the characteristics of infected/positive herds/flocks in terms of geographical location, size and type of production. This type of information enhances the validity of the data and supports the interpretation of the effectiveness of the control measures and the spread of the infection among animal populations and humans.
- Clear link of human cases to the location of infection and type of animal exposure since this infection is an ortho-zoonosis in which human cases are directly related to either infected animals or animal products.
- Available results from brucellosis survey or testing of wildlife.

2.1.1.3. Representativeness

The value from the existing surveillance for brucellosis should be optimised by presenting its population coverage. The distribution of the population at risk (denominator) should be presented so the significance of cases in selected regions can be identified.

2.1.1.4. Presentation of the brucellosis data

In terms of better understanding trends and sources, the report should clearly address the following points:

a. Based on information available on the exposure to animals or animal products, is the source of infection in humans identified?

b. Surveillance and control measures of animal brucellosis are effective in reducing the number of human cases based on:

- Clear denominator and numerators. The number of animal-level tests conducted or covered (surveillance, clinical investigation) and the number of animals testing positive.
- Possible link between reduction of animal seropositivity and human cases.

2.1.2. Q fever

2.1.2.1. Validity

With respect to the Q fever data, future reporting would benefit if each of the following were resolved.

There is a need for an agreed case definition both for Q fever (the disease) and for infection with *Coxiella burnetii* in animals, similar to that available in public health (International Classification of Diseases, ICD-10, World Health Organization, http://www.who.int/classifications/icd/en/index.html). The current case definition (EFSA, 2011) is confusing, and four case definitions are needed for:

- Q fever at animal level
- Q fever at herd level
- infection with *Coxiella burnetii* at animal level
- infection with *Coxiella burnetii* at herd level.

The definitions of suspect and confirmed cases in animals which have been previously proposed (Sidi-Boumedine et al 2010) should be taken into consideration.

There is a need for clear differentiation, at the time of data entry and during subsequent data analysis, between Q fever (the disease) and infection with *Coxiella burnetii* (the infection). Currently, the difference is not clearly captured in the reporting guidelines (EFSA, 2011). Some data (such as sample type, analytical method, etc.) may become redundant if strict use of clearly defined case definitions were adopted.

There is a need for clear differentiation, at the time of data entry and during subsequent data analysis, between data derived from herds and those from individuals, as is well reflected in the current reporting guidelines (EFSA, 2011).

There is a need for a clear indication, at the time of data entry and during subsequent data analysis, of the epidemiological situation in which samples are collected. Current EFSA coding (objective sampling, census, suspect sampling) is confusing, noting, fundamentally, that there are two categories:

- surveys conducted using random sampling (without regard to infection or disease risk); and
- suspect sampling, where sample collection is focused on high-risk situations (that is, in situations of likely high prevalence).

Further work is needed to improve the quality of denominator data, noting some inconsistency in their interpretation (population at risk). In some parts of the current report, it was not clear if this relates to the total number at risk (i.e., number of sheep on the outbreak farm), the epidemiological unit of concern on that farm, the total number of animals tested, etc.

2.1.2.2. Completeness

Based on the previous AHAW opinion on Q fever (EFSA Panel on Animal Health and Welfare, 2010), it is clear that a considerable number of data are missing. Further, there is a considerable difference between MSs in the degree of coverage. This is an issue for potential discussion within the Biological Monitoring Unit and the associated EFSA Task Force.

2.1.2.3. Representativeness

In the EFSA zoonoses database, an attempt has been made to distinguish data collected through active versus passive surveillance. However, the terms used in the zoonoses report (surveillance, control and eradication programmes, monitoring, survey) are ambiguous, and it is not possible to identify representative data with any level of confidence. This could be addressed with modifications to relevant sections of the current reporting guidelines (EFSA, 2011).

2.1.2.4. Presentation of the Q fever data

In addition to the material already presented, it would be very useful, in terms of better understanding trends and sources, if the report were able to clearly address the following two questions:

a. Is there a Q fever problem? This should be based on:

- number of farm-level outbreaks (clinical disease) where Q fever was confirmed.

b. How hard are people looking? This should be based on:

- total number of animals at risk
- number of animal-level tests conducted (surveillance, clinical investigation), number of positive test results
- whether there is a programme of active Q fever surveillance (representative, non-representative sampling): per cent farms seropositive, per cent animals seropositive?

2.1.2.5. Concluding comments

It is likely that lessons can be learned if the Biological Monitoring Unit were to liaise with the group within the World Health Organization that manages the annual World Health Statistics Report (http://www.who.int/gho/publications/world_health_statistics/en/index.html), based on data collected within the ICD-10 framework (http://www.who.int/classifications/icd/en/index.html).

2.1.3. Tuberculosis

As highlighted in the EFSA reporting guidelines (EFSA, 2011), key issues relevant to data collection are harmonised throughout the EU, in conformity with relevant legislation. Many of the issues raised with respect to Q fever were avoided for tuberculosis because of harmonised case definitions, data collection, etc.

The report would be of greater value, in terms of trends, if several of the key trend indicators were applied across all MSs, regardless of whether they are officially or non-officially tuberculosis free. The current maps do not provide any detail about the spatial distribution of infection within infected MSs. A note to this effect should be included, as the epidemiological presentation, including spatial distribution, of infection between MSs varies greatly.

