

ROLE OF EFSA IN CONTRIBUTING TO THE IMPROVEMENT OF ANIMAL HEALTH IN EUROPE

1. INTRODUCTION

The concept of animal health covers not only the diseases of animals, but also the critical relationship between animal welfare and animal disease, as well as its relevance to public health. While some animal diseases are important for animal welfare or their impact on trade (e.g. Bluetongue); many diseases also include a zoonotic aspect, i.e. they are relevant to public health. In particular, transmission of infection between animals and humans occurs, either via foodborne transmission, e.g. in the case of Salmonella, or via other routes, as is the case for rabies. Furthermore, wild animals can be an important source of emerging microbiological risks affecting both animal and public health (e.g. avian influenza). The safety and quality of feed is also essential for the animal health and can have also the effects on public health. High standards of animal health are thus an essential pillar for safeguarding public health, ensuring food safety, and securing animal welfare.

Through their disruption of the EU internal market and of international trade, contagious animal diseases such as foot and mouth disease and classical swine fever can also have severe socioeconomic consequences.

The International Committee of the World Organisation for Animal Health (OIE) has recognised that animal welfare is a complex, multi-faceted public policy issue which includes scientific, ethical, economic and political dimensions. Determinants of animal welfare may influence the occurrence of animal diseases and have a positive or negative effect on food safety. On the other hand, diseases often decrease the welfare of animals. For example, stress may increase susceptibility to infections, which in turn may lead to illness in animals or increased shedding of pathogens and contaminants into the food chain. On the other hand, whereas outdoor farming systems may improve animal welfare, they may also increase the exposure of animals to certain biological hazards.

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On the 19 of September 2007, the European Commission (EC) adopted a Communication setting out the EU's Animal Health Strategy (AHS) for 2007-2013. The strategy encompasses a 6-year programme of work, divided into four different pillars: 1) prioritisation of the EU intervention; 2) a modern and appropriate animal health framework; 3) better prevention, surveillance and crisis preparedness; and 4) science, innovation and research.

EFSA is the keystone of the EU risk assessment regarding food and feed safety and the related fields of zoonoses, diseases in wild and domesticated animals, animal welfare and plant health. In close collaboration with scientists as well as with national authorities and in open consultation with its stakeholders, EFSA provides independent scientific advice and communication on existing and emerging risks. Since EFSA's scientific advice serves to inform risk managers, a large part of EFSA's work is undertaken in response to requests from the EC, the European Parliament (EP) and EU Member States (MS). EFSA also undertakes scientific work on its own initiative, so-called self-tasking.

During its more than 5 years of existence, EFSA has provided scientific opinions and advice as well as technical support to risk managers as follows in the area of animal health:

- The EFSA Animal Health and Welfare Panel has delivered 48 scientific opinions on a variety of animal diseases and welfare issues
- The Panel on Biological Hazards has delivered 18 scientific opinions on zoonoses and 40 scientific opinions on BSE and other animal transmissible spongiform encephalopathies (TSE)
- The Panel on Additives and Products or Substances Used in Animal Feed has delivered 45 opinions on / related to animal health.
- The Panel on Contaminants in the Food Chain has delivered 37 scientific opinions on the area relevant to animal health
- EFSA's Zoonoses Unit, in collaboration with the EC and MS, has coordinated the annual analysis and reporting of zoonoses in the EU and supported the planning and analysing of baseline surveys for zoonoses
- Furthermore, the Zoonoses and Assessment Methodology units have provided scientific and technical assistance to support the EU decision-making through article 31 of Regulation (EC) No 178/2002 in the design, analysis, and reporting of surveys on zoonotic diseases such as Salmonella and Campylobacter, antibiotic resistance, and the epidemiological analysis of Bluetongue and avian influenza outbreaks.

The future challenges for EFSA and food safety in general, will need to be acknowledged and appropriate responses found to ensure that animal and public health is fully protected and consumer confidence maintained. The key challenges facing the Authority can be summarised as follows:

- Globalisation increases the likelihood of new or re-emerging risks to the European food supply
- EFSA will be faced with innovative technologies and evolving risk assessment practices
- Sustainability and climate change will emphasize the importance of an integrated approach to risk assessment

This paper is intended to further clarify the role of EFSA in animal health taking into account the AHS 2007-2013.

This paper presents the areas EFSA should work in the future i.e. the targets. The actual implementations plans, including the resources, will be further dealt with within the annual work plans.

