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SCIENTIFIC OPINION

Scientific Opinion on Risk Assessment Terminology[1]

EFSA Scientific Committee[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The Scientific Committee of the European Food Safety Authority (EFSA) reviewed the use of risk assessment terminology within its Scientific Panels. An external report, commissioned by EFSA, analysed 219 opinions published by the Scientific Committee and Panels to recommend possible ways of improving the expression and communication of risk and/or uncertainties in the selected opinions. The Scientific Committee concluded that risk assessment terminology is not fully harmonised within EFSA. In part this is caused by sectoral legislation defining specific terminology and international standards for specific fields of risk assessment and thus for specific Panels. The use of defined terminology for risk assessment is driven by three standard-setting organisations, the Codex Alimentarius Commission (CAC) in relation to food safety, the World Organisation for Animal Health (OIE) for animal health and the International Plant Protection Convention (IPPC) for plant health, under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) of the World Trade Organisation (WTO) of which the European Union is a member. Should the major purpose of risk assessment be international trade, the Scientific Committee concludes that particular care must be taken that the principles of CAC, OIE or IPPC are followed strictly. EFSA Scientific Panels should identify which specific approach is most useful in dealing with their individual mandates. The Scientific Committee considered detailed aspects of risk assessment terminology and identified their relevance for EFSA to adopt more harmonised use. These included examining definitions of risk and uncertainty, expressing uncertainty and different levels of risk, the merits of using qualitative and quantitative expressions and the use of glossaries of definitions to improve both the understanding and harmonisation of terminology across EFSA's scientific opinions. Follow-up action by EFSA is identified to develop appropriate detailed guidance to the Scientific Panels. Recommendations are made to improve the clarity, consistency and where possible the harmonization of risk assessment terminology within and across EFSA's scientific opinions.

KEY WORDS

Risk assessment terminology, harmonisation, EFSA, food safety.

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1 On request from EFSA, Question No EFSA-Q-2010-00705, adopted on 18 April 2012.

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3 Acknowledgement: The Scientific Committee wishes to thank the members of the Working Group on Risk Assessment Terminology for the preparation of this opinion: Tine Hald, Anthony Hardy, Andrew D. Hart, Sirpa Kärenlampi, Klaus-Dieter Jany, Riitta Maijala (as from October 2011), Antonio Mutti, Angelo Porta Puglia, Ivonne Rietjens, Frans Smulders, Hans-Herman Thulke; hearing experts: Villie Flari and Klaus Jurgen Henning and EFSA's staff member(s) Lucilla Gregoretti, Daniela Maurici, Laura Smillie, Franz Streissl for the support provided to this EFSA scientific output.

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SUMMARY

The European Food Safety Authority (EFSA) asked its Scientific Committee to develop an opinion on the use of risk assessment terminology and how increased harmonisation across its Scientific Committee and Panels could reduce ambiguity and improve the consistency and clarity of its technical risk assessments to risk managers, consumers and the wider scientific and stakeholder community. The aim of this opinion is to review EFSA's use of terminology, to identify possible reasons for differences in the use of language and terms, to identify where harmonisation is possible within and across the very wide food safety areas of EFSA's responsibility and to contribute to collaborative international work to improve the harmonisation of risk assessment terminology.

The international use of defined terminology for risk assessment is driven by three standard-setting organisations, the Codex Alimentarius Commission (CAC) in relation to food safety, the World Organisation for Animal Health (OIE) for animal health and the International Plant Protection Convention (IPPC) for plant health, under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) of the World Trade Organisation (WTO) of which the European Union is a member. Regulation (EC) 178/2002which establishes EFSA contains definitions of a number of risk-related general terms which are similar to those provided by CAC. Although the European legislator does not dictate which of the three methodologies (and associated terminology) is to be used, should the major purpose of risk assessment be international trade, the Scientific Committee concludes that particular care must be taken that the principles of CAC, OIE or IPPC are followed strictly. EFSA Scientific Panels should identify which specific approach is most useful in dealing with their individual mandates. Differences in approaches and terminology as defined by the various risk analysis standards have an impact on the terminology used by different EFSA Scientific Panels.

There are broadly two types of risk assessment carried out by the EFSA Scientific Panels where

- hazards are introduced into or occur in the food chain unintentionally (commonly carried out by the AHAW, BIOHAZ, CONTAM and PLH Panels)
- substances, products or processes are intentionally added to the food chain (commonly carried out by ANS, CEF, FEEDAP, GMO, NDA and PPR Panels). This may often result in a safety assessment, designed to identify whether a hazard, nutritional or other safety concern is present and, if so, to gather information on its nature and severity.

EFSA's founding regulation tasks EFSA both with risk assessment and risk communication. Transparency, unambiguity and consistency of terminology are key requirements to improve the clarity of the risk assessment messages to consumers, risk managers and the international food safety community. A number of international organisations have published scales of terms to describe the different levels of various measures relevant for risk assessment including, for example, levels of hazard, exposure, risk, probability or likelihood, uncertainty and evidence.

The Scientific Committee encourages the principle of harmonisation of terminology wherever possible but recognises the limitations to the extent to which this is feasible or desirable. EFSA commissioned an external review of 219 opinions published by the Scientific Committee and Panels to recommend possible ways of improving the expression and communication of risk and/or uncertainties in the selected opinions. Analysis revealed both similarities and differences in the use of language to express risk, benefit, efficacy and uncertainty within and between opinions of the Scientific Committee and Panels. Acknowledging this exhaustive comparative review, the Scientific Committee concludes that risk assessment terminology is not fully harmonised within EFSA. This is in part caused by sectoral legislation defining specific terminology and international standards for specific fields of risk assessment and thus for specific Panels. Such differences can strongly influence the phrasing of the terms of reference for EFSA mandates, which may determine the use of specific terminology by individual EFSA Panels.

The Scientific Committee considers that there are three levels at which harmonisation of terminology can be addressed in EFSA. These are harmonisation i) within an opinion (e.g. the consistent use of terms in abstract, summary and conclusions), ii) between different opinions of the same Panel (e.g. consistent use of terminology for duration, spatial extent, magnitude or severity of adverse effect), and iii) across EFSA Panels. Furthermore, explaining terms and clearly explaining differences between terms in different fields of risk assessment may help to overcome some of the problems.

The Scientific Committee considered detailed aspects of risk assessment terminology and identified their relevance for EFSA to adopt more harmonised use. These included examining definitions of risk and uncertainty, expressing uncertainty and different levels of risk, the merits of using qualitative and quantitative expressions and the use of glossaries of definitions to improve both the understanding and harmonisation of terminology across EFSA scientific opinions.

The Scientific Committee recommends that:

1) EFSA should be actively involved in harmonising risk assessment terminology where possible, and to that end should collaborate actively with international standard-setting organisations.
2) Further guidance on the harmonisation of risk assessment terminology within EFSA should be developed.
3) Three levels for harmonisation of terminology should be considered in EFSA:
    a. Within each scientific opinion. EFSA secretariats and the Scientific Committee and Scientific Panel(s) should ensure that the risk assessment terminology used is consistent within abstract, summary and conclusions on risk.
    b. Each Panel should ensure consistent use of risk assessment terminology across its opinions within the same scientific area.
    c. EFSA should take necessary measures to ensure better (or improved) harmonisation of risk assessment terminology across EFSA.
4) EFSA should develop a stepwise approach to implement harmonisation at these three levels. Harmonisation at the first level (within each scientific opinion) would be most easily achievable and the Scientific Committee strongly recommends that this should become best practice and be included in EFSA's standard operating procedures as soon as possible.
5) A short-term action that would facilitate each of the three levels of harmonisation would be the development of a central database of definitions which could be used as starting point to further harmonise terminology within and between the Scientific Panels across EFSA. This activity should be completed as soon as possible.
6) EFSA should collate and keep up to date a list of reference/source legislation for each Scientific Panel and the Scientific Committee. Each Panel and the Scientific Committee should examine closely the risk assessment terminology in the source legislation for their particular sector. Where the legislation for a sector does not include definitions of the specific risk assessment terms, the Scientific Committee recommends for consistency that Scientific Panels identify and use definitions given by CAC, OIE or IPPC and other relevant international authorities that serve the Scientific Panel activities. However, where a Scientific Panel sees a need to use a definition that is different from a definition of the same term established by the above-mentioned organisations, they should justify why this is necessary.
7) Terms used to express levels of risk and uncertainty should be consistent and well-defined. In order to reduce ambiguity, the Scientific Committee recommends that Scientific Panels work towards more quantitative expressions of risk and uncertainty whenever possible, i.e. quantitative expression of the probability of the adverse effect and of any quantitative descriptors of that effect (e.g. duration), or the use of verbal terms with quantitative

definitions. The associated uncertainties should always be made clear, to reduce the risk of over-precise interpretation.

8) Further guidance should be developed on approaches for both qualitative and quantitative expression of risk and uncertainty. Consideration should be given to intensify communication between EFSA and risk managers to enhance mutual understanding of the risk expressions and raise awareness of the potential for interpretational bias.
9) The Scientific Committee and the Scientific Panels should carefully consider the draft Terms of References (ToR) for every opinion/risk assessment mandate. Where appropriate, there should be interaction with risk managers to avoid wording that may require making risk management judgements or using terminology that might be interpreted as implying a judgement or expectation about the need for risk management action.
10) Certain words such us "negligible", "concern" and "unlikely", have risk management connotation in everyday language. The Scientific Committee recommends that, when used in EFSA opinions, they should be used carefully with objective scientific criteria (not involving value judgments) and be clearly defined so as to avoid the impression that risk assessors are making risk management judgments.
11) The glossary of each EFSA scientific output should include definition of the risk assessment terms used.
12) Uncertainties should be addressed in a substantive and explicit manner, using defined terminology, accompanied by an explanation of the basis on which they have been evaluated, and in a way that is clearly signposted so that it can be readily found by readers.

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BACKGROUND AS PROVIDED BY EFSA

Communication, transparency and consistency are three important issues associated with risk assessment, which may affect the efficiency with which EFSA is able to deliver its primary function as an international risk assessment organisation. Thus failure to communicate clearly, transparently and consistently and to get the published messages across unambiguously can have serious impact on the usefulness and uptake of the high-quality, technical assessments which EFSA's scientists produce across the very wide range of food safety areas within EFSA's responsibility. This issue is not new but is recognised as an important challenge for all organisations, whether national or international, to communicate clearly and unambiguously the risk assessments in their own particular field.

In the EU, inconsistent and varied terminology in risk assessment was identified as an important issue deserving attention by the Commission's multidisciplinary Scientific Steering Committee in its major opinions on the future harmonisation of risk assessment in Europe (EC 2000 and 2003). The International Programme on Chemical Safety (Joint UN Environment Programme, International Labour Organisation and WHO) published a harmonisation document on risk assessment terminology in 2004 (IPCS 2004). In 2007, European Commission DG Health and Consumers commissioned the UK's Central Science Laboratory to undertake a review of terminology used in risk assessments published by its non-food committees (DG Health and Consumers 2008). EFSA, in its opinion on the principles of transparency (EFSA 2009) recommended, where possible, that harmonised assessment terminology should be used, preferably based on internationally accepted terminology.

At the 34th EFSA Advisory Forum meeting held in Athens in November 2009, several Member States expressed the strong interest to be involved in the discussion on terminology and proposed to collaborate with EFSA with the aim of harmonising the risk assessment glossary used in the EU.

Through the annual meetings of the Chairs of the Community Scientific Committees and Panels responsible for risk assessment (Brussels 2005, 2006; Stockholm 2007; Parma 2008; Brussels 2009) this important issue has now become an activity supported by DG Health and Consumers. As part of this, a workshop on evaluating and communicating scientific evidence on environment and health issues was organised by the European Environment Agency in 2008.