2.1.4. Rabies

In a similar way to tuberculosis, key issues relevant to data collection are harmonised throughout the EU and Europe, in conformity with relevant legislation. This information is submitted voluntarily by the participating countries and collated by the WHO Collaborating Centre for Rabies Surveillance and Research, which makes the information available through a database (http://www.who-rabies-bulletin.org/Queries/Surveillance.aspx).

The database provides up-to-date information by country, animal category (domestic and wildlife) and animals tested negative. At present, information on lyssavirus infection of bat species is not included.

The report would benefit from utilising this information to present a succinct picture of trends and sources.

2.1.5. Echinococcosis

2.1.5.1. Validity

The current data do not provide an accurate picture of the epidemiological situation in the MSs. Considering that echinococcosis is as frequent in the human population as *Trichinella* (790 vs 748 confirmed trichinellosis cases), the validity of data may be enhanced by:

- The information provided for the two diseases should separately present information for *Echinococcus granulosus* and for *E. multilocularis*; separation would be particularly beneficial for
    - *E. granulosus* vs *E. multilocularis* in human cases (e.g., 22 % undetermined in 2010)
    - *E. granulosus* vs *E. multilocularis* in definitive animal hosts
    - clear distinction of detection in definitive hosts compared with the intermediate host.
- Standardised case definition should apply (Commission Decision 2008/426/EC and Regulation (EU) No 1152/2011), e.g., non-confirmed cases as reported in the report are not defined.

Diagnostic criteria for (confirmed case) at least one of the following five:

- histopathology or parasitology compatible with *E. multilocularis* or *E. granulosus* (e.g., direct visualisation of the protoscolex in cyst fluid);
- detection of *E. granulosus* pathognomonic macroscopic morphology of cyst(s) in surgical specimens;
- typical organ lesions detected by imaging techniques (e.g., computerised tomography, sonography, magnetic resonance imaging) and confirmed by a serological test;
- *Echinococcus* spp. specific serum antibodies by high-sensitivity serological test and confirmed by a high specificity serological test;
- detection of *E. multilocularis* or *E. granulosus* nucleic acid in a clinical specimen.

2.1.5.2. Completeness

- Data concerning spatial occurrence/distribution of *E. multilocularis* in the MS are sparse and scattered.
- There are considerable differences between MSs in the degree of regional and population coverage.
- There are considerable differences between MSs in the consistency of investigation.
- Data are incomplete to identify or compare regional risk sources or to disclose/demonstrate suggested trends, e.g., towards enlarged distributional range of the parasite in definite hosts.
- Population estimates as denominator for major definite host populations might support comparison of investigation efforts.

2.1.5.3. Representativeness

Regionalisation is a suggested important issue for *E. multilocularis* occurrence, therefore most of the data lack representativeness regarding heterogeneity of risk between and within regions and MSs.

Data on *E. granulosus and E. multilocularis* in both pets and wildlife other than foxes are of little value in their present form as they are not representative for disease, host species, risk region or level of incidence. A major reason for lack of representativeness is that surveillance in wild animals in Europe is minimal or absent in several MSs.

2.1.5.4. Presentation of the *Echinococcus* data

A map of the regional distribution of the surveillance effort would be informative and helpful, making the results of case detection more valuable.

2.1.5.5. Concluding comments

The supposedly regionalised risk distribution according to infestation rates in the definite host population, together with the documentation of (or changes in) spatial distribution and/or infestations level in endemic regions, would provide the main information to guide management and prevention efforts including targeted surveillance based on trends and sources.

Regional data are the only appropriate way to present *Echinococcus* information (e.g., *E. multilocularis* population prevalence in definite host differed between above 20 % to below 5 % on a distance of 20 km around endemic risk areas) (Hanosset et al. 2008).

2.1.6. Cysticercosis

2.1.6.1. Validity

The current data do not provide an accurate picture of the epidemiological situation in the EU and the MSs. The hazard related to zoonotic *Cysticercus* needs to be re-defined in the report. The disease in humans is taeniosis, caused by the adult forms of *Taenia solium* or *T. saginata*. Apart from intestinal taeniosis, humans infected by *T. solium* may also suffer from cysticercosis (infection of internal organs by the larval stage of the parasite). Disease in humans due to *T. saginata* is mild, and not reported to the zoonoses report. Disease in humans due to *T. solium* (cysticercosis) may be severe, but it is usually considered exotic to the EU, and no data are reported.

In animals *T. saginata* cysticercosis is seen most commonly in cattle, and *T. solium* cysticercosis is seen in pigs. Both infections localise mainly in the striated musculature.

2.1.6.2. Completeness

Data related to *T. saginata* cysticercosis in cattle and *T. solium* cysticercosis in pigs are not collected for the purpose of the zoonoses report.

2.1.6.3. Representativeness

In the zoonoses report, only data on *Cysticercus tenuicollis* are reported, which is not a zoonotic infection.

2.1.6.4. Presentation of the data

No data relevant to zoonotic risk of cysticercosis are presented.

