

Risk assessment in animal welfare – EFSA approach

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Abstract

Animal Welfare (AW) issues are becoming an increasing concern for food-producing and laboratory animals. Risk Assessment (RA) is usually used to describe and quantify the risk of introduction of infections, toxo-infections or residues coming from veterinary medicines, by importing live animals and their products or to identify options for the control of epidemic or endemic diseases. Recently, RA methods have been sought to be applied to AW as well. However, considering that this is a newly emerging area, for which no general guidelines have been produced, the above mentioned RAs cannot be always directly transferred. The use of a RA approach to evaluate issues related to AW can be useful to better identify and rank welfare risk factors, and to prioritise possible management measures. Possible approaches to AW RA are described and differences and similarities with the classical RA are discussed as well as the problems identified concerning the use of RA methodology for AW. A significant difficulty in AW RA consists in the quantification of the severity and of the probability of exposure of the identified hazards to welfare. Furthermore, data from different expert opinions are not always expressed using the same scale. The European Food Safety Authority (EFSA) has launched RA studies in which AW was considered as endpoint of interest. Examples are briefly discussed.

Keywords: animal welfare, risk assessment, hazard, EFSA

Introduction

Animal Welfare (AW) issues about food-producing and laboratory animals are becoming an increasing concern, but it is not an easy task to describe welfare of animals objectively, nor qualitatively or quantitatively. However, an overall welfare assessment seems necessary to implement standards in animal welfare.

Over some years, the use of Risk Assessment (RA) has considerably spread in biosciences. RA is usually used to describe and quantify the risk of introduction of infections, toxo-infections or residues coming from veterinary medicines, by importing live animals and their products or to identify options for the control of epidemic or endemic diseases. Specific guidelines have been produced to assess the risk of various hazards: international guidelines have been proposed by the World Health Organization (WHO)

for microbiological food safety (WHO, 1999) and by the World Organization for Animal Health (OIE) for assessing the risks of importing live animals and their products (OIE, 2004a, 2004b).

However, since the principles behind any RA are broadly similar and based on logic chains of events (pathways), guidelines already in existence for specific situations can be adapted for RA in other situations. For example, in microbiological RAs for food, the framework developed by Codex Alimentarius is often used (WHO, 1999), and this approach has also been suggested by the OIE for issues involving antibiotic resistance (Vose *et al.*, 2001).

Whereas risk assessment terminology is well established (OECD, 2003), the terms used in the areas of microbiological food safety and animal disease imports differ somewhat. This has been reviewed by

Vose *et al.* (2001), who compares the terminologies used in the two systems.

In the area of AW, no international guidelines on the conduct of risk assessments exist at this moment, but the use of a RA approach to evaluate issues related to AW may be useful to better identify and rank welfare risk factors, and to prioritise possible management measures. However, the existing methodologies cannot be readily applied to welfare.

The mission of the European Food Safety Authority (EFSA) is to provide scientific and technical advice for the European Union (EU) legislation and policies in all fields which have a direct or indirect impact on food and feed safety, including animal health and welfare (<http://www.efsa.europa.eu>). The Animal Health and Animal Welfare (AHAW) Panel of EFSA provides advice on specific risk factors related to animal diseases and welfare primarily of food producing animals, including fish and laboratory animals. EFSA uses a RA approach to the scientific questions studied and therefore has started to develop the use of RA in animal welfare.

This paper presents an overview of the approaches followed by the AHAW Panel and the AHAW Unit team of EFSA in the application of the risk assessment methodologies during the elaboration of the scientific reports on animal welfare.

General description of the risk assessment

RA is the result of the interactions between scientists from various backgrounds and consists of several steps, starting from the initial question posed by the risk manager. Answering to this question is an iterative process between the risk managers, the experts involved and the risk assessors.

As a first step, a risk profile, in which the question and the hazards will be clearly identified, is created. As a definition, a hazard is a factor with the potential to cause an adverse effect. This may either be a factor such as the level of temperature or the need of an animal which is not fulfilled. At the beginning, a list of needs may be identified as well as a list of potentially hazardous factors to the welfare of the animal. Depending on different production/laboratory systems, animal species or the question studied, slightly different approaches may be taken.

