# From risk analysis to risk governance - Adapting to an ever more complex future

Dirk U. Pfeiffer

*Veterinary Epidemiology, Economics and Public Health Group, The Royal Veterinary College, London, United Kingdom*

*Corresponding author at: Dirk U. Pfeiffer, Veterinary Epidemiology, Economics and Public Health Group, The Royal Veterinary College, Royal College St, London NW1 0TU, United Kingdom. Tel: +44 1707 666205, e-mail: pfeiffer@rvc.ac.uk.*

*Veterinaria Italiana* 2014, **50** (3), 169-176. doi: 10.12834/VetIt.313.1220.3
Accepted: 20.07.2014 | Available on line: 30.09.2014

**Conference 2013 on Risk analysis in the Mediterranean Basin, *Risk Analysis as a tool for the control of Animal Diseases and Zoonoses in the Mediterranean Basin*. November 5-7, 2013 - Teramo, Italy - Selected papers**

**Keywords**
Animal health,
Disease control,
Interdisciplinarity,
Policy,
Systems perspective.

**Summary**
Risk analysis is now widely accepted amongst veterinary authorities and other stakeholders around the world as a conceptual framework for integrating scientific evidence into animal health decision making. The resulting risk management for most diseases primarily involves linking epidemiological understanding with diagnostics and/or vaccines. Recent disease outbreaks such as Nipah virus, SARS, avian influenza H5N1, bluetongue serotype 8 and Schmallenberg virus have led to realising that we need to explicitly take into account the underlying complex interactions between environmental, epidemiological and social factors which are often also spatially and temporally heterogeneous as well as interconnected across affected regions and beyond. A particular challenge is to obtain adequate understanding of the influence of human behaviour and to translate this into effective mechanisms leading to appropriate behaviour change where necessary. Both, the One Health and the ecohealth approaches reflect the need for such a holistic systems perspective, however the current implementation of risk analysis frameworks for animal health and food safety is still dominated by a natural or biomedical perspective of science as is the implementation of control and prevention policies. This article proposes to integrate the risk analysis approach with a risk governance framework which explicitly adds the socio-economic context to policy development and emphasizes the need for organisational change and stakeholder engagement.

## Dall'analisi alla gestione del rischio per adattarsi ad un futuro ancora più complesso del presente

**Parole chiave**
Analisi del rischio,
Epidemiologia,
Gestione del rischio,
Interdisciplinarità,
Sanità Animale.

**Riassunto**
In campo veterinario l'analisi del rischio è uno strumento che permette l'integrazione dei risultati scientifici con i processi di gestione della sanità animale correlando tra loro epidemiologia, diagnostica e sierologia (vaccini). La recente diffusione di focolai (virus Nipah, SARS, influenza aviaria H5N1, Bluetongue sierotipo 8 e Schmallenberg virus) ha evidenziato la necessità di prendere in considerazione le interazioni tra fattori ambientali, epidemiologici e sociali. In questo contesto è determinante identificare l'influenza del comportamento umano sull'insorgenza e la diffusione dei focolai epidemici per poter definire protocolli e campagne di informazione che modifichino i comportamenti rischiosi. Sia l'approccio One Health sia quello EcoHealth evidenziano la necessità di adottare una prospettiva olistica nell'analisi e gestione del rischio. Tuttavia, le prospettive scientifiche naturale e biomedica sono ancora quelle dominanti negli impianti concettuali delle analisi del rischio contemporanee e nell'implementazione dei protocolli per il controllo e la prevenzione delle malattie. Questo studio propone di integrare l'analisi del rischio con una gestione del rischio che nel definire i protocolli di controllo e prevenzione prenda esplicitamente in considerazione il contesto socio-economico e che, inoltre, enfatizzi la necessità di rivedere i processi decisionali e i criteri di coinvolgimento di tutti gli operatori coinvolti.