2.1.6.5. Concluding comments

The usefulness of collecting cysticercosis data on humans and animals needs to be reviewed. The actual chapter on cysticercosis in the report does not focus on the zoonotic risk posed by these two parasites.

2.1.7. Tularaemia

2.1.7.1. Validity

The current data do not provide an accurate picture of the epidemiological situation in the EU and the MSs. When considering that tularaemia is a highly infectious emerging disease that is known to affect most of Europe:

- Reports should include all MSs. Currently reports are only available from few MSs.
- The original geographical range of tularaemia is expanding to include distant new areas. The regional locations of reported cases within MSs would facilitate a more valid information on the disease occurrence.
- *Francisella tularensis* has a very broad host range and a complex ecological transmission cycles including an aquatic cycle. More detailed information on, for example, the animal species or other sources and time of detection would be beneficial for a better understanding of the epidemiological situation and the epidemiological role of different animal species and of the cyclical outbreaks of mortality that often occur.

2.1.7.2. Completeness

- Available data are missing, in particular from MSs where the disease has a longer history of occurrence.
- There is an overlap in the distribution of human and animal tularaemia and more detailed epidemiological information on possibly available data from reported human cases would be beneficial for detection and understanding of the zoonotic epidemiological links and transmission pathways that could result in a more accurate monitoring of the disease occurrence.

2.1.7.3. Representativeness

For the different reasons presented above it is clear that the data presented so far in the EFSA's annual zoonoses reports do not provide an unbiased snapshot of the broader population in question. A major reason is that surveillance in wild animals in Europe is minimal or absent in most countries (Kuiken et al., 2011).

2.1.7.4. Presentation of the *Francisella* data

In addition to an updated description of the disease as specified in the previous AHAW opinion (EFSA Panel on Animal Health and Welfare, 2012), and appropriate tables and graphs, a map-guided presentation of the regional distribution would be helpful.

2.1.7.5. Concluding comments

For both animal and public health reasons, it is justified that *F. tularensis*, which has so far largely been neglected in the zoonoses report, is given more attention in line with other already established zoonotic pathogens. As an initial step it is highly recommended that, as a minimum, general surveillance of wild animals found dead be conducted, including shot (hunted) animals, which would improve the quality and analyses of data at EU level.

It is also recommended that guidelines and protocols are defined by the EFSA manual for reporting on zoonoses on detection of *F. tularensis* in various situations, considering also new methods for detection of pathogens in wildlife.

3. Additional zoonoses or zoonotic agents to be considered

It is important that the zoonoses report is reviewed and updated with zoonotic diseases of major concern. However, data collection and analysis have substantial costs and it is important to define criteria to decide which diseases to include. Prioritisation and selection of relevant zoonotic infections should first take into consideration public health impact. Once this selection is completed, the proposed additional zoonoses should be evaluated for relevance to the zoonoses report in terms of trends and sources.

The following criteria should be considered in assessing which diseases/agents could be included. The first two criteria regarding evidence of serious human health impact (as defined by public health

authorities) and regular reporting are proposed as inclusion criteria. The third criterion could be used to prioritise diseases to be included.

The criteria are:

1. The disease is considered a serious human health issue in Europe.

and

2. The disease is reported regularly in animals or humans in one or more MSs. Regularly reported diseases are those observed and recorded by MS public health and/or veterinary authorities. The monitoring can be based on their clinical manifestations (disease) in addition to regular reporting based on laboratory-based diagnosis (infection). Diseases that are not reported in this fashion are more difficult to include since they will require extra dedicated surveillance efforts. Nevertheless, those diseases that can be reported through their clinical manifestations or syndromes can be included in addition to regularly reported ones.

and

3. Monitoring and surveillance of the disease in animals must be epidemiologically justifiable[4] in terms of one or more of the following:

    3.1. monitoring in animals has added value for evaluation of trends and sources in either animals or humans.
    3.2. surveillance in animal populations has value for early detection of human cases and public health preventative measures; or
    3.3. control measures in animal populations contribute to mitigate public health impact.

The application of these criteria to a few examples of zoonotic agents is summarised in Table 1.

Table 1: The application of these criteria to a few exemplary zoonotic agents to demonstrate the identification of additional zoonoses for potential inclusion in the zoonoses report

Disease	**Criterion**				
	1	**2**	**3**		
	Serious human disease problem	**Regularly reported**	**3.1. Value for evaluation of trends and sources**	**3.2. Value for early detection of human cases and public health preventive measures**	**3.3. Control measures in animal populations can contribute to mitigate public health impact**
Borrelia burgdorferi	Yes	Yes	Yes	Yes	No
West Nile virus	Yes	Yes	Yes	No	No
Leptospira spp.	Yes	Yes	Yes	Yes	Yes (domestic animals)
Hantavirus	Yes	No	Yes	Yes	No
Crimean Congo haemorrhagic fever virus	Yes	Yes	Yes	Yes	No
Leishmania infantum	No	Yes	Yes	Yes	?

[4] Valid complete, representative.