The consequences of the hazards need to be characterized and the nature of their adverse effects can be evaluated qualitatively, semi-quantitatively or quantitatively. In a qualitative risk assessment, the probabilities are described in 'simple' terms, such as "high", "medium", "low" and "negligible", following the OIE methodology. However, it is not always easy to define exactly these categories. In a qualitative risk assessment, the various factors and risks are discussed in length to give information, for instance on uncertainty and variability, and to qualify the

description. In semi-quantitative methods, risks are scored and, in comparison to the purely qualitative analysis, the available information is quantified in categories. However, there is still a risk of differing interpretations of the scores and of inappropriate mathematical manipulations. Nevertheless, this may still be useful for prioritising or ranking risks. For the quantitative risk assessment quantitative data are required. These can be used in a deterministic – using single numbers rather than ranges to indicate probabilities – or a probabilistic or stochastic model using probability distributions, not only to represent the adverse event, but also variability and uncertainty. Simulation modelling is commonly used in stochastic risk modelling (EFSA, 2007a) using for example such software as @risk (Palisade Corporation, Ithaca, NY, USA).

For the purpose of a general AW RA, risk tables with the various hazards are produced and severity, duration of effect, likelihood of an individual being affected as well as uncertainty about the information are compiled by the experts. The second part, dealing with exposure assessment, is carried out in a similar procedure (frequency of exposure, duration during life stage and uncertainty).

In early welfare risk assessment, the hazard score was multiplied by the exposure score to give a risk score. This is a straight forward risk analysis of a semi-quantitative kind (Paton and Martin, 2006). However, this approach has been replaced with an approach taking more variables into account; here, the above mentioned variables – after mathematical standardisation - are multiplied to give the risk score.

If sufficient data are available, the probability distribution of the variables can be simulated using standard risk assessment procedures and give a range/distribution for the risk score.

To compare different production systems the risk factors of each system may be added up and the overall score compared.

Special considerations of risk assessment methodology in animal welfare

The RA of animal welfare differs from other RAs that hazards are less clearly defined - the hazard identification is a crucial step in the risk assessment process - compared with the case of the introduction of a pathogen into an area where it is so far unknown.

To obtain information on AW, a list of potential hazards for the animals has to be compiled taken into account the needs of the animals, which have to be identified for each species, life stages and production/laboratory systems. If the identified animal needs are not fulfilled, a welfare problem should be present.

The distinction between looking at population or individual level should be clearly identified. The quantitative measurement of welfare is another

challenge, as there may be qualitative data available for some parameter, but not often quantitative data (EFSA, 2007a). It was proposed to measure deviation from normality in a number of variables, measurable clinical signs, such as heart rate, respiratory rate, body temperature and body weight, and appearance as well as behavioural changes, such as unprovoked behaviour and behavioural responses to stimuli (Morton and Griffiths, 1985).

Different approaches represent an effort to achieve a measure of welfare, in order to quantify the welfare risk. One attempt to this RA methodology is the Animal Needs Index (ANI) (Bartussek, 1999) which considers different aspects of the animal's environment, graded by points. Another approach is the Bracke model for overall welfare assessment (Bracke *et al.*, 1999a, 1999b) which provides tables for specific housing systems and a general method to calculate and rank overall welfare scores. Another methodology is based on the composite measurement scale methodology, widely used in social fields (Streiner and Norman, 1999). However, in EFSA opinions an overall assessment of the hazards to the welfare by the experts has been attempted.

Open questions in animal welfare risk assessment

Due to the complex nature of AW, the RA approach has still to tackle some challenges, some of them are more connected to methodological aspects, but some others are related to a general approach to animal welfare.

For the latter, the question of how to deal with a very rare and very serious effect appropriately in a RA frame work so far depends on the individual case. A very serious effect which rarely ever happens will not stand out in a quantitative RA exercise. However, it may still be important to take this hazard into account since rare effects nevertheless may happen.

A further question in animal welfare RA is how the benefits of a husbandry system or another factor can be taken into account in assessing the welfare. So far in quantitative analysis the hazards are analysed, but not the benefits. For a risk manager decision benefits and risks have to be balanced. Benefits for AW shall be observed from human or animal points of view; for the first one, benefits may be related to economical aspects. Farming procedures which assure a high level of animal welfare could lead to an increase in cost or in productivity. The balance between these two aspects results in less or more benefits for the system in a broad sense. However, if all the benefits are included into a quantitative model, it would lead to very large models, which may be difficult to compile and not serve the purpose. It has to be borne in mind that, for instance, the benefits of a particular system of keeping the animals may have to be outweighed against certain risks to welfare.