Based on the outcomes of the 1st International Risk Assessment Conference held in Brussels in 2008, organised by the DG Health and Consumers Risk Assessment Unit, an international Working Group on evaluating uncertainty, weighing scientific evidence and using appropriate terminology in risk assessment has been established and currently involves Europe, the USA and Canada. The overall goals are to promote an improved common understanding of the approaches related to the issues mentioned above through the exchange of information, expert discussion and some practical tests, and to establish some common conclusions concerning the problem areas, to identify best practices and to set out possible common reference frameworks. In more detail, the operational objectives of the above-mentioned Working Group project are:

- Weight of evidence: to exchange information on practices and experiences and to establish a common conceptual framework to support a more consistent and transparent approach for evaluating evidence.
- Uncertainty in risk assessment: To exchange information on current practices for treating and expressing uncertainty and confidence (IPPC, EFSA etc.). To test selected approaches in a few case studies, report and assess results and conclusions and identify and recommend best practices.
- Risk assessment terminology: To exchange information on current ways to express the various dimensions of risk and to characterise risks in quantitative or qualitative terms, to make an assessment of problems posed and identify and recommend best practices.

Through further transatlantic discussions, it has been agreed that Europe will progress in all three areas, while in North America the two active areas of work will be uncertainty and risk

assessment terminology. It is intended to report progress, discuss, validate and disseminate the results of this ongoing project at the 2nd Risk Assessment International Conference, which was held in early 2011.

In parallel to this activity, EFSA awarded a 9-month contract to the UK's Food and Environment Research Agency (FERA) to provide a comparative review on the terminology used in the concluding sections of 219 opinions issued between 2008 and beginning of 2010 by EFSA. The report includes recommendations for improved approaches to expressing risk and uncertainty.

TERMS OF REFERENCE AS PROVIDED BY EFSA

Contribute to the ongoing international development and to improve harmonisation and the consistency of risk assessment terminology across EFSA's Scientific Committee, Scientific Panels and Units. EFSA asked the Scientific Committee to:

- Analyse the resulting report of the FERA contract (due October 2010) to examine the possibility of increasing harmonisation of risk assessment terminology across the EFSA Units, Panels and Committee.
- Make proposals and recommendations on the way forward where harmonisation and a more consistent approach in risk assessment terminology are needed.
- Contribute to the collaborative international work to improve harmonisation of risk assessment terminology.

In developing its evaluation and guidance, the Scientific Committee is requested to liaise with the EC Commission and with Member States and to consider the ongoing related activities of international organisations.

The Scientific Committee presented interim results at the 2nd International Risk Assessment Conference in Brussels in January 2011 and is requested to complete the work by the end of 2012.

ASSESSMENT

1. Introduction

Regulation (EC) . 178/2002 (European Commission, 2002), which establishes EFSA, stipulates that risk assessment should be objective, based on scientific evidence, and should be undertaken in an independent, objective and transparent manner. Moreover, it describes the principles of transparency, the general obligations of international food and feed trade and the specific mission and tasks of EFSA. It is specifically stated that EFSA is to ensure that "*the development of uniform risk assessment methodologies in the fields falling within its mission are promoted and coordinated (*Article 23, paragraph b) and that "*scientific and technical assistance with a view to improving cooperation between the Community, applicant countries, international organisations and third countries in the fields within its mission' is provided*" (Article 23, paragraph i). Hence, it is important that any communication from EFSA relating to risk analysis be formulated in transparent scientific terms that are easily understood, unambiguous and not open to differential interpretation by the interested parties.

The aim of this opinion is to build further on EFSA's previous discussions and recommendations to increase the harmonisation of risk assessment terminology across the areas of its food safety activities (EFSA 2006a, EFSA 2009) in compliance with international standards, guidelines and recommendations.

In its drive towards improving transparency and reducing ambiguity in its risk assessments, the Scientific Committee established a cross-Panel working group to examine the use of terminology by the EFSA Scientific Committee and Panels. In addition, EFSA contracted out an external review of 219 of its recently published scientific opinions (FERA 2010). That review was used as the starting point to address the mandate of the Scientific Committee on risk assessment terminology.

The current opinion evaluates the FERA report, taking into account the international and legislative contexts in which EFSA's risk assessments are carried out by the Scientific Panels, and considers the extent to which there is scope to harmonise the terminology used among different sectors. Other EFSA's outputs not produced by a Scientific Panel such as peer-review conclusions on plant protection products were not included in the analysis made by FERA. Recommendations are made for improvement within EFSA and the wider scientific risk assessment community.

This opinion deals with the terminology for the assessment and characterisation of risk but does not consider the terminology for the evaluation of benefits or efficacy. EFSA recognises that the harmonisation of risk assessment terminology is a developing activity and the present opinion aims at contributing to this ongoing international scientific debate to improve the harmonisation of risk assessment terminology, but that it is important to distinguish harmonisation from standardisation. The World Health Organisation (WHO) International Programme on Chemical Safety (IPCS)[4] considers harmonisation in a stepwise fashion, as an understanding of the methods and practises used by various countries and organisations in order to develop confidence in, and acceptance of, risk assessments that use different approaches. This further involves a willingness to work towards convergence of these approaches or methods as a longer term goal.

[4] http://www.who.int/ipcs/methods/harmonization/en/

2. Overview and use of existing international definitions of key terminology

2.1. Comparison of the key risk assessment terms

Existing international methodologies and guidance describing risk assessment terminology originate from the Codex Alimentarius Commission (CAC) of the FAO/WHO, the World Organisation for Animal Health (OIE, Office International des Epizooties), and/or the relevant international and regional organisations operating within the framework of the International Plant Protection Convention (IPPC). These are the relevant standard-setting organisations for food safety, animal health and plant health, respectively. These three organisations are important for risk assessment terminology because the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) of the World Trade Organization (WTO), states that all members (including the European Union) shall base their sanitary and phytosanitary measures on international standards, guidelines or recommendations of CAC, OIE and IPPC or, for matters not covered by these three organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organisations open for membership to all Members of WTO. Other international organisations involved in defining risk assessment terminology include e.g. IPCS (IPCS 2004) which feeds into CAC (see Appendix).

Risk assessment approaches of CAC, OIE and IPPC organisations cover in principle the same main questions:

- What can cause an adverse effect?
- How can it cause an adverse effect?
- What is the probability of an adverse effect occurring (i.e. what is the risk)?
- What are the consequences?
- What are the prerequisites for an adverse effect to indeed occur?

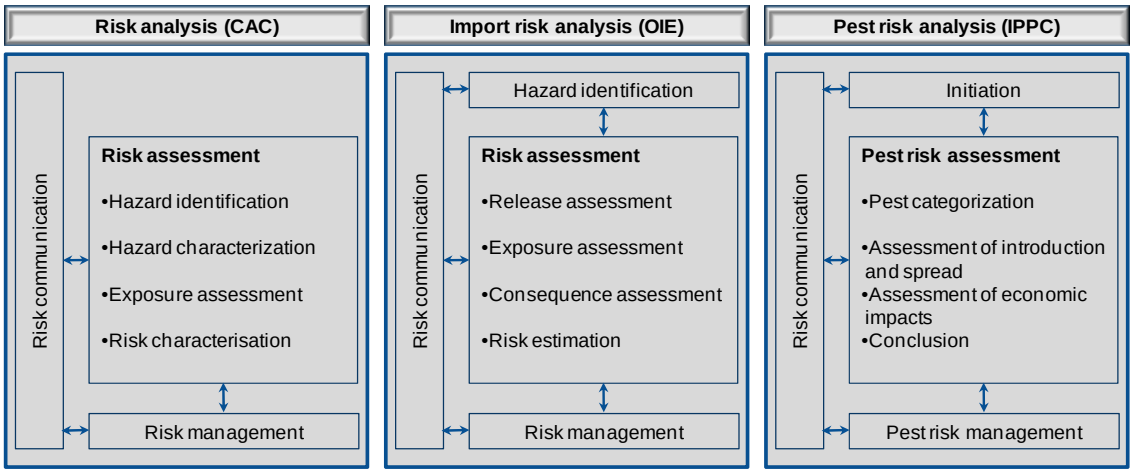

Figure 1: Comparison of risk assessment structures within the risk analysis frameworks of CAC, IPPC and OIE (modified from Maijala 2006).

Although the risk analysis framework is similar, CAC, OIE and IPPC each have their own defined scope for standard setting. Therefore, the risk assessment terms and definitions used by these three organizations differ from each other. The OIE and IPPC mainly focus on import risks, whereas CAC stresses domestic risks or risks related to specific substances or products. This difference is visible in the terms used within a risk assessment approach of these international standard-setting organisations (Figure 1). Furthermore, even if the risk assessment term would be the same, the definition may differ between CAC, OIE and IPPC (e.g. definition for "risk", see below). A more detailed overview of the core risk assessment terms defined by the CAC, OIE and IPPC is presented in Figure 1 and Table 1.

Table 1: Key terms in risk assessment as defined by the three standard-setting organisations (CAC, OIE and IPPC) relevant for EFSA's work. Some CAC definitions are further expanded in FAO/WHO references, which are included here.

Term	Organisation	Definition/explanations
Hazard/pest	**CAC**	a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect (CAC, 2011) A biological, chemical or physical agent in, or condition of, a good with the potential to cause an adverse health effect (FAO/WHO, 2008)
	OIE	Biological, chemical or physical agent in, or a condition of, an animal or animal product with the potential to cause an adverse health effect (OIE, 2011)
	IPPC	'Hazard' not specified; Pest is any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products (IPPC, 2011b) Contaminating pest is a pest that is carried by a commodity and, in the case of plants and plant products, does not infest those plants or plant products (IPPC, 2011b)
Risk/pest risk	**CAC**	A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food (CAC, 2011**)**
	OIE	Likelihood of the occurrence and the likely magnitude of the biological and economic consequences of an adverse event or effect to animal or human health. (OIE, 2011)
	IPPC	**Pest risk (for quarantine pests):** The probability of introduction and spread of a pest and the magnitude of the associated potential economic consequences (IPPC, 2011b) **Pest risk (for regulated non-quarantine pests):** The probability that a pest in plants for planting affects the intended use of those plants with an economically unacceptable impact (IPPC, 2011b)
Risk analysis	**CAC**	A process consisting of three components: risk assessment, risk management and risk communication. (CAC, 2011)
	OIE	The process composed of hazard identification, risk assessment, risk management and risk communication. (OIE, 2011)
	IPPC	The process of evaluating biological or other scientific and economic evidence to determine whether an organism is a pest, whether it should be regulated, and the strength of any phytosanitary measures to be taken against it (IPPC, 2011b)
Risk assessment	**CAC**	A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization. (CAC, 2011) **Qualitative Risk Assessment:** A risk assessment based on data which, while forming an inadequate basis for numerical risk estimations, nonetheless, when conditioned by prior expert knowledge and identification of attendant uncertainties permits risk ranking or separation into descriptive categories of risk. (FAO/WHO, 2008) **Quantitative Risk Assessment:** A risk assessment that provides numerical expressions of risk and indication of the attendant uncertainties (FAO/WHO, 2008)
	OIE	Evaluation of the likelihood and the biological and economic consequences of entry, establishment and spread of a hazard within the territory of an importing country (OIE, 2011)
	IPPC	**Pest risk assessment (for quarantine pests):** Evaluation of the probability of the introduction and spread of a pest and the magnitude of the associated potential economic consequences (IPPC, 2011b) **Pest risk assessment (for regulated non quarantine pests):** Evaluation of the probability that a pest in plants for planting affects the intended use of those plants with an economically unacceptable impact (see (IPPC, 2011b)
Exposure, entry, introduction, release, spread, establishment	**CAC**	**Exposure assessment**: The qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant (CAC, 2011)
	OIE	**Release assessment** consists of describing the biological pathway(s) necessary for an importation activity to 'release' (that is, introduce) pathogenic agents into a particular environment, and estimating the probability of that complete process occurring, either qualitatively (in words) or quantitatively (as a numerical estimate). The release assessment describes the probability of the 'release' of each