In addition to the recognised potential threats (see examples in Table 1), it is important to remain vigilant about (re)emerging new pathogens, particularly in animal populations, that can be transmitted to humans. The above criteria provide a pragmatic approach to guide any monitoring to be undertaken by MSs and subsequent assessment for inclusion in the zoonoses report. The inclusion of new zoonoses in the report should primarily be guided by information from the MSs which should be advised and encouraged by EFSA to such reporting . Based on such information as well as on other information provided, e.g., in EFSA opinions and from relevant EU and international sources, EFSA could produce a shortlist of possible candidates of zoonoses to be added to the report.

4. Data needs for risk assessment in animal health and welfare.

The last section in this opinion addresses the issue of data needs for risk assessment in animal health and welfare from the AHAW Panel perspective. This section provides an overview of the data needs and assesses the value of the zoonoses report with respect to these needs, and its value for responding to the AHAW risk questions.

Beyond the issue of individual infections and existing data collection systems, the Panel reflected on the value of the zoonoses report as a source of information to answer AHAW mandates regarding zoonotic risks. This was done based on a retrospective analysis of typical risk questions in AHAW mandates, a review of the data the AHAW Panel regularly needs for answering its mandates, and the identification of which of those needs could be addressed by the zoonoses report.

A retrospective analysis of risk questions addressed by the AHAW Panel and data needs to answer these questions in the period 2004–2010 was prepared by Bellet et al. (2012) and was considered here. The following types of questions were identified: (1) host/pathogen characteristics, (2) disease status, (3) potential risk of spreading to susceptible population/pathways of transmission and speed of the spread, (4) risk of (re)introduction, (5) risk of establishment, (6) effectiveness of surveillance measures, (7) diagnostic tools availability and efficiency, (8) effectiveness of prevention tools, (9) effectiveness of control measures, (10) effectiveness of bio-security measures, (11) treatment availability and efficiency and (12) vaccine availability and efficiency.

The risk questions that more frequently reappear in the AHAW mandates were (1) risk of (re)introduction; (2) risk of potential spread to susceptible population and/or the pathways of transmission and speed of the spread; and (3) effectiveness of control measures.

Data needs were classified in five categories with references to the previous risk questions typology: (1) disease general information, (2) descriptive epidemiological data, (3) analytical epidemiological data, (4) prevention and control data and (5) disease surveillance data.

The first category contains rather well-known and widely accepted knowledge and information, to which occasional new insights can be added, but which hardly change over long time periods. Depending on the infection, this can also be true for the second category. The other three categories contain both time- and space-sensitive data, data which are rather stable over time. This data categorisation gives a clear overview, with three levels of subcategories and thus offers a comprehensive list of data needs for AHAW mandates (Appendix).

The analysis of the data used in previous AHAW opinions shows that the data collected and synthesised for the zoonoses report were of limited value in supporting the AHAW risk assessment process even when mandates address infections which are included in the zoonoses report.

Data validity issues were raised in previous EFSA opinions (e.g., *Echinococcus* (EFSA, 2006) and Q-fever (EFSA Panel on Animal Health and Welfare, 2010)). In particular, the usefulness of the data was compromised by either a missing case definition or insufficient metadata, i.e., what test is applied, how are the samples selected, what host population is addressed, etc. Disease prevalence and regional or temporal differences in prevalence were difficult to quantify.

The data needed to address animal health recurrent risk assessment questions can mostly not be found in the zoonoses report. Essential data for answering such questions are up-to-date information regarding size of import streams, prevalence of the addressed infection outside the EU, the transmission dynamics of the infection within the EU and the impact of control measures.

Continuous data collection into a central EFSA database is expensive, time-consuming and also often not relevant for infections with a fast epidemic behaviour since such information will still not be sufficiently up to date, or sufficiently focused on the question at hand.

Most of the data described for AHAW needs do not belong in the zoonoses report, given its purpose to report on sources of and trends in important zoonoses within the EU. Therefore, we do not recommend adding such data as a specific improvement to data collection and data presentation for the zoonoses report in order to fit the purpose of different risk assessments.

Instead, further analysis of the data needs, such as the classification proposed in the Appendix (Bellet et al., 2012), should be made to increase AHAW preparedness for future mandates, thus allowing a faster response and more structured approach.

Background data which are stable over time include information on national health management surveillance systems, and data on farm management and population density with sufficient regional detail, and could be subject of routine data collection within the zoonoses report. Accurate knowledge regarding institutions that collect up-to-date surveillance data on animal infectious diseases and maintaining good contacts with the owners of commonly used data as listed in the tables in the Appendix is essential. Using such a solution will help solving the main recurring comments the AHAW Panel makes regarding the value of data and presentation thereof in the zoonoses report (i.e., not up to date, no reference data, not comparable).

It is recommended that EFSA explores options for further analysis of the results presented in the Appendix and analyses the possibilities for better preparedness based on these results.

Finally, it should be noted that the AHAW Panel is also interested in and tasked with issues which are not of a zoonotic nature, i.e., non-zoonotic animal diseases and welfare issues. These aspects can also be included when evaluating the type of data to be collected for risk assessment mandate preparedness, while they surely do not belong in the zoonoses report. In particular, collection of data regarding trends in welfare disorders will be a new and valuable addition to data collection, which may offer considerable new insight into welfare problems and their evolution over time.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

This review and suggestions for improvements were aimed at being helpful for the European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks by EFSA and ECDC (hereafter the zoonoses report) in its ability to assess trends and sources of zoonoses in the EU. It was recognised that the zoonoses report has continuously developed and improved since its first edition for the year 2004.