During the preparation of this paper, EFSA has consulted the Animal Health and Welfare Panel, the Panel on Biological Hazards, DG Agri (DG for Agriculture and Rural Development) the EU Health and

Consumer Directorate-General, the European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC), the Chief Veterinary Officers, the World Organisation for Animal Health (OIE), the World Health Organisation (WHO) as well as EFSA's Advisory Forum, Scientific Committee and Stakeholder Platform. The context has also been discussed at the Meeting of the EFSA Advisory Forum Experts in Animal Health (27-28 May 2008)

2. ROLE OF EFSA IN ANIMAL HEALTH STRATEGY

2.1 Prioritisation of EU intervention (Pillar 1)

"The new Animal Health strategy must be seen as an integrated risk assessment and management strategy focusing on biological and chemical risks of EU relevance."

Profiling and categorization of risks in animal health must, *inter alia*, be based on scientific knowledge of the disease, its occurrence and its impact on animal populations, public health and economy.

EFSA plays a key role in this area by providing scientific advice and risk assessments. The usefulness of this work depends on the approach taken to requesting scientific advice, the urgency of the question, the availability of pertinent data and their quality, and the risk assessment approach used to address the question in hand. In addition to risk assessments, EFSA is providing in quantitative microbiological risk assessments scientific input for subsequent risk-benefit analyses and could expand this area in the future, where appropriate.

Since decisions on prioritization of interventions must be based on sound science and appropriate risk assessment (Pillar 4), close collaboration between EFSA, EC and MS is essential in order to obtain useful scientific advice and risk assessment for decision making. Risk assessment must be based on sound data; this cooperation and data exchange between EFSA, EC, Member States and CRL, in association with EMA, ECDC and other relevant EU organizations as well as with international organisations such as OIE and WHO, enable EFSA to provide high-quality scientific advice in a timely manner (see section 2.4).

2.2 A modern and appropriate animal health framework (Pillar 2)

"Towards a single regulatory framework, with a greater focus on incentives rather than penalties, consistent with other EU policies and converging to international standards"

A modern animal health legislative framework relies on scientific information and modern systems to assess this information, such as described in sections 2.1, 2.3 and 2.4. Using risk assessment methods that are recognised internationally, EFSA will continue to develop recognition for its work within the international risk assessment community.

On the other hand, developing a single regulatory framework may have an effect on the animal nutrition policies as well as policies linked to animal diseases, animal welfare and public health and thereby would evidently influence on the practices in EU. These changes need to be taken into account also in future risk assessments.

As described above, EFSA plays an important role in the current regulatory framework on the monitoring of zoonoses. This is done in close collaboration with the EC, MS and CRL and ECDC. Based on the good experiences on this collaboration, it is recommended that the basis for the similar type

framework could be created and applied in future also to non-zoonotic endemic animal diseases for which control programmes exist.

2.3 Better prevention, surveillance and crisis preparedness (Pillar 3)

"Identifying problems before they take hold and being ready to manage outbreaks and crises"

Prevention

The risk assessments and scientific advice that EFSA provides can serve as a useful tool to evaluate the effect of various risk management options on risk reduction in line with the principle "prevention is better than cure". This advice together with the other legitimate factors can be used for planning the prevention or control of current and emerging animal diseases in domesticated or wild animals, for animal welfare, animal nutrition and/or for public health. Besides risk assessments on import, scientific advice can also enable risk managers to better focus on risk-based border inspections and to draft risk-based guidelines for biosecurity measures.

Surveillance

By providing scientific advice, risk assessments and technical support, EFSA can contribute to surveillance for animal diseases in the EU. A key factor in enabling effective data evaluation is the harmonization of various aspects of these programmes. This can take place through:

- recommendations in EFSA opinions on topics to be covered in the surveillance programmes;
- based on the specific legislative frameworks scientific support by EFSA in surveillance design of non-zoonotic animal diseases in collaboration with the MSs, as is common practice for EFSA on zoonoses and antimicrobial resistance together with ECDC ,
- development of indicators for animal welfare that could be used for surveillance purposes;
- scientific support for the post market monitoring of feed additives
- providing support in statistical analysis and guidance for reporting of surveys and surveillance studies.

Crisis preparedness

When there is added value for the Community, EFSA can also provide urgent scientific advice by using fast-track responses or statements (as defined in the Management Board decision in September 11th 2007) during crises and by providing technical support for data collection and analysis. For the optimal use of available resources, it is important to identify true urgent situations, where the use of fast-track responses or statements is needed. However, whenever possible, the scientific advice provided by EFSA should preferably be based on full risk assessment or scientific opinions.

It should be noted that it is essential that crisis preparedness be developed in 'peace time' so that, when the need to use the data and conduct data analyses arises, adequate and efficient data exchange is already ensured.

Support to risk managers in setting up surveillance systems may provide a good basis for smooth collaboration during crises.