		of the potential hazards (the pathogenic agents) under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures (OIE, 2011) **Exposure assessment** consists of describing the biological pathway(s) necessary for exposure of animals and humans in the importing country to the hazards (in this case the pathogenic agents) released from a given risk source, and estimating the probability of the exposure(s) occurring, either qualitatively (in words) or quantitatively (as a numerical estimate) (OIE, 2011)
	IPPC	**Entry**: Movement of a pest into an area where it is not yet present, or present but not widely distributed and being officially controlled; **Introduction:** The entry of a pest resulting in its establishment; **Pathway**: Any means that allows the entry or spread of a pest; **Spread**: Expansion of the geographical distribution of a pest within an area; **Establishment**: Perpetuation, for the foreseeable future, of a pest within an area after entry (IPPC, 2011b)
Consequence assessment	**CAC**	"Risk management should take into account the economic consequences"; "JECFA(*)'s communication of its risk assessments should not include the consequences of its analyses on trade or other non-public health consequence." (CAC, 2011) (*)*Joint FAO/WHO Expert Committee on Food Additives (JECFA)*
	OIE	Consequence assessment consists of describing the relationship between specified exposures to a biological agent and the consequences of those exposures. A causal process should exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability of them occurring. This estimate may be either qualitative (in words) or quantitative (a numerical estimate) (OIE, 2011).
	IPPC	Description of the "Assessment of potential economic consequences" (IPPC, 2011c) **Economic impacts of plant pests:** This includes both market measures as well as those consequences that may not be easy to measure in direct economic terms, but which represent a loss or damage to cultivated plants, uncultivated plants or plant products. (IPPC, 2011b)
Uncertainty (analysis)	**CAC**	**Uncertainty**: The (quantitative) expression of our lack of knowledge. Uncertainty can be reduced by additional measurement or information. (WHO/FAO, 2008); There are many types of uncertainty in exposure assessment, including process uncertainty, model uncertainty, parameter uncertainty, statistical uncertainty, and even uncertainty in variability: **Process uncertainty** refers to the uncertainty about the relationship between the food chain as documented in the exposure assessment and the processes that take place in reality. **Model uncertainty** comprises both the correctness of the way the complexity of the food chain is simplified, and the correctness of all the submodels that are used in the exposure assessment. **Parameter uncertainty** incorporates uncertainties dealing with errors resulting from the methods used for parameter estimation, like measurement errors, sampling errors and systematic errors. As part of this, **statistical uncertainty** is defined as the uncertainty quantified by applying statistical techniques such as classical statistics or Bayesian analysis. **Uncertainty:** Lack of knowledge regarding the true value of a quantity, such as a specific characteristic (e.g. mean, variance) of a distribution for variability, or regarding the appropriate and adequate inference options to use to structure a model or scenario. These are also referred to as model uncertainty and **scenario uncertainty** (FAO/WHO, 2003) **Measurement uncertainty** refers to the 'uncertainty' associated with data generated by a measurement process. In analytical chemistry, it generally defines the uncertainty associated with the laboratory process but may also include an uncertainty component associated with sampling. (CAC, 2006); non-negative parameter characterizing the dispersion of the values being attributed to a measure and, based on the information used (CAC, 2009); **Model uncertainty** Bias or imprecision associated with compromises made or lack of adequate knowledge in specifying the structure and calibration (parameter estimation) of a model (FAO/WHO, 2003) **Uncertainty analysis**: A method used to estimate the uncertainty associated with model inputs, assumptions and structure/form. (FAO/WHO, 2008)**;** an analysis designed to determine the contribution of the uncertainty associated with an input

		parameter to the degree of certainty in the estimate of exposure. (FAO/WHO, 2008)
	OIE	not specified (OIE, 2011)
	IPPC	Uncertainty is a component of risk and therefore important to recognize and document when performing PRAs [Pest Risk Analyses]. Sources of uncertainty with a particular PRA may include: missing, incomplete, inconsistent or conflicting data; natural variability of biological systems; subjectiveness of analysis; and sampling randomness. Symptoms of uncertain causes and origin and asymptomatic carriers of pests may pose particular challenges. (IPPC, 2011a)
Safety assessment	**CAC**	A Safety Assessment is defined by CAC as a scientifically-based process consisting of: 1) the determination of a NOEL (No Observed Effect Level) for a chemical, biological, or physical agent from animal feeding studies and other scientific considerations; 2) the subsequent application of safety factors to establish an ADI or tolerable intake; and 3) comparison of the ADI or tolerable intake with probable exposure to the agent (Temporary definition to be modified when FAO/WHO/JECFA definition is available). (CAC, 2011. In: Risk analysis principles applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods).
	OIE	not specified
	IPPC	not specified

Similarities and differences between the organisations' definitions are highlighted below.

Hazard, Pest – The definitions of hazard by CAC and OIE are similar, although not identical: *biological, chemical or physical agent* in or *condition* of, food/good/animal or animal product with the potential to cause an adverse health effect. The EFSA's founding regulation principally follows the CAC definition but includes 'food or feed'. The IPPC uses the term "pest" instead of "hazard" and defines it as any *species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products*. Thus all three organisations define hazard as something that has a potential to cause an adverse health effect or to be injurious to target populations.

Risk – The CAC definition of risk addresses the probability and severity of an adverse health effect consequential to hazards in food. The definition of OIE is wider, and includes both biological and economic consequences of an adverse event or effect to human as well as to animal health. Similarly, the IPPC definition includes the magnitude of potential economic consequences of the introduction and spread of a pest.

Risk analysis – Whereas in CAC approach hazard identification is included in the risk assessment phase, OIE considers hazard identification as a separate step preceding risk assessment. Both approaches, however, include the identification of hazard(s) and establishing whether further assessment is needed (see Figure 1). Without using those same terms, IPPC considers risk analysis as the process of evaluating evidence to determine whether an organism is a pest (i.e. risk assessment) and whether it should be regulated (i.e. risk management), and the strength of any phytosanitary measures to be taken (i.e. risk management). Furthermore, the evidence included by IPPC in the

definition covers both biological or other scientific evidence as well as economic evidence. Risk communication is not mentioned in the definition of IPPC.

Risk assessment – The CAC defines risk assessment as a scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterisation, (iii) exposure assessment, and (iv) risk characterisation. While different from the CAC definition, OIE and IPPC have similar definitions for risk assessment: evaluation of the likelihood/probability[5] of the introduction/entry/establishment/spread of a hazard/pest and the (biological and) economic consequences (see Figure 1). The IPPC further differentiates between quarantine and regulated non quarantine pests. Only CAC has definitions for both qualitative and quantitative risk assessment.

Exposure, entry, introduction, release, spread and establishment – In the risk assessment of CAC, exposure assessment covers the whole transmission route of a pathogen or relevant exposure path for a chemical or biological hazard. In the OIE procedure, release assessment is followed by exposure assessment (animals and humans exposed in a country), which highlights the different aspects involved in import risk assessment. However, in OIE and CAC approaches, the release and exposure route share many similar features. Due to the nature of pests, the IPPC has definitions for introduction (entry and establishment) and spread.

Consequence assessment – Both OIE and IPPC have definitions for or describe consequence assessment. For OIE, the consequences include adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The direct consequences include e.g. animal infection, disease and production losses as well as public health consequences. The indirect consequences include, e.g. surveillance, control and compensation costs, potential trade losses and adverse consequences to the environment. The IPPC has historically maintained that the adverse consequences (impact) of plant pests, including those concerning uncultivated/unmanaged plants, wild flora, habitats and ecosystems, are measured in direct or indirect economic terms. The CAC indicates that risk management, not risk assessment, should take into account the economic consequences.

Uncertainty – Addressing uncertainties in a structured way is relatively new in risk assessment. This is also reflected in the lack of established terminology relating to uncertainty in the latest CAC Procedural Manual or in OIE or IPPC glossaries. Definitions for some terms associated with uncertainty may be found in Microbiological Risk Assessment Series 3 (FAO/WHO, 2003) and 7 (FAO/WHO, 2008), including definitions for terms such as uncertainty (analysis), measurement uncertainty, model uncertainty, parameter uncertainty and process uncertainty.

The available CAC, OIE and IPPC guidelines are subject to modifications in the light of developments in the science of risk analysis. Short descriptions of several other organisations that have established lists of terms and definitions that may have relevance for EFSA risk assessment terminology can be found in Appendix A and are referred to in Table 2.

In order to allow EFSA to conduct and further co-develop risk assessment in the different areas, careful consideration of the risk assessment terminology is necessary and EFSA should remain vigilant to keep abreast of the periodical changes in risk methodology-related formulations and definitions.

[5] The Scientific Committee noted that the terms likelihood and probability are often used interchangeably (see for example FAO/WHO use of likelihood in table 1 under the term probability) and is aware that the word "Likelihood" has a specific meaning in a probabilistic context (see also chapter 6.5).

2.2. Use by EFSA's Panels of international methodologies and guidance documents defining risk terminology

In Regulation (EC) 178/2002, Article 3, the legislator has defined a number of risk related general terms (hazard, risk, risk analysis, risk assessment, risk management, risk communication). These basic definitions are similar to those provided by CAC with the only exception being the definition of "hazard" in which the term "feed" has been introduced. Whereas the European Community is held by the SPS Agreement of WTO to base its risk analysis approaches on either of the three accepted approaches (CAC, OIE, IPPC; see chapter 2.1), the European legislator does not dictate which of the three methodologies (and associated terminology) is to be used. However, should the major purpose of risk assessment be international trade, particular care must be taken that the principles of CAC, OIE or IPPC are followed strictly. Hence, for reasons of transparency, it would be advisable that the various EFSA Panels identify which specific approach is most useful in dealing with their specific mandates as was done, for instance, by the AHAW Panel that declared to adopt the CAC approach and related terms when addressing animal welfare issues (Smulders, 2009). Although there are differences in definitions between OIE and IPPC, their approaches for risk assessment are quite similar.

EFSA, according to its remit but differently from IPPC and OIE, does not take into account the economic consequences. However the PLH Panel does assess the impact in terms of other consequences, for example, for crop yield and the environment. Although the PLH Panel recognises the "Guidelines on pest risk analysis – Decision-support scheme for quarantine pests" (EPPO, 2011) as a possible option for conducting pest risk assessment and the identification and evaluation of pest risk management options, the scheme followed by EPPO (European and Mediterranean Plant Protection Organization) has been adapted for this purpose following the principles of independence and transparency (EFSA Panel on Plant Health, 2010).

The Scientific Committee is of the opinion that the Scientific Panels should ensure that the terminology used in their assessment is in alignment with that used by the relevant international standard-setting organisation for their sector.

It should also be noted that, in the absence of specific international initiatives and in line with its mission, EFSA has taken the lead in developing guidelines on the methodologies of (and specific terminology used in) animal welfare risk assessment (EFSA Panel on Animal Health and Welfare (AHAW), 2012). This was achieved by adapting CAC's risk analysis definitions (CAC, 1999) for this purpose (Ribó and Serratosa, 2009; Smulders, 2009).

Finally, in conducting risk assessment, it may become clear that certain new terms deemed necessary to analyse hazard or risk issues are missing or not defined clearly enough, or are unsuitable for the specific purpose. Should this be the case, it is necessary to include in a glossary a clear definition of what is understood by the term in the context of that EFSA scientific output. This is discussed further in section 6.

3. Consideration about Terminology and Terms of reference in EFSA mandates

Differences in approaches and terminology as defined by various risk analysis standards have also a significant impact on the terminology used by different EFSA Scientific Panels. Most of the Panels work within the area of CAC; OIE, although mainly focusing on animal health and welfare (therefore relevant to the AHAW Panel), provides also standardisation for zoonoses whereas IPPC standards form an important basis within the area of the PLH Panel (Figure 2).

Moreover, some Scientific Panels refer to general documents widely accepted by the international scientific community. Within EFSA, some Scientific Panels carried out environmental risk

assessment but cannot follow the international standard-setting organisations. Where considered necessary, some Panels have developed guidance documents that are focussed on particular aspects of the risk assessment specific for the mandate of the Panel.