Whether the data presented in the zoonoses report are giving an accurate picture of the epidemiological situation is surely true for those infections which have an EU harmonized monitoring system. This offers a good basis to present a valid, complete and representative picture of the epidemiological situation. Extending this to the other infections would further improve the zoonoses report.

Generally the data analysis applied in the zoonoses report is limited to descriptive and summarising methods. Further analyses could be valuable for specific purposes, but are mostly not relevant within the scope of the zoonoses report ,which is reporting on trends and sources. Further quantification of the trends could be considered, where changes in the trend are observed.

The collection of sample-based data instead of aggregated (population) data could potentially improve the quality and value of the report, but only if the background information and metadata are sufficiently clear. In general, specific information for each zoonosis should contain (i) a clear and agreed case definition, (ii) a clear description of sampling techniques and diagnostic tests used, (iii) relevant epidemiological characteristics and (iv) relevant control measures or surveillance.

In regard to the question of extending the data collection to additional zoonoses, or zoonotic agents, such as vector-borne zoonoses, the AHAW Panel considered that prioritisation regarding infections, especially regarding the importance of the disease in humans, is not within its remit.

It is proposed to use criteria to assess the value of adding a specific infection to the report, while leaving the proposal of naming diseases or infections to other authorities. The proposed criteria are (1) disease or infection is reported regularly in animals and humans in one or more MSs; (2) the disease must be considered a serious human health issue; and (3) monitoring in animals must be epidemiologically justifiable. The first two criteria are inclusion criteria while the third one is used to prioritise the diseases for being included in the report.

Possible improvements to the data collection and presentation of the data in the zoonoses report were addressed by evaluating the value of the data in the report for AHAW mandates, while keeping the purpose of the report in mind. In the past, data in the zoonoses report have been of limited value in supporting the AHAW risk assessment process. The usefulness of the data is often compromised by a missing case definition or insufficient metadata. Furthermore, the most recent report is usually outdated, with respect to the AHAW risk questions addressed, especially when infections with fast spread or an epidemic behaviour are addressed. Data collections for risk assessment in animal health and welfare should best be driven by the risk question, which makes the zoonoses report (and data libraries in general) a less suitable data source. However, background data which are stable over time, such as information on national surveillance systems and local-level population density data, could be regularly collected, to prevent losing time in a crisis situation, eg. evaluating a fast spreading epidemic in Europe. This does not typically fit within the zoonoses report or lead to improvement, but could be taken up separately aiming at increased the preparedness of EFSA.

RECOMMENDATIONS

Efforts should continue to improve and develop the European Union Summary Report on trends in and sources of zoonoses, zoonotic agents and food-borne outbreaks aiming at making the data presented as valid, complete and representative as possible.

Duplications between data collection and reporting exercises should be avoided. Any proposed change in the data collection, analysis and reporting should be shared, discussed and agreed with the Commission, the data providers and ECDC.

The AHAW Panel proposes that inclusion of new zoonoses in the zoonoses report should start with a list of infections proposed from a public health point of view, subsequently to be evaluated for inclusion in the zoonoses report by using the proposed criteria. Such an assessment should be performed on a regular basis for the list of diseases included in the zoonoses report to be pertinent.

It is recommended that data needs are analysed further to help improve the AHAW preparedness to answer risk assessment questions in the form of some readily available, more stable data and good knowledge of ad-hoc data sources throughout the EU.

It is recommended that the Biological Monitoring Unit liaise with the World Health Organization group that manages the annual World Health Statistics Report regarding experience gained within the ICD-10 framework.

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APPENDIX

A total of 75 opinions were adopted by the AHAW Scientific Panel from 2004 to 2010. Out of these 75 opinions, 39 were exclusively related to animal health issues. These 39 opinions were included in a retrospective analysis conducted by a consortium comprising the French Agency for Food, Environmental and Occupational Health and Safety (France), the University of Liege (Belgium) and the Central Veterinarian Institute (The Netherlands).

A summary of the typical data needs, as they follow from frequently addressed risk questions, is given in the following tables, separated into 5 main categories. A further analysis of these data needs will help AHAW in creating preparedness for future mandates.

Specifically those data which change little over time, between region and between strains could easily be collected in a basic data library, since aspects like being up to date and relevant for the specific conditions addressed are less of an issue. Those data which do easily change over time or space, can also be assessed, but in the sense that awareness and knowledge is collected in the data library, regarding the locations and institutions at which such data could be collected, and the accessibility of the data in such locations.

The tables below could be a good starting point for creating a data library to help in gathering data and knowledge for support in future AHAW mandates..