Risk factors do not often act separately but they can interact with other hazards and they can also show a cumulative effect. The complex features of breeds, species, production/laboratory systems, geographical position, farm environment, etc. can be taken into consideration for a precise identification of the risk. However, no straightforward method has been developed to take interaction and cumulative effects of hazards into account in this type of risk assessment. A possibility to include interactions is to categorize hazards on the basis of other factors; for instance, a specific hazard could be judged within the context of different conditions such as high and low temperatures. Some interactions may be incorporated using subdivided data.

The "death as endpoint" is another difficulty in the RA approach; in the view of some AW scientists, death is not a welfare problem, because they focus on the suffering of the animal. However, when calculating the duration of the effect of a certain hazard over the life time, it has to be decided how to judge the concept of "life time". Life time can be the "potential life time": if an animal immediately dies of a certain hazard, than the duration of the effect over the potential life time is very short. However, life time can also be the "actual (real/ absolute) life time", if the effect of the hazard over the real life time of that particular animal is considered than the duration would be 100%. At the present, no conclusion has been reached on this aspect and the approach may vary due to the questions studied. A compromise would be to calculate RA with both possibilities to point out the different dangers that the animal will suffer for a long time or that the animal will inevitably die very quickly. Even though death may be not a welfare problem, it is still an indication for the state of the population.

EFSA state of play of risk assessment in animal welfare

EFSA has been actively involved in developing risk assessment for AW since 2003. In order to discuss the state of the art regarding the RA in food producing animals, a Scientific Colloquium was organized by EFSA on December 2005 and held in Parma (EFSA, 2006c). One of the main conclusions from the colloquium was that no specific standardized RA methodology exists in the field of the AW and that it would be worthwhile to set up a working group to define a standardized methodology and international guidelines for RA in AW.

Since 2004, the AHAW Panel adopted several Scientific Opinions on AW dealing, among others, with laboratory animals, stunning and killing methods, piglet castration and animal transport. In 2006, two Scientific Opinions on the welfare of intensively kept calves (EFSA, 2006a) and the health and welfare

Table 1. Evolution of the RA approach amongst the AHAW Opinions (http://www.efsa.europa.eu/en/science/ahaw/ahaw_opinions.html)

AHAW Opinion on Animal welfare	Year	RA	Hazard Id.	QI RA	Semi-Qt RA	Qt RA
Welfare of animals during transport - updated	2004	-	-	-	-	-
Welfare aspects of various systems of keeping laying hens	2004	-	x	x	-	-
Impact of the current housing and husbandry systems on the health and welfare of farmed domestic rabbits	2005	-	x	x	-	-
Welfare of weaners and rearing pigs: effects of different space allowances and floor types	2005	-	x	x	-	-
Biology and welfare of animals used for experimental and other scientific purposes	2005	-	x	x	-	-
Welfare aspects of the main systems of stunning and killing applied to commercially farmed deer, goats, rabbits, ostriches, ducks, geese and quail	2006	-	x	x	-	-
The risks of poor welfare in intensive calf farming systems	2006	x	x	-	x	-
Animal health and welfare risks associated with the import of wild birds other than poultry into the European Union	2006	x	x	-	x	-
Welfare of pig – Sows, boars and piglets	2007	x	x	-	-	x
Welfare of pig – Fattening pigs	2007	x	x	-	-	x
Welfare of pig – Tail biting	2007*	x	x	-	-	x
Welfare of fish – Atlantic Salmon	2007*	x	x	-	x	-
Stunning and killing methods for seals	2007*	x	x	x	-	-

Hazard id.: hazard identification; QI RA: qualitative RA; Semi-Qt RA: semi-quantitative RA; Qt RA: quantitative RA.
*: currently under development

risks of the import of wild birds inside EU (EFSA, 2006b) were adopted and a RA approach was there tentatively initiated. At present, new scientific reports dealing with pig and fish welfare are under development and the RA approach will be improved. The scientific opinions are compiled by a working group composed of several experts in different fields in order to get a multidisciplinary approach. There has been an evolution since 2003 to now concerning the degree of involvement of the stakeholders in the RA procedure in EFSA. Between 2003 and 2005, no consultation with stakeholders took place; however, since 2006 a positive input has been identified by the involvement of the stakeholders in some scientific opinions (EFSA, 2005; EFSA, 2006a). EFSA is trying to introduce in the RA procedure the stakeholder consultation as a step for obtaining information due to the high level of uncertainty. The evolution of the RA approach amongst the different AHAW Opinions is presented in Table 1.