## Introduction

Risk analysis frameworks for animal health and food safety, as defined in the OIE Animal Health Code (Anonymous 2013a) and the Codex Alimentarius (Anonymous 2013b) have had major influence on the adoption of science-led decision making in animal health around the world (Anonymous 2010). Veterinary authorities in most countries have used it to inform the development of disease control and prevention policies. The emphasis of these frameworks has been on risk pathways defined by epidemiological system characteristics taking account of scientific knowledge in relation to the relevant infectious pathogen, its host's characteristics and the associated diagnostic methods. This has resulted in an improved transparency of the policies for disease control and international negotiations. At the same time, however, the risk of emergence and spread of existing and new pathogens has increased as a consequence of global changes in food production, animal-human interfaces and human movement networks, as well as many other factors that characterise the age of the anthropocene (Crutzen 2002; McMichael 2014). Examples for such events in relation to animal health have been the emergence of bluetongue virus serotype 8 and Schmallenberg virus in Northern Europe, the Nipah virus outbreak in Malaysia and the highly pathogenic avian influenza virus (HPAIV) H5N1 epidemics in South-East and East Asia. This increased disease threat has led to the realisation that effective control and prevention of animal and human diseases require the development of new approaches to risk management that integrate knowledge about epidemiological risk factors with environmental and social risk factors. The One Health and ecohealth approaches are a result of this vision; but while the risk analysis framework provides sufficient flexibility to accommodate the holistic principles of a One Health or ecohealth approach, established practice around the world currently focuses primarily on biomedical and epidemiological system aspects. The following is a brief review of the scientific principles underlying risk analysis and its role in policy development. The article concludes stressing the need to embed risk analysis in animal health within risk governance frameworks so as to allow the development of more effective risk management policies, particularly when dealing with significant uncertainty in relation to the likelihood of disease occurrence and its consequences.

## Science and knowledge

As has been remarked by Hansson and Aven, it is essential to reflect on the role of science in the context of decision making when examining the use of risk analysis in policy development (Hansson and Aven 2014). An important purpose of science is to generate the knowledge that allows us to understand cause-effect relationships within the world we live in (Van den Hove 2007). Until the end of the 19th century, it was believed that these relationships were of a deterministic nature, in that with complete knowledge it will be possible to precisely predict the behaviour of natural systems. The fact that uncertainty is an inherent feature of natural systems has only been recognised since the beginning of the 20th century (Sarewitz and Pielke 1999). General public thinking is still dominated though by a conscious or subconscious preference for deterministic interpretation of cause-effect relationships. It is the aim of scientific research to reduce and where possible remove the uncertainty about cause-effect relationships, thereby improving the ability to effectively prevent or control diseases both in animal and human health. In this respect, the traditional perspective has been to emphasize the importance of the biomedical sciences, and the general view was that only reductionist science would lead to meaningful advances in scientific knowledge. This resulted in a specific research focus at the organism and the molecular level. As a consequence, the importance of the effects generated by the interactions between entities within complex systems was not recognised or at least underestimated (Parkes *et al.* 2005). The emphasis on reductionism also resulted in the development of rigid boundaries separating different scientific disciplines, hence compromising the effectiveness of interdisciplinary approaches (Gieryn 1983). While research projects involving multiple disciplines have been encouraged by funding agencies for some time, such activities typically lead to working in parallel (i.e. multidisciplinary projects) rather than in an integrated fashion (i.e. interdisciplinary projects). As a result the outputs of this type of research may well be of high scientific quality from a single discipline perspective but typically are unlikely to generate integrated knowledge. It is now recognised that to be able to deal with disease threats more effectively, it is essential to appreciate the complexity of the underlying system, including its biological, environmental and social dimensions (Fish *et al.* 2011; Leach and Scoones 2013). High quality reductionist and disciplinary science is necessary, but its outputs need to be integrated using inter- and transdisciplinary approaches (Lowe *et al.* 2013; Stokols *et al.* 2008; Wilkinson *et al.* 2011). In order to generate knowledge suitable for designing effective risk management policies, scientific researchers also need to recognise the potential importance of integrating a wide variety of knowledge perspectives in addition to scientific ones (Parkes *et al.* 2005). It is also important for policymakers and society in general to accept that certainty about cause-effect relationships in complex systems is never completely attainable (Jasanoff 2007).