Table 2: Disease general information data needs

Category	Sub-category level 1	Sub-category level 2	Sub-category level 3	DATA NEEDED
DISEASE GENERAL INFORMATION	**Disease information**	Etiologic agent	Viral, Bacterial, Fungal, Parasite, Prionic	General categories, taxonomic classification (family, genus, species), common name of the disease or condition, pathogen strain or serotype
		Host(s)	Principal	List of susceptible species (man included if zoonotic/common disease)
			Intermediate	List of susceptible species (man included if zoonotic/common disease)
			Accidental	List of susceptible species (man included if zoonotic/common disease)
		Pathogenicity	Source	Sources of the causative agent(s)
			Infection	Incubation period, latency period, pathogenicity, tissue pathogen loads, clinical signs (live animals), gross lesions, duration of clinical signs
			Transmission	Routes of transmission (direct/fomites), dose-response, excretion
		Diagnosis	Clinical diagnosis	Pathognomonic signs, differential diagnosis of the disease
			Lab diagnosis	Sample type, test used (procedure, sensitivity, specificity, threshold...)
		Immune response		Type of immune response, maternal derived antibody protection, level of immune response, duration of immune response (Ab+), serotype/strain cross-protection

		Genetics	Pathogen	Evolutive character of the pathogen (mutations, genetic re-assortments)
			Host	Genetic resistance against the pathogen
Category	**Sub-category level 1**	**Sub-category level 2**	**Sub-category level 3**	**DATA NEEDED**
DISEASE GENERAL INFORMATION		Resistance of the pathogen		Pathogen resistance to chemical (including treatment) and physical agents
	Vector information	Vector species		List of vector species
		Vector competence		Factual evidence of local vector(s) competence, list of potential local vector species
		Habitat / Environment		Vector type of habitat, optimal range of T°, relative humidity, wind speed, altitude range
		Distribution area		Distribution area (continent/country/region), density of vectors
		Vector activity		Type (indoor/outdoor), period (day/night), duration and seasonality
		Cycle		Duration, lifestages, overwintering
		Pathogen transmission		Infectious load, type of transmission (trans-stadial, trans-ovarial), maximal distance of potential spread
		Resistance to insecticides		Reported resistance(s) to insecticides, list of insecticides for which resistances have been reported
		Climatic information	Climate Classification	Köppen-Geiger climate classification
			Climatic data	Average/minimal/maximal temperatures, average relative humidity, rainfalls, sunlight, wind speed and prevailing direction
			Drought	Palmer Drought Severity Index
		Altitude		Altitude

Table 3: Descriptive epidemiology data needs

Category	Sub-category level 1	Sub-category level 2	Sub-category level 3	DATA NEEDED
DESCRIPTIVE EPIDEMIOLOGY	**Morbidity**			Prevalence, Incidence
	Mortality			Mortality rate
	Case-fatality			Case-fatality rate

	Spatio-temporal distribution	Annual prevalence, annual incidence, form of the disease (epizootic, endemic, etc.)...
	Demography of hosts	Populations and subpopulations, herds/flocks/groups of animals

Table 4: Analytical epidemiology data needs

Category	Sub-category level 1	Sub-category level 2	Sub-category level 3	DATA NEEDED
ANALYTICAL EPIDEMIOLOGY	**Disease factors**	Reservoir		List of reservoir species
		Optimal climatic and environmental conditions for pathogen survival		Optimal relative humidity, optimal soil pH, maximal radiant flux, duration under optimal conditions
		Ecology		Land cover, length of pasture-edges, symbiotic factors
		Industry and management		Industry and management factors affecting disease transmission and spread: confinement operation, biosecurity practices, industry awareness…
	Factors of disease introduction	Importations/entries	Animals	N importations of livestock species and horses , N entries of domestic and exotic pets, vaccination status of arriving animals, illegal trade of live animals, migratory birds
			By-products	N importations of livestock and horse by-products by categories (1/2/3), illegal trade of by-products by categories (1/2/3)
			Vectors	Capacity of vector spreading by the air, transports…
			Biological products	N importations of lived and attenuated vaccines
			Humans	Human entries (arrivals) from areas at risk
			Plants	List of the risky plants, N importations of plants by type of plants
			Fomites	List of the fomites, N importations of high-risk fomites
	Factors of disease spreading and establishment	Exportations/exits	Animals	N exportations of livestock species and horses , N exits of domestic and exotic pets
			By-products	N exportations of animal by-products by categories (1/2/3)
			Vectors	Capacity of vector spreading by the air transports…
			Biological products	N exportations of semen, embryos, lived and attenuated vaccines
			Humans	Human exits
			Plants	N exportations of plants
			Fomites	N exportations of high-risk fomites

	Basic reproductive rate		Basic reproductive rate (R0)
	Reproduction programme		Type of reproduction programme (AI vs. natural)
	Production system	Industries	Cattle production systems, N animals in meat and dairy industries, N livestock herds/flocks in meat and dairy industries
			Goat production systems, N animals in meat and dairy industries, N flocks in meat and dairy industries
			Sheep production systems, N animals in meat and dairy industries, N flocks in meat and dairy industries
			Swine production systems, N animals in meat industries, N herds in meat industry
		Farming systems	Cattle: N animals and herds/flocks under intensive vs. extensive farming systems
			Goats: N animals and herds/flocks under intensive vs. extensive farming systems
			Sheep: N animals and herds/flocks under intensive vs. extensive farming systems
			Swine: N animals and herds/flocks under intensive vs. extensive farming systems
	Local establishment		Risk of establishment in local vector(s), domestic/wild host(s) and environment