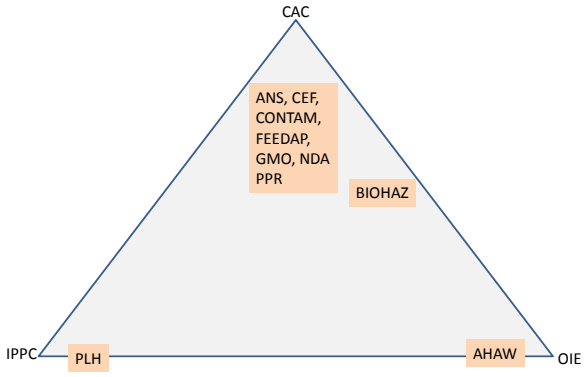

Figure 2: Relevance to the risk assessment activities of EFSA's Scientific Panels, of the three international standard-setting organisations (CAC, OIE and IPPC) listed in the SPS Agreement.

Furthermore, the Terms of Reference (ToR) received from the requestor (mainly the European Commission) also play an important role in defining the terminology used within a scientific output.

In addition to risk assessments of hazards introduced into or occurring in the food chain unintentionally (such as the risk caused by lead in foodstuffs or the risk caused by BSE in cattle), Scientific Panels can produce risk assessments on substances, products or processes intentionally added into or applied to food/feed (e.g. food/feed additives, GMOs or recycling processes). The latter type of risk assessment is often conducted as a safety assessment, which is designed to identify potential hazards of concern and, if it presents a hazard, to gather information on its nature and severity (CAC, 2003).

The basis for such safety assessment can often be found in the legislation; for example, article 6.1.(a) of Regulation (EC) N° 1333/2008 of the European Parliament and of the Council sets, as the general condition for inclusion and use of food additives in Community lists, that the food additive "does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer at the level of use proposed". Chapter II, article 4(b) of Regulation (EC) N° 1334/2008 of the European Parliament and of the Council sets, as the general condition for use of flavourings or food ingredients with flavouring properties, that "they do not, on the basis of the scientific evidence available, pose a safety risk to the health of the consumer". From a scientific point of view, the term "safety risk" is confusing because risk always contains a certain probability of harm. Furthermore, the Scientific Committee notes that absolute safety cannot be demonstrated on scientific grounds. IPCS defines safety as "the practical certainty that adverse effect will not result from exposure to an agent under defined circumstances" (IPCS, 2004). This definition implies that there might be a residual risk. The point at which this risk becomes acceptable is then a risk management decision.

Some of the general features of these two types of risk assessment carried out by EFSA's Scientific Panels are given below.

Risk assessments of hazards introduced into or occurring in the food chain unintentionally, common in AHAW, BIOHAZ, CONTAM and PLH Panels:

- Although these outputs are often supporting and developing the EU legislation, risk managers have considerable flexibility in formulating the ToRs depending on their needs.
- They often follow CAC, OIE or IPPC standards in their terminology.
- Risk is usually assessed for one main target population such as humans, pigs or cereals, which can be further sub-divided into sub-populations (e.g. children and adults, piglets or sows).
- The final outcome is an estimate of the risk composed of the probability and magnitude of the occurrence of an adverse event.

Risk assessment of substances, products or processes intentionally added into the food chain, common in ANS, CEF, FEEDAP, GMO, NDA and PPR Panels:

- Risk managers have hardly any flexibility in formulating the ToR since wording needs to be compatible with the sectoral legislation.
- The approach throughout the scientific opinion is linked with the specific sectoral legislation under which the EU authorisation is processed, whereas the legislation relevant for the different Panels does not usually include definitions for risk assessment terminology. Safety is often evaluated for multiple target populations such as consumers, animals, environment and/or occupational health.
- The final outcome concludes on the safety, i.e. the practical certainty that adverse effects will not result from exposure to an agent under defined circumstances.

Furthermore, it is to be noted that, within each of these risk assessment types, the approach used differs depending on the hazard being considered. For example, there are some differences between the approaches to chemical risk assessment (CRA) and microbiological risk assessment (MRA) in food. These differences are mostly explained by the different nature of the hazards and their adverse effects. In MRA most hazards are easily identified (e.g. *Salmonella*) and the adverse effects occur as a consequence of single exposure. The adverse effects are mostly acute (e.g. campylobacteriosis), although there are hazards that result in chronic effects (e.g. BSE/CJD) or complications (e.g. Guillain-Barré syndrome). In CRA, the hazards may result from long-term exposure to the substance through food and possibly other sources and the effects often have a more chronic course (e.g. cancer). Also in CRA, exceptions exist such as acute poisoning caused by for instance marine biotoxins. When it comes to exposure assessment, the level of exposure in MRA (i.e. the number of pathogens) is highly variable due to multiplication or inactivation of the pathogen through the food production chain. Exposure (i.e. dose) at the time of consumption is therefore difficult to estimate and typically requires complex mathematical modeling. In contrast in CRA, the level of exposure at the time of consumption is estimated based on food consumption data and stable levels of the hazards in the various food categories.

It should also be noted that the division between these two main types of risk assessment is not so clear-cut since many scientific outputs include several elements of both types of risk assessments. Therefore, defining the descriptors of risk assessment in a transparent and harmonised way is important for each scientific area (see chapter 6).

Specification of the outcome of interest often requires reference to multiple dimensions: for example a description of the type of adverse effect, combined with characterisation of its magnitude or severity, its duration and, where relevant (e.g. for environmental impacts), its spatial extent. The type of effect has to be described qualitatively, as precisely as possible (e.g. a specific type of health effect). To minimise ambiguity, other dimensions (e.g. severity or duration of that effect) should be expressed quantitatively when possible.

EFSA is sometimes also asked to evaluate the impact of various management options on risk. These options (such as heat treatment of import lot, vaccination of animals or post-authorisation environmental monitoring programs) are usually pre-listed by risk managers within the ToR, but EFSA Scientific Panels can also identify them based on scientific knowledge. In such evaluations, risk management options are described including whether the aim is to prevent or reduce the risk and how effective this would be (i.e. impact).

4. Existing terminology for expressing levels of risk

Terminology used by the EFSA Panels for expressing levels of risk is reviewed in Section 5. In this section we describe examples of scales of terms used by other authorities external to EFSA. Levels of risks may be expressed qualitatively (e.g. low, high etc.) or quantitatively. Scales of terms have been published to describe different levels of measures relevant for risk assessment, including levels of hazard, exposure, risk, probability or likelihood, uncertainty and evidence. Although the Scientific Committee did not make a comprehensive search, it appears that only a limited number of such scales have been published. Examples of these are presented in Table 2, together with some definitions.

Table 2. Examples of categories for different levels of risk, uncertainty and other risk assessment terms. Words used to describe the categories are shown in *italics.*

Term	Categories used to scale the term
Hazard	ECHA (2008, Part E): Hazard categories: *high*, *moderate*, *low* (these are further defined in detailed tables)
Exposure	FAO/WHO (2009): p. 38: Example definitions of exposure frequency: *negligible* (Indistinguishable from 0 exposures per year), *very low* (1–2/y), *low* (3-10/y), *medium* (10-20/y), *high* (20-50/y), *very high* (>50/y)
	ECHA (2008, Part E): Level of exposure: *1(occasionally), 2 (sometimes during the working days and for a short periods of time, 3 (several times during the working days for a short period of time), 4 (continuously; several times during the working day for prolonged periods of time).*
Risk	OGTR (2009): *negligible* (risk is insubstantial and there is no present need to invoke actions for mitigation), *low* (risk is minimal, but may invoke actions for mitigation beyond normal practices), *moderate* (risk is of marked concern that will necessitate actions for mitigation that need to be demonstrated as effective), *high* (risk is unacceptable unless actions for mitigation are highly feasible and effective)
	CONCAWE (2003): s*ignificant* (worthy of concern and/or remedial action), *insignificant risk level* [a measure of risk which has broad public or regulatory acceptance (e.g. via legislation)]
	FAO/WHO (2009): p. 34: Qualitative risk analysis matrix (likelihood vs. consequence): *low*, *moderate*, *high*, *very high*; p. 43/44: Segregation of risks into *low*, *medium* and *high* severities by severity scores
Probability	BfR (2010): Probability of occurrence of an event: *certain* (e.g. in more than 99 out of 100 cases or by a comparison with known probabilities), *probable*, *possible*, *improbable*, *practically impossible*; Frequency of adverse event: *often*, *occasionally*, *rarely*, *unknown to have occurred* (no definitions)
	OGTR (2009): *highly unlikely* (may occur only in very rare circumstances), *unlikely* (could occur in some circumstances), *likely* (could occur in many circumstances), *highly likely* (is expected to occur in most circumstances)
	IPCC (2010): Probability of outcome *very likely* = 90-100% (see also Table 4 of this document)
	Neutra et al. (2002): *strongly believe* = 90-98% probability
	FAO/WHO (2009): p. 34: Likelihood: *almost certain* (is expected to occur in most circumstances); *likely* (will probably occur in most circumstances); *possible* (might occur or should occur at some time); *unlikely* (could occur at some time); *rare* (may occur only in exceptional circumstances); p.38: Example definitions of probability (probability range; probability of event per year): *negligible* (indistinguishable from 0), *very low* (< 10^{-4}, except 0), *low* (10^{-3} to 10^{-4}), *medium* (10^{-2} to 10^{-3}), *high* (10^{-1} to 10^{-2}), *very high* (> 10^{-1}, not 1), *certain* (1)
	ECHA (2008, Part E): *probable*, *low probability*
Uncertainty	IPCC (2010): confidence *very low, low, medium, high, very high*; validity of a finding is evaluated both in terms of evidence and the degree of agreement (*low*, *medium*, *high*), which together contribute to the scale of confidence
	IPCS (2008, Fig. 7, p. 41): *low* (known outcomes and known distributions), *medium* (known outcomes and unknown distributions), *high* (unknown outcomes and unknown distributions)
	FAO/WHO (2009): p. 45: Expressing uncertainty about a risk category (impact vs. events per year)

	ECHA (2008, Chapter R.19): Magnitude: *low*, *medium*, *high* (smallest to largest contributors or defined with reference to the estimated variation of the risk outcome in terms e.g. of orders of magnitude); Direction: *low*, *moderate* and *high* over/underestimate
Evidence	BfR (2010): Evidence of risk: *generally recognised proof* (causality verified and accepted by the scientific community)
	IPCC (2010): *limited, medium, robust* ("Generally, evidence is most robust when there are multiple, consistent independent lines of high-quality evidence")
	IPCS (2008): Scientific backing *extended, independent, none* (no definitions)
	(IARC 2006): *sufficient* (causal relation established)
	(GRADE 2008): *high quality* (further research is very unlikely to change confidence in estimate of effect)
	FAO/WHO (2009): p. 84: Sensitivity analysis: In examining an association between an agent and a putative adverse health effect, widely accepted criteria (e.g. Hill's Criteria) have been established for determining whether the evidence is *weak, moderate* or *compelling* (reference to e.g. Tomatis, IARC 1990)
	ECHA (2008, Chapter R.4): Reliability of information: *1* (reliable without restrictions), *2* (reliable with restrictions), *3* (not reliable), *4* (not assignable)

Considering these examples and the documents they derive from, the Scientific Committee makes the following observations.