To respond to the needs of risk managers EFSA has identified three priority action fields:

1. The EFSA scientific panels, in particular those of AHAW and BIOHAZ, are able to assess risks associated with known emerging diseases and evaluate the likelihood of these being introduced to the European Union.
2. EFSA can provide scientific and technical support in the event of an emergency situation, such as the detection of a food-borne outbreak through epidemiological analysis. EFSA plays an important role in the monitoring of zoonoses. This is done in close collaboration with the EC, MS, CRL and ECDC. Based on the good experiences on this collaboration, it is recommended that the basis for the similar type framework could be created and applied in future also to animal diseases, including emerging conditions.
3. Finally, EFSA must help risk managers to identify at an early stage and characterise the risks associated with emerging diseases. To that end, we set up a unit specialised in emerging risks at the beginning of 2008. The unit, which has been fully operational since its inception, will work closely with the European Commission and Member States, with European agencies (European Medicines Agency and the European Centre for Disease Control) and with the OIE (World Organisation for Animal Health), the FAO (Food and Agriculture Organization), and the WHO (World Health Organization).

2.4 Science, Innovation and Research (Pillar 4)

"To stimulate and coordinate risk analysis, science, innovation and research, hence contributing to a high level of public health and to the competitiveness of EU animal health businesses."

While the scientific activities of EFSA are of an applied nature, EFSA aims to use the best available science to carry out its tasks. Therefore, it is essential for EFSA to mobilise and coordinate scientific resources throughout the EU to provide high-quality and independent scientific advice and risk assessments. In practice, this takes place by means of its scientific panels, working groups, task forces, grants and the contracting-out of scientific work, as well as in other ways of networking with scientists. EFSA is also actively collaborating with DG Research on the research needs identified during risk assessment work and with EMEA, ECDC and other relevant EU agencies.

EFSA has developed guidance for conducting risk assessment in animal health and collaborates with the Joint Research Centre for the establishment of criteria for the evaluation of diagnostic tests for the detection of TSE.

Animal health questions usually address specific factors that may affect the introduction, establishment and spread of a particular disease. To answer such questions, information is needed on the disease itself as well as on its occurrence in domestic animals, wildlife and the environment, diagnostics, vaccines, current farming and trading practices, and any uncertainties in the available data. While basic information on a disease is usually available in the peer-reviewed scientific literature, information on the other aspects is either unavailable or fails to cover situations in different MS. Furthermore, data extracted from scientific literature can suffer from publication bias. Hence, in order to be able to provide

scientific advice in a timely manner, in addition to studies published in scientific literature, the following information should be readily available for EFSA to carry out a risk assessment:

1. Reliable EU and non-EU disease outbreak data reported through the notification systems (Animal Disease Notification System, OIE, WHO) as well as EU surveillance data;

2. Knowledge on diagnostic test performance characteristics. This is made available via the CRL and national reference laboratories (NRL), the OIE, the test sponsor, and peer reviewed literature;
3. Information on the role of vaccines in the control of disease in close collaboration with EMEA;
4. ECDC data on zoonoses
5. Data on agriculture, transport, production, processing and consumption;
6. Reports of studies funded by DG Research;
7. Trade Data collected by Eurostat.

For risk assessments on animal diseases and welfare, EFSA often depends on the above organizations to provide these data. Whereas EFSA has been mandated by the Commission to collect data on zoonoses – and within the framework of TSE surveillance, data has been readily available for EFSA – collaboration between EFSA and EC/CRL/NRL will have to be strengthened for major non-zoonotic animal diseases. As the EC is responsible for these networks, it is in the key position to facilitate an adequate exchange of information and to promote networking between EFSA and these organizations in order to avoid duplication of effort and to improve efficiency and validity of the data for risk assessment purposes.

The optimal approach to providing scientific support to risk managers may vary according to time constraints and hence needs careful consideration. The 'traditional' approach typically involves a request for the delivery of a risk assessment for a specific disease. An import risk assessment conducted for a specific exotic disease following established international guidelines can be a very laborious exercise requiring a significant input of time and resources to complete. It has been noted on occasion that, by the time a risk assessment on an exotic disease is available, the disease has actually entered the EU. Therefore, alternative approaches should also be considered for imminent threats requiring urgent action. Such approaches should be based on science, including expert opinion, without the need to elaborate a full risk assessment. Routine timely identification and initial evaluation of rapid alerts provides another possibility to be pro-active.

Comprehensive animal welfare databases, which could give important support for EFSA risk assessment and the possible influence on animal health status, are currently not available at EU level. There is also a lack of harmonization of indicators for animal welfare despite the fact that there are already some good examples of relevant and reliable indicators available in some MS and industry. EFSA, in line with mandates received from the EC, will start to assess the indicators for the welfare of food-producing animals with a view to developing a harmonised European monitoring system assessing the quality of farming systems and their impact on the diseases and welfare of animals according to the outcome-based approach described in the Community Action Plan on the Protection and Welfare of Animals (2006-2010). Such indicators could be integrated into future legislative proposals and provide the basis for the development of an EU label for animal welfare proposed by the EC. In this context, EFSA will provide the future European Centre for the Protection and Welfare of Animals with the scientific advice needed to implement the activities described in the Action Plan and the integration with animal health policies.