Table 5: Prevention and control data needs

Category	Sub-category level 1	Sub-category level 2	Sub-category level 3	DATA NEEDED
PREVENTION - CONTROL	**Veterinary Services (VS)**	Identification		Name of the veterinary service
		Veterinary Statutory Body		Level of authority, capacity to implement its functions and objectives in conformity with OIE standards
		Evaluation	Resources	Professional profile of VS staff, skills of veterinarians and para-professionals, N veterinarians involved in epidemiosurveillance, N vets employed at border inspection points, access to physical resources, ability to access financial resources for continued operations and in emergency situations
			Organisation	Stability of structures and sustainability of policies, centralization vs. decentralization, internal/external coordination, mechanisms for consultation with stakeholders
			Education	Existence of continued education and awareness campaigns for professionals involved in animal health, public targeted, frequency

		Legislation		Authority/capability to participate in the preparation of national legislation and regulations, programmes/activities to ensure stakeholder compliant with relevant legislation and regulations, authority/capability to be active in the international harmonisation of regulations and sanitary measures and to ensure national legislation/regulations take into account international standards, authority/capability to certify animal, animal products, services and processes in accordance with national legislation/regulations and international standards, authority/capability to negotiate, implement and maintain equivalence and other types of sanitary agreements with trading partners
		Compartmentalisation		Authority/capability to establish and maintain disease-free zones/compartments in accordance with OIE criteria
	Disease inspection practices	Quarantine		Number of inspection points, N animals quarantined, average duration
		Mandatory slaughters		N mandatory slaughters
		Animal movement and traceability		Identification of live animals and by-products, follow-up of movements (live animals and by-products)
Category	**Sub-category level 1**	**Sub-category level 2**	**Sub-category level 3**	**DATA NEEDED**
PREVENTION - CONTROL	**Biosecurity practices**	Biosecurity protocol, control and certification	In the production systems	Biosecurity protocol, control and certification in farms/inspection posts (livestock herds, insemination centres, pet shops, horse farms, riding schools, border posts) and for transports
			During animal transport	Biosecurity protocol, control and certification for transport of live animals and by-products, for embryo transfer, at animal groupings (markets, shows, competitions), at slaughterhouses
		Manufacturing process of the feed	Feed composition	Type of animal feed (pasture, concentrates,etc.), nature of animal feed (animal vs. non-animal), nutritional characteristics
			Certification	Protocol of good manufacturing practices (GMP), control of GMP, existence of ISO standards, control of ISO standards
			Treatment	treatment of feed, chemical treatment of water
			Control	Existence of feed and water control, type of samples, sample size, frequency
		Distribution process of the feed	Origin	Country of origin, year of manufacturing, origin (farm vs. manufacture), animal vs. non-animal, Quantity of feed distributed
			Network	N intermediates between supplier and user, list of sale points, control of sale points, frequency of controls, type of water supply
		Waste management		Type of waste management for feed, water, contaminated materials and instruments (veterinary)
		Supplementary inputs		Existence of supplementation with nutritional additives, list of nutritional additives used in routine

		Systematic treatment		Existing systematic treatment distributed with feed, list of specific treatments used as feed supplements (antibiotics, etc.)
	Reservoir(s) and vector(s) control	Reservoir(s)		Existence of a control of reservoir(s), methods, place and effectiveness
		Vector(s)		Existence of a control of vector(s), methods, place and effectiveness
	Treatment	Treatment strategy		Authorized vs. prohibited, category of molecule(s), duration, posology, withholding periods in milk and meat
	Vaccination	Vaccine	General information	Type of vaccine, serotype/strain, DIVA
			Protocol	Route of administration, N doses for a regular protocol, N doses primo-vaccination, interval between 2 doses of primo-vaccination, interval between primo-vaccination and booster, frequency of vaccination
Category	**Sub-category level 1**	**Sub-category level 2**	**Sub-category level 3**	**DATA NEEDED**
PREVENTION - CONTROL			Efficacy	Duration of vaccinal protection, existence of cross-protection, list of pathogens for which cross-protection is reported, potential risk of pathogen excretion
			Safety	List of reported side-effects and adverse-effects, subpopulations exempted from vaccination, vaccine safety surveillance system
		Programme	Mandatory	Status of vaccination (mandatory/facultative/prohibited)
			Strategy	Doses of vaccine used at the national level, N animals vaccinated at the national level, frequency of vaccination, type of vaccination programme (national, regional)
			Distribution	Delay between exit from pharmaceutical industry and use in the field, vaccinator, actors of the distribution network
			Conservation	Duration of vaccine conservation, temperature conditions, percentage of doses really used

Table 6: Surveillance data needs

Category	**Sub-category level 1**	**Sub-category level 2**	**Sub-category level 3**	**DATA NEEDED**