## Interdisciplinary and transdisciplinary research

The effective development of inter- and transdisciplinary research is compromised by a disciplinary and epistemological silo mentality amongst scientists which is still promoted by research and academic institutions as well as funding agencies (Syme 2008). The most difficult barrier to overcome is the one between the 2 disciplinary blocks comprising the natural and social sciences (Lele and Norgaard 2005). An element of such a process will have to be that scientists become more comfortable with epistemological pluralism (Miller *et al.* 2008). Lyall et al (2011) provide a practical introduction to the implementation of interdisciplinary research projects. An integrated perspective towards the research question can be facilitated by developing an agreed conceptual framework outlining the relevant elements in the underlying eco-social system, such as the one described by Coker *et al.* (2011). The definition of transdisciplinary research varies in that some researchers view it as several disciplines working together for extended periods of time and developing novel conceptual and methodological frameworks, whereas others define it as adding a participatory dimension to interdisciplinary research (Klein 2008). The terms team science and action research have also been used to emphasise the translational aspect of transdisciplinary research (Stokols 2006; Stokols *et al.* 2008).

A particular challenge in inter- and transdisciplinary research is the need to use and integrate qualitative and quantitative data analysis approaches. Social scientists are usually very comfortable with this, whereas natural scientists tend to believe that qualitative data lacks scientific rigour and are therefore not suitable for generating knowledge that enhances our understanding of cause-effect relationships (Lele and Norgaard 2005). Quantitative approaches emphasise the importance of measurement precision and representativeness in relation to a larger or other population to which inferences from the research are to be applied. A recognised strength of qualitative data is the accuracy of the data collected concerning individuals in the sample. However, such data are less, if not completely, unsuitable for inferences beyond the sampled individuals. Mixed methods analysis techniques have been used in social sciences for some time to integrate qualitative and quantitative data analysis, which are for this reason able to benefit from the strengths of both approaches in data collection and analysis (Creswell 2014).

## Systems perspective (Ecohealth/ One Health)

Since the emergence of HPAIV H5N1, there has been increasing recognition that the complexity of eco-social systems needs to be better understood to be able to deal effectively with current and future endemic, emerging and new infectious disease threats (Leach and Scoones 2013; Pfeiffer 2013; Pfeiffer *et al.* 2013; van Helden *et al.* 2013). The One Health and ecohealth approaches are a result of this development; while these approaches vary somewhat in the underlying concepts, they are now likely to converge towards a single approach which should reduce confusion and therefore increase acceptance amongst stakeholders (Zinsstag 2012). The animal health scientists and policymakers found it relatively easy to accept the relevance of these concepts, while it appears to have been more difficult in human health. For risk questions suitable in the context of a One Health approach, the active engagement of ecological and environmental sciences and associated policy development is still quite poor, the situation is even worse with respect to the social sciences. But it is inevitable that as a result of the need for more effective risk management, policymakers will increasingly demand use of integrative approaches, and therefore the research communities will have to accept their relevance and integrated research will eventually also become part of mainstream academic education. One example of a major challenge that humanity will have to urgently deal with is the emergence and spread of antimicrobial resistance (Laxminarayan *et al.* 2013). Antimicrobials have become an essential risk management tool for protecting animal and human health from infectious disease threats as well as for achieving food security and safety. As a result, enormous quantities of antimicrobials are used in humans and animals for curative and preventive purposes, which in turn have become a major driver of emergence of resistance. There are also still some antimicrobial compounds that are used both in humans and animals, whereas many are now restricted to only human use. Attempts to regulate usage need to adopt a systems perspective able to take into account the variety of economic and social drivers that influence antimicrobial usage in humans as well as animals.