3. FUTURE DIRECTIONS IN THE AREA OF ANIMAL HEALTH

The main goals for future work and actions in EFSA in the area of animal health including diseases of animals and also the critical relationship between animal welfare and animal disease, as well as its relevance to public health:

Goal 1: To deliver the best scientific advice at the right time and in the most appropriate manner for decision making of risk managers.

Action:

- applying, when appropriate, the integrated approach to risk assessment associated with animal nutrition¹, animal diseases, animal welfare, and public health (2008-2013)
- further improving the methods of risk assessment in animal welfare in combination with animal diseases and food safety (2008-2012)
- defining and assessing indicators for animal welfare for food producing animals that could be used in a harmonised European monitoring system (2008-2010)
- improving risk assessment–risk management dialogue between EFSA, the EC and MS to guarantee the optimal use of resources in risk assessment of animal health (2008-2009)
- collecting feedback from the EC and MS on the opinions produced by EFSA in the area of animal health to further improve the quality of risk assessments (2008-2010)
- establishing a formal internal and external quality improvement system for risk assessment at EFSA (2008-2009)
- improving the provision of scientific input for risk-benefit analyses (2009-2010)

Goal 2: To decrease the time needed for risk assessment and scientific advice on animal health and welfare by enabling the rapid access and use of already collected data by **data exchange** between EFSA and the EC including FVO, MS, CRL and NRL, in association with EMEA, ECDC and other relevant EU institutions

Action:

- developing further the collaboration on data exchange for the purposes of data analyses and risk assessment in the animal health area by EFSA (2008-2010) including both the urgent issues/emerging risks as well as other scientific advice

¹ In respect to the animal nutrition, it is of value mentioning that the Regulation (EC) No 1831/2003 on additives for use in animal nutrition, in it is Art. 5(3), establishes the functions of the feed additives, one of them is directly related to the animal welfare: “*The feed additive shall favourably affect animal production performance or welfare*”

Goal 3: To provide scientific support for EU **surveillance programmes** for animal diseases, zoonoses and animal welfare as well as analysing the results of surveillance

Action:

- providing scientific input for the design of data collection schemes including diagnostic techniques in order to enhance the suitability of the data collected for risk assessment purposes in the area of animal health (2008-2013)
- upon request of the Commission and the Member States, EFSA shall expand disease reporting beyond zoonoses to include other animal diseases, where considered appropriate e.g emerging diseases (2010–2013)

Goal 4: To provide scientific support for EU **crisis preparedness**

Action:

- implementing the EFSA Management Board decision of 11 September 2007 for accelerated procedures of scientific advice for urgent matters by using fast-track response or statements when relevant and without compromising the quality of the scientific opinions delivered (2008-2013)
- setting up a specific network for emerging risk detection in the area of animal health (2008-2009)
- creating and validating a system for the early detection of emerging risks with an emphasis on the safety of the food chain (2008-2010)
- providing technical support for data collection in the area of animal health and data sharing during crisis situations from a scientific point of view for EC and MS (2008-2013)

Goal 5: To **avoid unnecessary divergence** in opinions between EFSA and MS competent authorities or other relevant EU institutions (e.g. EMEA and ECDC)

Action:

- identifying the reasoning behind the different opinions, if any, in a transparent manner and in accordance with Article 30 of Regulation 178/2002
- introducing an effective methodology to compare different risk assessments (2008-2009)
- enhancing collaboration between animal health risk assessment bodies during all the steps of the risk assessment process (2008-2010):
 - at the initiation of risk assessments: notification of MS and other EU institutions of the initiation of the risk assessment and providing input on selection of experts and adopting consistent approaches in line with best practice

- during risk assessments: requesting and exchanging input for the risk assessment, as needed, and mutually informing on the progress of risk assessments in EFSA and MS
- upon completion of risk assessments: sharing of scientific opinions under embargo with the objective of detecting and resolving unnecessary divergence at an early stage
- by agreeing an appropriate communication plan when divergence of opinion cannot be avoided and it is necessary to explain the scientific rationale for the differing views.

Goal 6: To mobilise and **coordinate scientific expertise** throughout the EU on issues within the remit of EFSA

Action:

- networking with national, EU and international organizations via the scientific panels and their working groups, the Advisory Forum and its Focal Points, and other networks in the area of animal health
- creating a database of experts
- contracting scientific work via Article 36 of EFSA's founding regulation and grants
- organising scientific colloquia and other scientific events to review knowledge and stimulate debate on future scientific developments in the area of animal health
- follow up closely the science development and new research in the area of animal health
- collaborating with the EC for the identification of research needs as well as enhancing the use of research results in risk assessment in the area of animal health