SURVEILLANCE	**Surveillance Networks**	Organisation		Stakeholders (policymakers, information users, beneficiaries of the surveillance information, data providers) and responsible parties (responsible of surveillance system design, implementation and leadership, data application design, development and implementation, data application support and maintenance, data collection, laboratory testing, detection of the cases, confirmation of the cases, reports of the cases, training of data collectors, data analysis and interpretation, result dissemination and reporting, action based, action based on surveillance findings, review of surveillance system effectiveness): role, title, group name or agency, N officers involved, N levels
		Characteristics		Field of surveillance networks, type of surveillance, situation of the disease(s) surveyed, population(s) surveyed, mode of data collection, dependence towards fighting actors
		Evaluation		Existing evaluation, type of evaluation (internal/external), list of performance indicators, frequency
	Objectives and decision criteria	Objectives		Description of the purpose and rationale for surveillance: estimate the magnitude and baseline status of a problem, determine the geographic and demographic extent of an outbreak, predict possible spread and provide data for disease regionalization, describe the natural history of a pathogen or disease, detect unusual clusters of disease, providing for early detection, generate hypothesis and stimulate research, define or assess the health status of a population, providing the foundation for market confidence, detect changes in health practices, risk factors or exposure, facilitate planning of national control or eradication programs and strategies, evaluate control measures and intervention efforts, identify factors associated with a disease agent that may be used in conducting surveillance elsewhere and in modelling pathogen spread and determine times of year when most case are observed
		Decision criteria		List of criteria for surveillance (criteria prioritization, such as impacts on trade and productivity, animal welfare concerns, feasibility of control, cost of surveillance and public health implications), list of decision criteria for active vs. passive surveillance
	Study design	Type of the surveillance		Type of the surveillance (active vs. passive), proportion of active vs. passive surveillance, surveillance at markets, border inspection points, animal groupings, wildlife, clinical vs. syndromic surveillance
Category	**Sub-category level 1**	**Sub-category level 2**	**Sub-category level 3**	**DATA NEEDED**
SURVEILLANCE		Expected outcomes		Information resulting from the surveillance effort, which is then used for decision-making, policy development and action

	Population description and characteristics	Sampling Units		Simple units (individuals) or aggregated units (herds or flocks), geographical or spatial measure included, time constraints, if present, are included
		Target population		Population about which statistical inference will be made (general population at risk), should be identified and clearly defined or estimated, if different from the study population, the rationale for inference should be provided, size of target population
		Study population		Population from which the sample is to be drawn, size of study population, sample frame (list of units to be sampled)
		Targeted population		Population defined by specific disease variables inherent to the disease in question
		Administrative units		Which units are included in the surveillance system (states, province, sample grid reference…)
		Size of sample		Number of reporting unit, should include geographic area serviced per unit sampled, number of eligible units served by reporting unit (per unit of geographic area being serviced)
		Animal and group type		Species, breed and type (if applicable) of animals should be evident; include breeds and crosses, define the animal by appropriate production phase concept, age categories, including all appropriate categories pertinent to the surveillance objectives
	Case definition	Clinical description and case definition		List of criteria for positive case, negative case, and others as applicable
		Epidemiological criteria and restrictions		Criteria that: may restrict case definition to individual animals, herds, flocks or premises that possess specific epidemiological characteristics, may relate to the geographic location of an animal, farm or premises; a particular point in time or season of the year; a particular behaviour associated with disease transmission or risk factor, may compartmentalized the surveillance within a segment of a vertically integrated industry, age group or commodity type, may include variables related to habitat, environmental conditions, seasonality, climate,...
		Laboratory criteria		Description of the tests' specificity, sensitivity, identification of the limitations of the tests used for the disease confirmation, type of the diagnostic test and cut-off point or dilution used to define categories of cases, particular additions specific to the testing
Category	**Sub-category level 1**	**Sub-category level 2**	**Sub-category level 3**	**DATA NEEDED**
SURVEILLANCE		Case classification		Definition of the so called suspect, probable and confirmed case categories, levels of the classification certainty
	Outbreaks	Definition		Decision criteria of an outbreak notification

		Notification	N outbreaks reported and N animals affected per outbreak
	Sampling methods		Description of the field and laboratory data collection techniques: simple random, systematic, cluster, stratified or complex sampling, probability sampling, methods for randomization and stratification, level of detection, statistical level of confidence, diagnostic sensitivity of the sampling, predictive value, time intervals and frequency of data collection, geographic extent of the study area under surveillance, methods of data collection and handling (how raw data are gathered from the field, sample handling protocol, cold chain measures, sample degradation factors), sources of potential bias, trigger for data collection, transmission of collected data (web-based data, e-mail, fax, software...)
	Laboratory	Diagnostic test	Date of sampling collection and lab test, test(s) used, sensitivity and specificity, chosen threshold of detection
		Accreditation	Existence of accreditation programs, list of standards for accreditation programs, existence and frequency of proficiency testing
	Early warning system		Existence of an early warning system, type, list of indicators used, website
	Risk and exposure factors		Population risk factors that may influence the outcomes of the study, confounders should be included
	Communication		Awareness Campaigns, Communication and feedbacks

ABBREVIATIONS

AHAW	Animal Health and Welfare Panel
BIOHAZ	Biological Hazards Panel
ECDC	European Centre for Disease Prevention and Control
EFSA	European Food Safety Authority
EU	European Union
MS	Member State
T0R	Term of reference
WG	*Ad hoc* working group