## Risk analysis and risk governance

A more effective link between scientific knowledge and policy development/implementation has been achieved by the widespread adoption of risk analysis frameworks concerning animal health, food safety and many other areas (Anonymous 2009; Anonymous 2010; Anonymous 2011; Vose 2008). A key component of this framework is communication amongst the stakeholders involved or affected by the particular risk that is to be mitigated. Where risk management policies have been ineffective, poor communication between risk managers and risk assessors has often been mentioned as one of the reasons. A particular challenge is the communication of uncertainty by scientists to both decision makers and stakeholders affected by the decisions. It is widely recognised that quantitative information in relation to risk and uncertainty is difficult to communicate, as a result of differences in education and/or variation in risk perception amongst recipients of the relevant information (Hermans *et al.* 2012). Nonetheless, this admittedly very important issue has also detracted attention from the fact that the emphasis of risk assessment and management on biomedical drivers of the disease process often misses some of the key eco-social factors influencing disease risk, and that these may well be a more important reason for ineffective risk management. For example, human behaviour has significant influence on animal disease emergence and the impact of any intervention (Aven and Renn 2010). Kasperson et al (1988) developed a conceptual framework describing the influence of psychological, social, institutional and cultural processes on risk (i.e. the social amplification of risk). Slovic et al (2004) emphasized the various dimensions of the concept of risk by referring to 'risk as analysis', 'risk as feelings' and 'risk as politics'. Given the extensively developed scientific theory and practical knowledge in relation to human behavioural drivers of risk, it is surprising that animal health risk assessment and management rarely take these factors explicitly into account (Brown 2008). Furthermore, the emphasis on independence between risk assessment and management has had a detrimental effect on the utility of the generated outputs, in that risk assessors and risk managers often find it difficult to work together (Anonymous 2009; Anonymous 2011; Ely *et al.* 2009a). While it is essential to maintain a conceptual separation between risk assessment and management, and thereby prevent risk managers from introducing undue bias into the risk assessment process, it is important to consider risk management options in the process of assessing the risk. Indeed, this also more appropriately reflects the difference between what Jasanoff (1995) defined as 'research science' and 'regulatory science', in that risk assessment as a scientific approach is usually conducted in response to a specific policy need and may inform actual regulatory actions, as distinct from scientific endeavours primarily aimed at improving knowledge. The influence of institutional and organisational factors also needs to be considered in the process of risk-based policy development. Rothstein and Downer (2012) and Huber and Rothstein (2013) found that various aspects of organisational culture can adversely affect the impact of adopting a risk analysis approach in a government department. It was suggested that risk-based approaches were used to 'cloak' entrenched behaviours and perceptions as 'rational' and transparent policy. In another study, Rothstein *et al.* (2013) concluded that the adoption of risk-based policymaking (i.e. risk analysis) varies significantly between 3 European countries as a result of differences in societal, organisational and/or political norms and accountability in relation to risk governance. Stakeholders usually interpret animal health and food safety risk analysis frameworks as technical tools to support decision making, without realising or wanting to realise that they usually also require changes in institutional and organisational structures as well as behaviours, if they are to be effective. As part of a comprehensive review of risk analysis, the International Risk Governance Council (IRGC) identified 25 different deficits in risk governance structures and processes (Aven 2011). Apart from technical deficiencies, such as incomplete understanding of underlying biological processes, these included, for example, incomplete stakeholder consultation, inability to acknowledge incompleteness of knowledge and failure to take account of important factors, such as risk perception and risk acceptance.

Many of the aspects discussed above can also be examined in the context of the direction of the flow of information and the sequence of actions involved in risk analysis, and how all this influences the effectiveness of the resulting policies for risk management. Usually, a linear information flow underpins the development of risk management policies, in that following a risk problem identification (i.e. hazard identification) a risk assessment is conducted, which tends to be dominated by a biomedical science perspective. The output from the risk assessment informs the policy development which is then communicated to relevant stakeholders. A commonly used variation on this approach is that the interpretation or evaluation of the outcomes of the risk assessment and the development of the risk management strategy are shaped by other information, such as the one concerning social and economic factors. Millstone et al (2004) named the first option the technocratic and the second the decisionistic model. Given their linear nature and the biomedical science focus, both approaches do not adequately acknowledge the influence of system complexity including feedback loops on risk, stakeholder perceptions in response to risk and/or risk mitigation, and the potential for endorsing different mitigation options. Millstone et al (2004) therefore proposed the need to adopt a transparent model


*Veterinaria Italiana* 2014, **50** (3), 169-176. doi: 10.12834/VetIt.313.1220.3

based on a process that starts with development of a risk assessment policy grounded on socio-economic and political considerations involving a wide group of stakeholders rather than starting with risk problem identification performed by a narrow group of stakeholders, which often ends up being just the policymakers. This approach places major emphasis on communication and stakeholder participation during risk analysis which, while being more demanding on resources, should enhance the likelihood of policy acceptance by key stakeholders.