In the Calf Welfare and Captive birds scientific opinions (EFSA, 2006a, 2006b), the overall risk on AW was estimated by integrating the hazard characterisation and the exposure assessment into risk estimations (major, minor or negligible risk).

Since this approach omits some essential information, further variables were included. The hazard characterization was improved in the following opinions (Pig and Fish welfare), where the parameters of intensity, likelihood, duration and uncertainty of the exposure to the hazard and the severity of the hazard were introduced. The final table for hazard assessment and for exposure assessment currently

followed for the deployment of the Scientific Report on Fish welfare (EFSA, 2007b, under development) is presented in Table 2.

This approach, including the evaluation of the likelihood/intensity and the duration and uncertainty in both hazard characterisation and exposure assessment, will be followed for the risk estimation of the Pig and Fish Welfare Scientific Opinions. For the fish, a semi-quantitative approach has been adopted due to the lack of knowledge and the numerous factors implicated.

Following the OIE methodology, the uncertainty, as a measure of the knowledge about the information and the data used to perform the RA, was also added in the ongoing EFSA Opinions. If papers are available on the various risks giving even quantitative information, then a quantitative risk assessment may be relatively straight forward. However, particularly in welfare, this may not be the case, since not many quantitative data are available, due on one side to the fact that welfare is difficult to measure and, on the other hand, that for certain questions not many studies have been undertaken. Here, risk assessors only rely on expert knowledge. OIE definitions of uncertainty and level of uncertainty on animal welfare issues treated in the AHAW Opinions are presented in Table 3.

EFSA is ready to launch a self-mandate on the development of general guidelines and working methodology on RA for AW, as no specific international guidelines are currently available. For the development of these guidelines, in line with Article 36 of Regulation 178/2002, the AHAW Panel

Table 2. Hazard characterization and Exposure Assessment – Fish welfare

Hazard assessment					
Hazard description	Adverse effect description	Severity	Duration of effect	Likelihood	Uncertainty
		4	0 - 100 %	5	1
		3		4	
		2		3	2
		1		2	
		0		1	3
				0	
Exposure assessment					
Frequency of exposure	Duration during life stage			Uncertainty	
5	0 - 100 %			1	
4					
3				2	
2					
1				3	
0					
<i>Severity: 0 = Negligible; 1 = Limited; 2 = Moderate; 3 = Severe; 4 = Very Severe.</i>					
<i>Likelihood: 0 = Negligible; 1 = Extremely low; 2 = Very low; 3 = Low; 4 = Moderate; 5 = High.</i>					
<i>Uncertainty: 1 = Low; 2 = Medium; 3 = High.</i>					
<i>Frequency of exposure: 0 = Negligible; 1 = Extremely low; 2 = Very low; 3 = Low; 4 = Moderate; 5 = High.</i>					

Hazard assessment and exposure assessment are all columns which are equally treated and are normally shown next to each other and only due to the presentation format are presented on top of each other.

Table 3. OIE definitions of uncertainty and level of uncertainty on animal welfare issues treated in the AHAW Opinions (OIE, 2004b, modified).

Uncertainty level	Description
Low	Solid and complete data available; strong evidence provided in multiple refs; authors report similar conclusions.
Medium	Some but no complete data available; evidence provided in small number of refs; authors' conclusions vary from one to other. Solid and complete data available from other species which can be extrapolated to the species considered.
High	Scarce or no data available; rather evidence provided in unpublished reports, based on observations or personal communications; authors' conclusions vary considerably between them.

is seeking proposals from the competent bodies to carry out a project to define the main subjects and the RA working methodology. The guidelines should also provide a list of possible risk factors affecting AW and the description of the most suitable indicators (including their selection criteria) for the RA of AW.

Conclusions

RA in Welfare is a transparent method of assessing the risks for animal welfare since the data used are presented and the assumptions are detailed. This way

results can be more easily cross-checked. RA in the field of animal welfare can provide a basis for the decisions of the risk manager. Particularly, RA is a tool for risk ranking and thus prioritizing management measures. However, there are still a number of problems, including clear measurements of animal welfare, which have methodologically to be resolved or at least borne in mind when dealing with this type of risk assessment.

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