1. Some of the terms listed in Table 2 are accompanied by definitions in the source documents (e.g. the exposure terms from FAO/WHO (2009)), but many are not (e.g. terms for probability and frequency from BfR (2010)). Where no definitions are provided, the meaning of the terms is ambiguous, i.e. could be interpreted in different ways by different people and in different context.
2. Verbal definitions help in clarifying the meaning of verbal terms but only partially reduce their ambiguity.
3. Since risk is the probability of an adverse effect, to be complete, descriptions of consequences often need multiple dimensions, e.g. the severity and duration of an impact and, where relevant, its spatial extent.
4. Where quantitative definitions can be provided, their meaning is unambiguous (e.g. IPCC terms for probability in Table 4; IPCC, 2010).
5. The Office of the Gene Technology Regulator of Australian government (OGTR) and the Oil Companies' European Association for Environment, Health and Safety in Refining and Distribution (CONCAWE) definitions of level of risk shown in Table 2 include references to the need for concern or mitigation and, therefore, imply a risk management judgment.
6. Some of the examples shown under "probability" in Table 2 relate to the frequency of repeated events or outcomes (e.g. often, occasional, some/many circumstances). Two examples refer to the likelihood of a single event or outcome (probability of event, probability of outcome). One example uses probabilities to express the assessor's subjective degree of belief about risk questions (Neutra et al., 2002). It is important always to define in which sense probability is being used, as this will affect its interpretation.
7. The examples of terms for uncertainty in Table 2 are both ambiguous, and open to varying interpretations. An earlier version of the IPCC guidance (IPCC, 2005) defined terms for confidence in terms of the chance of a statement being correct (e.g. high confidence = about 8 out of 10 chance), which is a form of probability statement.
8. All the examples of terms for level of evidence in Table 2 are verbal, and open to varying interpretations.

These observations are taken into account when developing recommendations for the use of harmonised terms by EFSA (see section 6).

5. Comments on the Food and Environmental Research Agency (FERA) report

5.1. Summary of the FERA report

EFSA commissioned the Food and Environmental Research Agency (FERA) of UK to undertake a review of the terminology employed to express risk and uncertainty in the assessments issued by the EFSA Scientific Committee and Panels. This action followed a previous research on reviewing the terminology employed by the European Union non-food scientific committees in a project commissioned by the European Commission in 2007 (Hart et al., 2007).

The FERA report is based on a comparative review of terms (or combination of terms) of expression of risk and/or uncertainties in particular sections, i.e. abstract, summary, concluding sections and conclusions, of 219 opinions issued by the EFSA Scientific Committee and Scientific Panels as published in 2008, 2009 and in the beginning of 2010. The purpose of the work was also to recommend possible ways of improving the expression and communication of risk and/or uncertainties within the scope of published opinions by the EFSA Scientific Committee and by the Scientific Panels.

In the review a number of quantitative or qualitative descriptors employed to describe or characterise risk, benefit, efficacy, and/or uncertainties was identified by FERA. In order to facilitate the analysis of the findings, a database (in Microsoft Access 2007) was constructed in which all identified qualitative and quantitative descriptors were recorded.

The analysis demonstrated a number of similarities and differences in approaches used for the expression of risk, benefit, efficacy, and/or uncertainty either within a published opinion (i.e. between different sections of the opinion), or among opinions produced by the EFSA Scientific Committee and Panels.

FERA identified a wide range of verbal expressions employed to describe benefit, efficacy, risk and/or uncertainty. The great majority of the identified descriptors (3557/3888) in the database were qualitative. A large number of the most commonly employed descriptors appeared to be specific to each scientific body of EFSA (i.e. the Scientific Committee or the Panels).

Only a small number (331/3888) of quantitative descriptors were identified. FERA indicated that this result does not imply that quantitative measures were absent from the assessments included in their research. Based on this observation FERA recommended that employing quantitative measures of benefit, efficacy, risk and/or uncertainty, if these are already part of an assessment, could be a way towards harmonising communication messages in the documents produced by EFSA Scientific Committee and the Scientific Panels.

The FERA report also stated that in cases where only qualitative assessments are performed, it could be suggested to convert qualitative messages into quantitative ones following the approach pioneered by the Intergovernmental Panel for Climate Change (IPCC, 2007).

In addition, the FERA report recommended that to improve the precision of verbal expressions of benefit, or efficacy, risk and/or uncertainties, the creation in each document of a glossary of the qualitative terms and the indication of some type (not necessarily numerical) of boundaries for each of these terms is suggested. FERA suggested that these glossaries could be either specific to each EFSA Panel, to accommodate for the individuality of the types of benefit, or efficacy or risk assessed by each Panel, or be more generic.

The FERA report indicated that, in any case, the employment of such glossaries could improve the communication of the assessments' outputs to risk managers and the public. The report also concluded that such glossaries could offer a basis towards harmonising the approaches to be followed to address

the challenges associated with the employment of verbal expressions for communicating assessment outputs.

FERA further concluded that their analyses indicated that only in a small number of qualitative descriptors (161/3557) uncertainty was perceived to have been conveyed intentionally, and that the terms "uncertain" or "uncertainty" or "uncertainties" were cited directly only in a small number of the phrases that were included in the database (212/3888). Additionally, it was found that clearly defined sections dedicated to a type of uncertainty analysis were included only in a minority of the documents reviewed (30/219).

FERA concluded that their findings indicated that the consistency in approaches employed by the EFSA Scientific Committee and Scientific Panels to communicate uncertainties in their assessments can be improved, for example, by employing structured, systematic ways to analyse uncertainties. The FERA report indicated that such structured approaches (e.g. the uncertainty tables approach described in EFSA 2006 b) were employed in a very small number of the documents reviewed (4/219). The FERA report concluded that the uncertainty tables approach comprises a user-friendly communication tool that allows the reader to navigate quickly and efficiently though uncertainties considered, and provides essential information on how a particular conclusion or decision was made, thereby increasing confidence in the conclusions. The report recommends that wider employment of similar types of uncertainty analysis in the assessments produced by EFSA Scientific Panels could be a further step towards harmonisation.

5.2. Scientific Panels consultation on the FERA report

As a follow-up of the FERA report, Panels were asked for their views and comments on this report. This section provides an overview of the views collected.

5.2.1. General comments and definitions of terminology

The general view expressed by the Scientific Panels was that the FERA report provides an exhaustive comparative review of terms and expressions of risk and/or uncertainties in the reviewed EFSA opinions and statements. Several Scientific Panels indicated that the report illustrates that there is a need for further action to provide more precise and concrete proposals on how to harmonise and improve risk assessment terminology.

The Scientific Panels, however, also stressed that the peculiarity of the work within their specific fields of risk assessment may necessarily create different ways to express concepts. This should be acknowledged and taken into account when suggesting ways for harmonising risk assessment terminology. It was also noted that in some fields the use of risk assessment terminology is directed by legal mandates and regulations.

Most Scientific Panels indicated that they have established list of abbreviations and/or glossaries with definitions. Though a useful tool, the Scientific Panels suggested that it might prove difficult to establish a common glossary that fits all Scientific Panels.

Risk terminology may be described in Guidance documents for the relevant fields, but these different Guidance documents may not necessarily be harmonised between sectors and are often based on different legislation or Guidelines from other organisations in the relevant field.

5.2.2. Use of the language from Terms of Reference (ToR) when drafting conclusions

Several Scientific Panels indicated that usually the wording of the ToR is used to draft conclusions. This may cause differences in risk assessment terminology used in opinions especially when drafting conclusions since wording of ToR may reflect terminology in the sector legislation rather than the international standards for risk assessment terminology. Another issue to take into account may be that

a ToR may not always fully respect the boundaries between risk assessment and risk management. Clarification of the ToR may sometimes be needed.

5.3. Considerations by the EFSA Scientific Committee

Based on the FERA report and on the comments provided by the different Scientific Panels, the Scientific Committee concludes that risk assessment terminology is not fully harmonised within EFSA. This is in part caused by Regulations defining specific terminology and international standards for specific fields of risk assessment and thus specific Scientific Panels.
The Scientific Committee considers that within EFSA, there are three levels at which harmonisation of terminology applies. These are harmonisation i) within an opinion (e.g. consistent use of terms in abstract, summary and conclusions), ii) between different opinions of the same Panel (e.g. consistent use of terminology for duration, spatial extent, magnitude or severity of adverse effect) and, and iii) across EFSA Scientific Panels. Concerning point iii), explaining terms and clearly explaining differences between terms in different fields of risk assessment may help to overcome some of the problems.

The Scientific Committee also notes that FERA recommended that employing quantitative measures of benefit, efficacy, risk and/or uncertainty, if these are already part of an assessment, can be a way towards harmonising communication messages in the documents produced by the EFSA Scientific Committee and Scientific Panels. The report also recommends that wider employment of similar terms for expressing uncertainty in the assessments produced by the EFSA Scientific Committee and Scientific Panels could be a further step towards harmonisation. The Scientific Committee considers these to be valuable recommendations. The FERA report recommended that every opinion should include a separate section on uncertainties, to encourage an appropriate level of consideration of uncertainties (consistent with earlier Scientific Committee opinions, EFSA 2006b and 2009) and to ensure that information on uncertainty is readily found by readers of the opinion. The Scientific Committee is of the view that expressing uncertainties in a substantive and clear manner will contribute to the harmonisation of risk assessment terminology. However, additional work is necessary to develop a more harmonised approach to quantitative expression of uncertainties.

A social science analysis of the uncertainty framework proposed by the UK Committee on toxicity suggested that all people including experts were not good at understanding and using uncertainty estimate of verbal or numerical form but that the context in which an uncertainty is expressed plays an important role in how people understand terms (Rowe 2010).

In addition, the FERA report recommended the inclusion in each document of a glossary of the qualitative terms and the indication of some type (not necessarily numerical) of boundaries for each of these terms. FERA suggested that these glossaries could be either specific to each EFSA Scientific Panel, to accommodate the individuality of the types of benefit, or efficacy or risk assessed by each Panel, or be more generic. The Scientific Committee considers this a useful recommendation and this is discussed further in section 6.7. An example of a glossary is given in Appendix B.

6. Development of a harmonise approach to risk assessment terminology in Efsa

6.1. Definition of risk

Before discussing terminology for different levels of risk, it is necessary to clarify the concept of risk itself. The Regulation EC 178/2002 defines risk as “a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard”. For some areas of EFSA’s work, different definitions have been established in legislation or by relevant international authorities (CAC, OIE and IPPC, see Table 1). EFSA is dealing with environmental risk assessment which is not health-related. Hence it is unrealistic to attempt to establish a single definition of “risk” throughout EFSA’s work. Nevertheless, it would be valuable to achieve more consistency in those areas where the definition of risk is not prescribed externally.

Although they differ in detail, most definitions of risk have a common core – that risk is the probability of an adverse outcome. It follows that expressions of risk should comprise a specification of the outcome of interest, and an expression of its probability. Both should be expressed as clearly and unambiguously as possible, to facilitate clear understanding by risk managers and stakeholders.

Many outcomes of EFSA's risk assessments do not include explicit reference to probability although quantitative expressions are used such as, for example, a margin of exposure (MOE) and margin of safety (MOS) or the ratio of exposure to toxicity as, for example, the ratio of predicted environmental concentration to predicted no-effect concentration (PEC/PNEC).

Considering the complexity of specifying the outcome of interest, the Scientific Committee concludes that it is essential to define clearly, within each EFSA output, each measure or expression of risk that is used (see chapter 3).

6.2. Terms for expressing levels of risk

When expressing the level of a risk, it is necessary to refer to each of the dimensions included or implied in the definition of that risk. Often, some of the dimensions will be determined in advance, e.g. the time scale (acute, chronic) and spatial scale. Other dimensions (e.g. the frequency of effects) will be estimated in the assessment, and need to be expressed on a suitable scale.

It is important to ensure that the form of expression is unambiguous, to avoid it being interpreted in different ways by different people. Ambiguity may be reduced by using quantitative expressions for the level of risk or by using verbal terms with quantitative definitions. However, verbal definitions only transfer the ambiguity from one phrase to another. The advantages and disadvantages of verbal and quantitative expressions are discussed in more detail in section 6.4.

In some areas, defined verbal terms are prescribed for expressing levels of risk, e.g. by legislation or international convention. In some cases these terms imply or suggest a risk management interpretation (e.g. "safe", "high risk", etc.). The risk management meaning of such terms is sometimes specific to their context. For example, the phrase "low concern" is interpreted as implying a need for risk management action when applied to a food additive, but not when applied to an environmental contaminant. Where terms such as these are used, it is important that they are defined so that their meaning is unambiguous and can be used by risk assessors without requiring them to make risk management judgments.