Recognising the limitations of the risk analysis framework, some scholars (Renn 2005, Aven and Renn 2010) have proposed the IRGC risk governance framework that explicitly integrates the factual dimension of risk with its socio-cultural context. The term 'risk governance' reflects the wider societal context of policy making. It can be defined as "the totality of actors, rules, conventions, processes, and mechanisms concerned with how relevant risk information is collected, analysed and communicated and management decisions are taken" (Aven and Renn 2010; Hermans *et al.* 2012). The components of the IRGC risk governance framework are pre-assessment, risk appraisal, tolerability & acceptability judgement and risk management (Renn 2005). Pre-assessment, tolerability and acceptability components have a particularly strong stakeholder engagement emphasis, whereas risk appraisal and risk management are broadly similar to the risk assessment and risk management components in the OIE's risk analysis framework for animal health. Roodenrijs et al (2014) evaluated the feasibility of applying the IRGC framework for recent Q-fever and Schmallenberg virus outbreaks in the Netherlands. They found it to be broadly applicable but noted that one of the challenges will be to decide on the breadth of stakeholder input that will be required, particularly during the early phases of a disease outbreak when the situation is dominated by uncertainty. Through its extensive stakeholder engagement, the IRGC framework performs particularly well for risks associated with significant ambiguity, for example when there is wide variation in societal values and risk perception and therefore disagreement with respect to the appropriateness of different policy options. The IRGC risk governance framework has recently been adapted for application in food safety governance (Dreyer and Renn 2009). The resulting general framework consists of the 4 sequential components of risk framing, risk assessment, risk evaluation and risk management (Ely *et al.* 2009b). Both, risk framing and evaluation involve integrating socio-political considerations into the risk governance process, and thereby expand the very broad and somewhat vaguely defined risk communication component in the risk analysis framework.

## *Policy development and implementation*

Decision-making in relation to risk has become more challenging not only because of the physical and biological aspects of ecological and environmental changes together with vastly increased global connectedness, but also due to the increasing heterogeneity in social values and individual preference associated with educational and economic development. Rittel and Webber (1973) already recognised this trend as one of several factors contributing to the difficulty of policymakers being able to deal effectively in particular with so-called 'wicked problems'. There are various examples of this type of decision-making challenge, including global issues such as climate change or locally relevant ones such as tuberculosis control in cattle in Great Britain.

Policy development is ultimately about making a judgment leading to a decision for a particular risk mitigation strategy, which will then either be effective (and potentially also accepted by stakeholders) or not. This decision will be informed by several factors, such as risk estimates, resource availability, stakeholder values and legislation. It therefore integrates facts with values (Hansson and Aven 2014), The knowledge about the likelihood of event occurrence and the significance of its consequences together are widely interpreted as the 'risk'. Traditional risk assessment will aim to quantify this risk. Nonetheless, it is important to recognise that risk is a complex multidimensional concept (Kasperson *et al.* 1988; Slovic *et al.* 2004) and therefore primarily focusing on scientific knowledge as the basis for a risk mitigation strategy is unlikely to achieve the desired outcomes (Hermans *et al.* 2012). To more adequately reflect this complexity, Stirling (2010) developed an uncertainty matrix which uses the knowledge in relation to the probability of the event and its consequences (including. risk management options) as its 2 dimensions. He thereby defines the 4 knowledge states of 'risk', 'uncertainty', 'ambiguity' and 'ignorance'. Using this approach, the detection of bovine spongiform encephalopathy (BSE) during the first couple of years after detection represents an example of the knowledge state of 'ignorance' where there is major uncertainty with respect to probability of occurrence and lack of knowledge about the consequences of occurrence. The situation with bovine tuberculosis in Great Britain offers an instance for the 'ambiguity' knowledge state, in that there is relatively good knowledge about the probability of infection in cattle but significant variation in knowledge and opinion about the consequences of occurrence and any interventions. An example for the knowledge state of 'risk' is the occurrence of bovine virus diarrhoea (BVD) in intensive livestock production systems where the probability of BVD occurrence is relatively well understood and the consequences are known and there is little disagreement about the management options. It may indeed be more appropriate to refer to this particular knowledge state as 'simple risk' (Renn *et al.* 2011). The knowledge state of 'uncertainty' applies to exotic diseases such as foot-and-mouth disease, where the introduction of the causative virus is subject to uncertainty but the consequences are well understood and the management tools established. The risk analysis framework for animal health performs best for the knowledge state of 'simple risk', less so for that of 'uncertainty', but it is of limited utility when confronted with 'ambiguity' or 'ignorance'. Policy makers should use these 4 broad categories to inform their choice of tools for integrating different types of knowledge such that it optimises their chances of being able to make good decisions. It is very understandable that policy makers are most comfortable in the knowledge state of 'simple risk', since they have to deal with very limited uncertainty in relation to event occurrence and its consequences. At the same time, it is surprising that both the science-policy interface and government decision making processes are usually 'optimised' for the 'simple risk' states and to a lesser extent for 'uncertainty' knowledge states, despite of both these representing less difficult challenges for decision making compared with the knowledge states of 'ambiguity' and 'ignorance'. Indeed, there have been many challenges to animal health in the past 20 years that have been in the 3 knowledge state categories of 'uncertainty', 'ambiguity' or 'ignorance'. In these situations, targeted public engagement strategies become particularly important and knowledge generated using qualitative analytical methods is likely to be as useful or even more useful than quantitative analysis (Stirling 2012). These cases unveil the limitations of risk analysis frameworks for animal health and food safety which have a primary biomedical focus (Ely *et al.* 2009b). The risk framing phase of the IRGC risk governance framework will allow policy makers to clarify which knowledge state applies to a particular hazard, and inform decision making in relation to the most appropriate risk assessment methods. It involves explicit interaction between risk assessors and managers as well as any other important stakeholders. The evaluation of the findings from the risk assessment is aimed at assessing the tolerability or acceptability of the risk and, therefore, determines whether nothing will have to be done, further risk assessment or a risk mitigation policy will be required. This is also the stage where a decision to invoke the precautionary principle can be made (Renn 2008; Stirling and Gee 2002). Public engagement is a key aspect of the IRGC risk governance framework, and it needs to be based on a detailed stakeholder analysis to be conducted during the risk framing phase. Mills *et al.* (2011) present an example of this process for identifying stakeholder groups with 'interest' and 'influence' in plant health issues, and they emphasize that appropriate stakeholder choice for involvement in a risk assessment will strongly benefit the acceptance of any risk management policies. Overall, the IRGC risk governance framework should be used as a model for an evolutionary adaptation of the current risk analysis frameworks for animal health and food safety that will take advantage of the experience with their use in the last 20 years and our improved understanding of decision making processes, particularly in terms of the role of a wider range of sciences.

## Conclusions

As a result of technological development, globalisation, environmental change and modern society's expectations, policy development in animal health has become an ever more challenging process. The still widely used linear technocratic models for policy development have limited effectiveness when dealing with risks occurring within complex eco-social systems. The utility of the established risk analysis frameworks for animal health and food safety could be enhanced if they were subsumed into a risk governance framework that better recognises the wider meaning of the term 'risk'. Specifically, the addition of risk framing and risk evaluation to the current animal health risk analysis components of hazard identification, risk assessment, management and communication places a more explicit emphasis on the socio-economic and participatory dimensions of policy responses to risk. Furthermore, the risk assessment process itself has to take account of the breadth of factors influencing pathogen transmission from the molecular to the population/landscape/regional level, including socio-economic factors, and interactions between factors as well as emergent properties at system level. This requires an inter- or transdisciplinary research approach which is comfortable with bringing together knowledge from different scientific disciplines including that generated by quantitative and qualitative approaches, rather than being dominated by the natural and biomedical sciences and quantitative methods, as is currently the case. It is also important to consider the impact of organisational culture on risk management. Indeed, organisational behaviour varies within and between countries and regions, such that it may be possible to implement effective science-led decision making in some countries with relative ease but only with major difficulty or not at all in others. Finally, and may be most importantly, a risk governance approach will have to optimise its public engagement component based on the socio-economic risk characteristics of the hazard, since this will positively influence appropriateness and acceptance, and therefore impact of policies.

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