Sometimes Panels are asked to assess changes in risk that would result from specified risk management option. In such situations it is again important to define clearly any terms used to express the change in level of risk.

6.3. Expressing uncertainty

There is increasing recognition of the need to express clarly the level of uncertainty.. The CAC Working Principles for Risk Analysis state "*Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable*" (CAC, 2011).

Some EFSA opinions, for example those on pig welfare, have used a defined ordinal scale comprising low, medium or high uncertainty: for example, low uncertainty is defined as "solid and complete data available; strong evidence provided in multiple references; authors report similar conclusions" (Smulders, 2009). In risk assessment schemes for pest risk analysis (PLH, 2010), users are required to express their uncertainty in three categories (low, medium and high), which are not further defined. These approaches provide a relative measure of the degree of uncertainty.

It is essential to describe uncertainties affecting a risk assessment, but this alone is not enough. Risk assessors also need to characterise the impact of uncertainty on the assessment outcome. This

information is needed by risk managers as they have responsibility for resolving the impact of uncertainty on the risk management decision (CAC, 2011).

Uncertainty and risk can be expressed either qualitatively or quantitatively. Using verbal terms such as "conservative estimate" or "unlikely" are ambiguous, and open to differing interpretations by different people. This problem can be reduced by using verbal expressions with quantitative definitions, although care is required to avoid the verbal terms being interpreted as carrying risk management overtones.

6.4. Advantages and disadvantages of quantitative and qualitative expressions

Until now, the large majority of expressions of risk and uncertainty in EFSA opinions have been qualitative or verbal, and quantitative expressions are rare (FERA, 2010). The same is true of opinions of the non-food scientific committees of the EU (Hart et al., 2007). The most commonly found terms of qualitative expression in EFSA opinions are listed in Table 3.

Table 3. Most frequently used qualitative descriptors for risk and uncertainty in EFSA Scientific Panels, and the number of instances these terms are used in 219 EFSA opinions published in the period from 2008 to early 2010 (for a complete dataset, see table 6 of the FERA report, 2010).

Term	No. of instances
Low	62
High	61
Safe	36
Very low	35
Moderate	29
Unlikely adverse effects / Unlikely to have any adverse effects	27
Negligible / Negligibly	26
Higher	26
No safety concern(s)	23
Increases / Increased / Increasing / would increase	22
As safe as (...)	20
Below (endpoint or limit of detection)	17
Moderate to high	15
Does not raise safety concern(s) / Do not raise safety concern(s) / Did not raise safety concern(s)	15
Very unlikely	14
Unlikely	12
Highest	11
Conservative	11
Below the threshold of concern	11
Potential for establishment and spread	11
Relatively low	10

Verbal expressions are inherently ambiguous. This is recognised by FAO/WHO (2009, section 3.2.3), which states "*For a qualitative description of a risk to be useful to a risk manager, the assessor and manager must have similar perceptions of the meaning of subjective terms such as "low", "negligible", etc., or other descriptors. A final risk characterization label, e.g. "low", is largely meaningless to a risk manager without some sort of indication of what constitutes "low" in the eyes of the author of the report*". There is a substantial body of scientific literature showing that people differ widely in how they interpret verbal representations of probability. Based on a meta-analysis of ten such studies, Theil (2002) concludes "*there is no consensus about probability translations*".

Therefore, qualitative terms that have no quantitative definition will be interpreted differently by different people. This implies that members of a Scientific Panel may agree on a verbal expression even though their assessment of the risk or uncertainty is different; different Scientific Panels might use the same verbal term to express different levels of risk or uncertainty; risk managers may interpret a verbal expression in a different way than a Scientific Panel intended; the same expression may be interpreted in different ways by different decision-makers, leading to inconsistencies in decision-making; and the same expression will be interpreted in different ways by different stakeholders and members of the public.

Quantitative expressions of risk and uncertainty have two fundamental advantages over verbal expressions: they are less ambiguous and avoid implying risk management judgments.

On the other hand, there are potential disadvantages to quantitative expression of risk and uncertainty, which must be addressed. It is often argued that quantitative expressions can give an exaggerated sense of precision, and some research suggests that people's willingness to use quantitative terms depends on the precision of the available data (Wallsten et al., 1993). However, this argument should not apply if the resulting uncertainty is clearly communicated, as required by risk managers (e.g. CAC, 2011) and intended by EFSA (2006a, 2009). An important way of doing this is to give ranges for quantitative expressions, rather than single values. The width of the range can then be used to express the degree of uncertainty or imprecision.

There is evidence that both numerical and verbal expressions of probability are prone to biased interpretation. Smits and Hoorens (2005) found an optimistic bias in the interpretation of verbal chance terms relating to the subject's own future, while Teigen and Brun (2000) found that the same numerical probability may sometimes be perceived as positive and sometimes as negative, but biased towards a favourable interpretation and dependent on context. As these tendencies to interpretational bias seem to apply to both verbal and quantitative expressions, risk managers need to be aware of them and try to avoid introducing them in their deliberations.

Several studies have shown that people, including experts and decision-makers, prefer to use verbal phrases rather than numerical probabilities when communicating uncertainty. However, the same studies show that the same groups prefer to receive information on uncertainty numerically (e.g. Erev and Cohen, 1990; Fillenbaum et al., 1991; Wallsten et al., 1993).

A potential concern is that requiring quantitative expressions may cause assessors to introduce arbitrary judgments into their assessments. However, this should not occur, because assessors should give the same level of care and consideration to making and expressing their judgments quantitatively as they currently apply to choosing qualitative expressions. The chance of arbitrary judgments should be further decreased if assessors use a systematic approach, such as the tabular approach for evaluating uncertainty, as described by EFSA (2006). There may be a perception that assessors are being asked to quantify the unquantifiable, or to convert "unknown unknowns" into "known unknowns". This should certainly be avoided.

In conclusion, the Scientific Committee recommends that Panels, in order to facilitate further harmonisation of risk assessment terminology, work towards more quantitative expressions of risk and uncertainty. The basis of each quantitative expression should be made clear, to avoid approximate estimates being wrongly interpreted as precise estimates. Where quantitative expressions are not feasible, then consistent, well-defined, qualitative terms should be used. The Scientific Committee also recommends that further guidance be developed on approaches for both qualitative and quantitative expression of risk and uncertainty. Consideration should be given to intensify communication between EFSA and risk managers to enhance mutual understanding of the risk expressions and raise awareness of the potential for interpretational bias. In cases where the assessor believes the available evidence will not support a quantitative expression, the assessor should consider whether it really supports a qualitative expression and, if so, ensure that this is expressed in verbal terms that convey the conclusion as unambiguously as possible.

6.5. Harmonised definitions for expressing levels of risk and uncertainty

The Scientific Committee considered whether it might be useful to establish lists of defined terms for harmonised use by EFSA and its Scientific Panels. The former Scientific Steering Committee of the European Commission recommended developing *'a short list of descriptive terms for the expression of levels and likelihood of risk'* (SSC, 2003, page 93). In fact, it is likely that multiple lists would be required, because EFSA's Panels assess risk for many different types of outcomes (e.g. different types of health effects). Therefore, if such lists were considered useful, they would probably be specific to the needs of particular Panels.

In some cases, the legislation served by Panel opinions includes phrases expressing the level of safety that is required, or the level of risk that is acceptable. For example, Article 6 of Regulation (EC) No. 1333/2008[6] states that a food additive may be included in the Community lists in Annexes II and III to the Regulation only if, among other requirements, "*it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer at the level of use proposed"*. Where such requirements are included in legislation, it is likely to be helpful to risk managers if Panels express their conclusions in the same language. In the example above, this would mean expressing risk in terms of whether or not there is a safety concern, as is often done by for example the ANS and CEF Panels. The Scientific Committee considers it essential to establish unambiguous definitions for such phrases, both for transparency and to make it possible to assess them scientifically. Furthermore, because they carry risk management implications (e.g. eligibility for listing in Annexes II and III of Regulation (EC) No. 1333/2008), it is essential that the definitions are established in consultation with risk managers.

Although the outcomes for which risk is assessed differ between Panels, expression of probability is relevant to all Scientific Panels, so for this a common harmonised scale might be feasible. Tavana et al. (1997) showed that within a restricted group in the same profession (30 financial analysts in a single company) it was possible to develop and use an agreed set of verbal probability terms. This suggests that it might be possible to establish a harmonised scale for probability for use by EFSA and its Panels. An example of such a scale is the likelihood scale used by the Intergovernmental Panel on Climate Change (IPCC, 2005, 2010) shown in Table 4.

Table 4. Example of a harmonised list of probability terms, used by the Intergovernmental Panel on Climate Change (IPCC) to express the likelihood of an outcome occurring. Note that although expressed differently, the 2005 and 2010 definitions are equivalent and, in both cases, the probability ranges for different terms overlap (e.g. likely and very likely).

Term	IPCC (2005)	IPCC (2010)
Virtually certain	> 99% probability	99-100% probability
Very likely	> 90% probability	90-100% probability
Likely	> 66% probability	66-100% probability
About as likely as not	33 to 66% probability	33 to 66% probability
Unlikely	< 33% probability	0-33% probability
Very unlikely	< 10% probability	0-10% probability
Exceptionally unlikely	< 1% probability	0-1% probability

[6] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008)

The Scientific Committee noted that the IPCC scale is not suitable for expressing frequencies of adverse health effects, as this may require discrimination of probabilities much smaller than 1% (e.g. cancer risk). Moreover, if a harmonised scale is developed for use across EFSA, careful consideration should be given to the choice of terms, their underlying criteria, the definition of the probability ranges, and their applicability to the work of different Scientific Panels.

IPCC (2010) state that the scale reproduced in Table 4 should only be used for situations where there is robust evidence and/or high agreement, and propose more qualitative verbal expressions where evidence or agreement are weaker. In contrast, a report of the US Climate Change Science Program (CCSP, 2009, page 21) argues that expressions using subjective (numeric) probabilities can be appropriate for any level of evidence, agreement or uncertainty, while retaining the axioms of probability. This is an issue that would need to be considered if a scale similar to the example in Table 4 is developed for use of the EFSA Scientific Committee and Panels.

One potential concern about using the word "likely" in harmonised terms is the potential for confusion with colloquial use of the word "likely"[7]. The risk of confusion could be reduced by capitalising the terms when used with the defined meanings and by always presenting the term together with its defined quantitative meaning in parentheses, e.g. "Likely (>66% probability)", which will also be helpful for readers unfamiliar with the definitions. Another option would be to base the harmonised terms on the word "probable" or "probability" instead of "likely", as they are less commonly used colloquially in EFSA opinions (FERA, 2010).

Another potential concern about adopting defined verbal terms for probability is the possibility that terms such as "very likely" (or "unlikely") might be interpreted as implying an expectation that risk management action is needed (or not). Presenting the numerical definition immediately adjacent to every use of the defined verbal term should help to avoid readers interpreting the terms as expectations for risk management. Similar precautions should be applied to any scales of defined terms that might be established by individual Panels.

In conclusion, the Scientific Committee recommends that a set of harmonised terms for expressing levels of risk and uncertainty, where possible, in EFSA opinions be developed. Finally, the Scientific Committee emphasises that all expressions of risk and uncertainty, in whatever form, should be accompanied by a summary of the evidence on which they are based, and that a full evaluation of the evidence should be included in the main body of the opinion (EFSA, 2009).

6.6. Key statements in the abstract, summary and conclusions of the scientific outputs

The Scientific Committee noted that the report made by FERA includes a tabular presentation of the number of times a specific descriptive term was encountered in either the Abstract (A), Summary (S) or Conclusion (C) sections of the reviewed documents[8]. This table in the FERA report also shows how often a term was used in the abstract and summary (A&S) sections or in all three (A&S&C) sections of the opinion analysed. From this overview it is evident that a specific descriptor used in 70 abstracts was also used in 37 summary sections (A&S) but in only 29 opinions was the same specific descriptor used in all three sections (A&S&C).

This indicates that the same risk assessment terminology does not seem to be fully harmonised between these three important sections of a document. The Scientific Committee noted that there can be good reasons why Scientific Panels chose not to repeat the same description when formulating the different sections of the opinions, for example, word limitation for abstracts. However, given the possibilities for different interpretation of different risk assessment terminologies by different readers, the Scientific Committee considers that a more harmonised strategy in risk assessment terminology,

[7] See footnote 5 in section 2.
[8] Table 3, page 30 of FERA 2010 (http://www.efsa.europa.eu/en/supporting/pub/101e.htm)

reducing potential ambiguity, is for the Scientific Panels to use the same wording for the essential conclusion on the risk or safety assessment in the different sections in the opinion. This first level of harmonisation would be most easily achievable and should become best practice to be included in EFSA's standard operating procedures.

6.7. The use of glossaries to further the harmonisation of terminology in EFSA

In 2009 the Scientific Committee stated that establishing a "central" (universal) glossary for EFSA with contributions from its scientific Panels would be desirable (EFSA, 2009). However, in commenting on the FERA report, the Scientific Panels, while confirming the usefulness and desirability of glossaries in general, questioned the feasibility of constituting a universal glossary serving all Scientific Panels equally well. While there are some generally applicable terms used in the terminology of risk assessment and uncertainty, their precise interpretation may vary slightly according to the discipline or context of a specific Scientific Panel.

These issues may be illustrated by considering an example, the term "dose-response relationship". IPCS (2004) have proposed a harmonised definition for this term: "*Relationship between the amount of an agent administered to, taken up by, or absorbed by an organism, system, or (sub)population and the change developed in that organism, system, or (sub)population in reaction to the agent"*. Although developed in the context of chemical hazard and risk assessment, this definition is constructed broadly enough to cover uses of the term in other fields including microbiological and GM risks, although it may be less well suited for use in the area of animal welfare. However, the broad wording that makes the definition widely applicable, also limits its usefulness for communication, especially with less technical audiences. Such a definition would be of limited help to readers if included in the glossary of an opinion on a particular risk, where it would be preferable to use a more readily understandable definition of "dose-response relationship", more specific to the hazard under assessment.

This example suggests a need for two types of definition: general and specific. The purpose of a specific definition would be to provide an explanation of the specific meaning of a term in the context of a particular opinion, and would be included in the glossary to that opinion. The purpose of a general definition would be to help avoid conflicts between the specific definitions used by different Scientific Panels, by providing a broad umbrella definition. Although not providing a fully harmonised terminology, this approach is a practical compromise that should ensure that the use of the same term by different Scientific Panels is not contradictory, while maintaining effective communication by allowing specific definitions to vary according to the needs of particular contexts.

The FERA report recommended the creation in each document of a glossary of the qualitative terms and the indication of some type (not necessarily numerical) of boundaries for each of these terms. FERA suggested that these glossaries could be either specific to each EFSA Scientific Panel, to accommodate for the individuality of the types of risk assessed by each Panel, or be more generic. The Scientific Committee agrees that the development of a glossary of risk assessment terms would facilitate harmonisation within EFSA and notes that the development of such a glossary would also facilitate transparency (EFSA, 2009). Figure 3 shows how the collation of definitions of key risk assessment terms from sectoral legislation can be combined with the establishment of glossaries discussed above. Every single opinion/report should include a specific "stand alone" glossary, i.e. with definitions of both technical (scientific discipline-specific) as well as risk assessment terms, but addressing only terms used in that opinion or report. These glossaries should be based on and feed into a single, centralised EFSA glossary of general definitions of technical and risk assessment terms used by multiple activities of EFSA Scientific Panels (section 6.7). It is suggested that this centralised EFSA glossary should have a unique name as for example "risk assessment terminology database" to avoid confusion with other "glossaries". To avoid any further confusion and to maintain consistency, any other initiative within EFSA to develop risk assessment terminology database/glossary should feed out of the central glossary (see Figure 3) and not be independently developed.

The resultant central database of definitions can be used as starting point to further harmonise terminology within and between Scientific Panels across EFSA. This should be addressed during the next Scientific Panel mandates and be included in their operating guidance. When completed, this database should also contribute to collaborative international work to improve the harmonisation of risk assessment terminology.

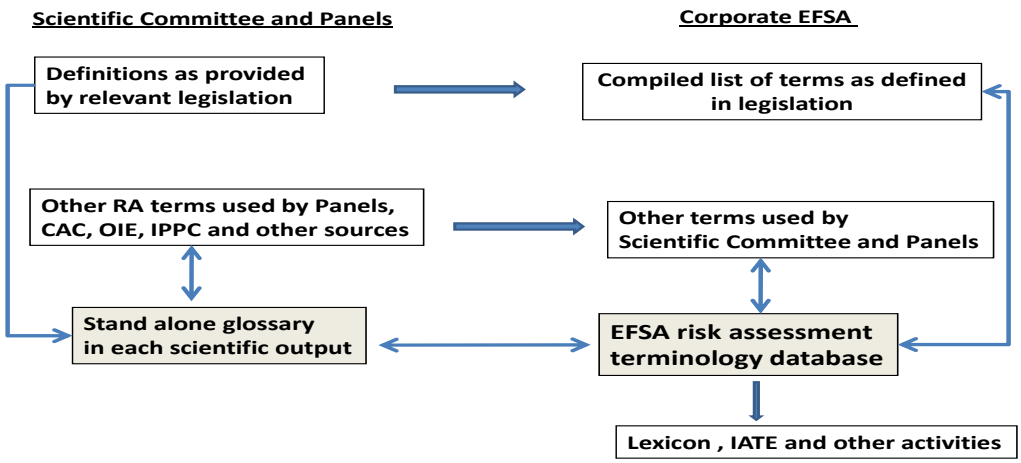

Figure 3: Compilation of definitions of risk assessment terms for use by the Scientific Committee and Scientific Panels and Corporate EFSA.

The Scientific Committee is aware of other ongoing EFSA activities such as the "Lexicon Project" that has been initiated by EFSA's Communications Directorate in collaboration with the Advisory Forum's Communications Working Group (AFCWG). This joint initiative with communication representatives from each of the National Competent Authorities, aims to foster understanding of risk assessment work through the simplification of complex scientific terms while remaining true to their meaning; explaining references and measures to add greater meaning to the work of risk assessors. The project also aims to enhance consistent and coherent communications throughout the EU through the use of harmonised terminology and layman explanations to reduce potential confusion and mixed messages. The Scientific Committee recommends that ongoing EFSA's activities such as the Lexicon Project should be consistent with the proposed risk assesssment terminology database

CONCLUSIONS AND RECOMMENDATIONS

EFSA's founding regulation (EC 178/2002) tasks EFSA with risk assessment and risk communication. Transparency, unambiguity and consistency of terminology are key requirements to improve the clarity of the risk assessment messages to consumers, risk managers and the international food safety community. In this context, the Scientific Committee encourages the principle of harmonisation of terminology wherever possible but recognises the limitations to the extent to which this is feasible or desirable. The Scientific Committee concludes that it is important that the use of harmonised terminology be further developed and encouraged across the risk assessments carried out by the Scientific Panels within EFSA whenever possible.

The Scientific Committee concludes that the FERA report provided a comparative review of the terms and expressions of risk and uncertainty in the sample of EFSA opinions and statements published by EFSA's Scientific Committee and Scientific Panels. Overall it may be concluded that the FERA report

illustrates that risk assessment terminology is not yet fully harmonised across EFSA. However, the Scientific Committee recognised that full harmonisation of risk assessment terminology across EFSA is limited by differences in the existing legislation within the specific fields of the different Scientific Panels.
The Scientific Committee acknowledges that legislation and ToRs may both influence the use of terminology but concludes that key risk assessment terms used should always be defined in the respective EFSA opinions.

The Scientific Committee is aware that the risk assessment approaches of standard-setting organisations CAC, OIE and IPPC are not harmonised.. As a consequence, full harmonisation of terminology within EFSA would not be a feasible, since the chosen risk assessment approach should be the best one to address each risk assessment question. It is unlikely that one approach would fit to all types of situations. However, increased harmonisation, especially within the same field of science, would increase the quality as well as the usability of risk assessment outputs.

An internal survey of EFSA's current procedures and the key legislative documents used by individual EFSA Scientific Panels revealed that most referenced/source documents for each sector do not include definitions of the specific terms used in risk assessment. Where the referenced/source documents for each sector do not include definitions of the specific risk assessment terms, the Scientific Committee recommends for consistency that Scientific Panels use the definitions given in the founding regulation or by CAC, OIE or IPPC, unless there is specific justification not to do so. The Scientific Committee also stresses that the peculiarity of the work within specific fields of risk assessment may necessarily create different ways to express concepts. This should be taken into account when suggesting ways for harmonising risk assessment terminology.

EFSA should play an active role in harmonising risk assessment terminology and should focus not only on harmonisation within EFSA, but also engage with the international scientific community in this activity. EFSA should collaborate with international standard-setting organisations involved in defining risk assessment terminology, including the CAC of the FAO/WHO, the OIE, and/or the relevant international and regional organizations operating within the framework of the IPPC.

RECOMMENDATIONS

The Scientific Committee recommends that:

1) EFSA should be actively involved in harmonising risk assessment terminology where possible, and to that end should collaborate actively with international standard-setting organisations.
2) Further guidance on the harmonisation of risk assessment terminology within EFSA should be developed.
3) Three levels for harmonisation of terminology should be considered in EFSA:
    a. Within each scientific opinion. EFSA secretariats and the Scientific Committee and Scientific Panel(s) should ensure that the risk assessment terminology used is consistent within abstract, summary and conclusions on risk.
    b. Each Panel should ensure consistent use of risk assessment terminology across its opinions within the same scientific area.
    c. EFSA should take necessary measures to ensure better (or improved) harmonisation of risk assessment terminology across EFSA.
4) EFSA should develop a stepwise approach to implement harmonisation at these three levels. Harmonisation at the first level (within each scientific opinion) would be most easily achievable and the Scientific Committee recommends that this should become best practice and be included in EFSA's standard operating procedures as soon as possible.

5) A short-term action that would facilitate each of the three levels of harmonisation would be the development of a central database of definitions which could be used as starting point to further harmonise terminology within and between the Scientific Panels across EFSA. This activity should be completed as soon as possible.
6) EFSA should collate and keep up to date a list of reference/source legislation for each Scientific Panel and the Scientific Committee. Each Panel and the Scientific Committee should examine closely the risk assessment terminology in the source legislation for their particular sector. Where the legislation for a sector does not include definitions of the specific risk assessment terms, the Scientific Committee recommends for consistency that Scientific Panels identify and use definitions given by CAC, OIE or IPPC and other relevant international authorities that serve the Scientific Panel activities. However, where a Scientific Panel sees a need to use a definition that is different from a definition of the same term established by the above-mentioned organisations, they should justify why this is necessary.
7) Terms used to express levels of risk and uncertainty should be consistent and well-defined. In order to reduce ambiguity, the Scientific Committee recommends that Scientific Panels work towards more quantitative expressions of risk and uncertainty whenever possible, i.e. quantitative expression of the probability of the adverse effect and of any quantitative descriptors of that effect (e.g. duration), or the use of verbal terms with quantitative definitions. The associated uncertainties should always be made clear, to reduce the risk of over-precise interpretation.
8) Further guidance should be developed on approaches for both qualitative and quantitative expression of risk and uncertainty. Consideration should be given to intensify communication between EFSA and risk managers to enhance mutual understanding of the risk expressions and raise awareness of the potential for interpretational bias.
9) The Scientific Committee and the Scientific Panels should carefully consider the draft ToRs for every opinion/risk assessment mandate. Where appropriate, there should be interaction with risk managers to avoid wording that may require making risk management judgements or using terminology that might be interpreted as implying a judgement or expectation about the need for risk management action.
10) Certain words such us “negligible”, “concern” and “unlikely”, have risk management connotation in everyday language. The Scientific Committee recommends that, when used in EFSA opinions, they should be used carefully with objective scientific criteria (not involving value judgments) and be clearly defined so as to avoid the impression that risk assessors are making risk management judgments.
11) The glossary of each EFSA scientific output should include definition of the risk assessment terms used.
12) Uncertainties should be addressed in a substantive and explicit manner, using defined terminology, accompanied by an explanation of the basis on which they have been evaluated, and in a way that is clearly signposted so that it can be readily found by readers.

REFERENCES

BfR (Bundesinstitut für Risikobewertung), 2010. Guidance document for health assessments. 2010 Edition. Federal Institute for Risk Assessment, Germany.

CCSP (Climate Change Science Program), 2009: Best practice approaches for characterizing, communicating, and incorporating scientific uncertainty in decisionmaking. [M. Granger Morgan, Hadi Dowlatabadi, Max Henrion, David Keith, Robert Lempert, Sandra McBride, Mitchell Small, and Thomas Wilbanks (eds.)]. A Report by the Climate Change, Science Program and the Subcommittee on Global Change Research. National Oceanic and Atmospheric, Administration, Washington, DC, 96 pp.

CAC (Codex Alimentarius Commission), 1999. Principles and guidelines for the conduct of microbiological risk assessment. CAC/GL 30-1999.

CAC (Codex Alimentarius Commission), 2003. Principles for the risk analysis of foods derived from modern biotechnology. CAC/GL 44-2003.

CAC (Codex Alimentarius Commission), 2006. Guidelines on estimation of uncertainty of results. CAC/GL 59-2006.

CAC (Codex Alimentarius Commission), 2009. Guidelines on analytical terminology. CAC/GL 72-2009.

CAC (Codex Alimentarius Commission), 2011. Procedural Manual, Twentieth Edition. Joint FAO/WHO Food Standards Programme. Available at; ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_20e.pdf

CONCAWE (The Oil Companies' European Association for Environment, Health and Safety in Refining and Distribution), 2003. Report No 3/03. European oil industry guideline for risk-based assessment of contaminated sites (revised). http://www.concawe.be/DocShareNoFrame/docs/1/CDEDGGHDEKPMHHBPODGGDLPIVEVCB6969YBDA3BYC6E3/CEnet/docs/DLS/Rpt_03-3-2003-01836-01-E.pdf

DG SANCO 2008. A comparative review of terminology and expressions used by the three non-food committees established by the Commission decision 2004/210/EC and by their predecessors established by Commission decision 97/579/EC (repealed by Commission decision 2004/210/EC) www.ec.europa.eu/health/ph_risk/documents/risk_rd01_en.pdf

EC 2002. Regulation (EC) No. 178/2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Official Journal of the European Union, L31, 1

ECHA (European Chemicals Agency), 2008. Guidance on information requirements and chemical safety assessment.

EFSA 2006a. Transparency in risk assessment carried out by EFSA: Guidance document on procedural aspects. The EFSA Journal (2006), 353, 1-16.

EFSA 2006b. Guidance of the Scientific Committee on a request from EFSA related to Uncertainties in Dietary Exposure Assessment. The EFSA Journal, 438, 1-54.

EFSA 2009. Guidance of the Scientific Committee on Transparency in the Scientific Aspects of Risk Assessments carried out by EFSA. Part 2: General Principles. The EFSA Journal (2009), 1051, 1-22.

EFSA 2010. Guidance on a harmonised framework for pest risk assessment and the identification and evaluation of pest risk management options by EFSA. The EFSA Journal (2010), 8,1495.

EFSA Panel on Animal Health and Welfare (AHAW) 2012. Guidance on risk assessment for animal welfare. The EFSA Journal (2012), 10, 2513. 30 pp.

EPPO (European and Mediterranean Plant Protection Organisation), 2011. Guidelines on Pest Risk Analysis. Decision-support scheme for quarantine pests. 11-17053, PM 5/3 (5)

Erev I, Cohen BL. 1990. Verbal versus numerical probabilities: efficiencies, biases, and the preference paradox. Organizational Behavior and Human Decision Processes, 45: 1-18.

European Commission, 2000. First report on the harmonisation of risk assessment procedures. Scientific Steering Committee.

European Commission, 2003. Second report on the harmonisation of risk assessment procedures: The future of risk assessment in the European Union. Scientific Steering Committee.

FAO/WHO (Food and agricultural Organization of the United Nations/World Health Organization), 2003. Hazard characterization for pathogens in food and water. Guidelines. Microbiological Risk Assessment Series, No. 3.

FAO/WHO (Food and Agricultural Organization of the United Nations World Health Organisation), 2008. Exposure assessment of microbiological hazards in food. Guidelines. Microbiological Risk Assessment Series, No. 7.

FAO/WHO (Food and Agricultural Organization of the United Nations World Health Organisation), 2009. Risk characterisation of microbiological hazards in foods. Guidelines. Microbiological Risk Assessment Series, No. 17.

Fillenbaum S, Wallsten TS, Cohen D, Cox JA, 1991. Some effects of available vocabulary and communication task on the understanding and use of vague probability expressions, American Journal of Psychology, 104, 35-60.

Gigerenzer, G. 2002. Calculated risks: how to know when numbers deceive you. Simon & Schuster, New York.

GRADE 2008: an emerging consensus on rating quality of evidence and strength of recommendations. British Medical Journal 336; 924-926.

FERA (Food and Environmental Research Agency, UK), 2010. Flari and Wilkinson: Terminology in risk assessment used by the scientific panels and scientific committee of EFSA. http://www.efsa.europa.eu/en/supporting/pub/101e.htm

Hart A, Roelofs J, Hardy AR and Macleod A, 2007. Comparative review of risk terminology. Final report to European Commission Directorate for Health and Consumer Protection (SANCO). available at http://ec.europa.eu/health/ph_risk/documents/risk|_rd01-en.pdf.

IARC (International Agency for Research on Cancer) 1990. Tomatis L. Cancer: Causes, Occurrence and Control.

IARC (International Agency for Research on Cancer) 2006. Preamble on IARC monographs on the evaluation of carcinogenic risks to humans. WHO/IARC publication.

IPCC (Intergovernmental Panel on Climate Change), 2005. Guidance notes for lead authors of the IPCC fourth assessment report on addressing uncertainties. WMO and UNEP.

IPCC (Intergovernmental Panel on Climate Change), 2007. Climate change 2007: The physical science basis. Summary for policymakers. IPCC WG I Fourth Assessment Report. WMO and UNEP.

IPCC (Intergovernmental Panel on Climate Change), 2010. Guidance note for lead authors of the IPCC fifth assessment report on consistent treatment of uncertainties. WMO and UNEP.

IPCS (International Programme on Chemical Safety), 2004. IPCS Risk Assessment Terminology. Part 1: IPCS/OECD key generic terms used in chemical hazard/risk assessment. Part 2: IPCS glossary of key exposure assessment terminology. World Health Organization.

IPCS (International Programme on Chemical Safety), 2008. Uncertainty and data quality in exposure assessment. Part 1: Guidance document on characterizing and communicating uncertainty in exposure assessment. Harmonization Project Document No. 6. World Health Organisation.

IPCS (International Programme on Chemical Safety), 2009. Environmental Health Criteria 240: Principle and methods for the risk assessment of chemicals in food. FAO/ILO/WHO

IPPC (International Plant Protection Convention), 2011a. Framework for pest risk analysis. International standards for phytosanitary measures. ISPM No. 2.

IPPC (International Plant Protection Convention), 2011b. Glossary of phytosanitary terms. International standards for phytosanitary measures. ISPM No. 5.

IPPC (International Plant Protection Convention), 2011c. Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms. International standards for phytosanitary measures. ISPM No. 11.

Lipkus, IM, Samsa G, Rimmer BK. 2001. General performance on a numeracy scale among highly eductaed samples. Medical Decision Making, 21 (1), 37-44.

Maijala R, 2006. Risk assessment as a tool for evaluating risk management options for food safety. In: FJM Smulders (Ed.). Towards a risk-based chain control, Wageningen Academic Publishers, The Netherlands, pp. 19-32.

Morgan MG, Dowlatabadi H, Henrion M, Keith D, Lempert R, McBride S, Small M and Wilbanks T, 2009. Best practice approaches for characterizing, communicating, and incorporating scientific uncertainty in climate decision making. U.S. Climate Change Science Program. Synthesis and Assessment Product 5.2.

Neutra RR and Delpizzo V, 2002.Transparent democratic foresight strategies in the California EMF program, Public Health Rep. 117, 553-563.

OGTR (Office of the Gene Technology Regulator), 2009. Risk analysis framework. Australian Government, Department of Health and Ageing.

OIE (World Organisation for Animal Health), 2011. Terrestrial Animal Health Code.

Rowe G, 2010. Assessment of the COT uncertainty framework from a social science perspective: A theoretical evaluation. A report for the Food Standard Agency (UK). available at: http://www.food.gov.uk/multimedia/pdfs/evaluncertframework.pdf

Ribó O and Serratosa J, 2009. History and procedural aspects of the animal welfare risk assessment at EFSA, In: FJN Smulders, B Algers (Eds.) Welfare of production animals: assessment and management of risks, Wageneingen Academic Publishers, The Netherlands, pp. 305-335.

Regulation (EC) 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food low, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

Smits T. and Hoorens V., 2005. How probable is probably? It depends on whom you're talking about. Journal of Behavioural Decision making 18(2), 83-96.

Smulders FJM, 2009. A practicable approach to assessing risks for animal welfare – methodological considerations. In: FJM Smulders, B Algers (Eds.) Welfare of production animals: assessment and management of risks, Wageningen Academic Publishers, The Netherlands, pp. 239-274.

Tavana, M., Kennedy, DT, Mohebbi, B. 1997. An applied study using the analytic hierarchy process to translate common verbal phrases to numerical probabilities. Journal of Behavioural Decision making, 10, 133-150.

Theil, M. 2002. The role of translations of verbal into numerical probability expressions in risk management: a meta-analysis. Journal of Risk Research, 5 (2) 177 – 186.

Wallsten TS, Budescu DV, Zwick R, Kemp S. 1993. Preferences and reasons for communicating probabilistic information in verbal numerical terms, Bulletin of the Psychonomic Society, 31, 135-138.

WTO (World Trade Organisation), 1994. Agreement on the application of sanitary and phytosanitary measures. Available at: http://www.wto.org/english/tratop_e/sps_e/spsund_e.htm.

ABBREVIATIONS

AFCWG: Advisory Forum's Communications Working Group
AHAW: EFSA Scientific Panel on Animal Health and Welfare
ANS: EFSA Scientific Panel on Food Additives and Nutrient Sources Added to Food
BSE: Bovine Spongiform Encephalopathy, or Mad Cow Disease
CJD: Creutzfeldt-Jakob Disease
BfR: Bundesinstitut für Risikobewertung (Federal Institute for Risk Assessment)
CAC: Codex Alimentarius Commission
CCSP: Climate Change Science Program
CEF: EFSA Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CLP: Classification, Labelling and Packaging of chemical substances and mixtures
CONCAWE: Conservation of Clean Air and Water in Europe (The Oil Companies' European Association for Environment, Health and Safety in Refining and Distribution)
CONTAM: EFSA Scientific Panel on Contaminants in the Food Chain
DG SANCO: Directorate general Health and Consumers (Sante et Consummateurs)
EC: European Commission
ECHA: European Chemicals Agency
ECDC: European Centre for Disease Control and Prevention
Eionet: European Environment Information and Observation Network
EMA: European Medicines Agency
EEA: European Environment Agency
EPPO: European and Mediterranean Plant Protection Organisation
ETDS: Environmental Terminology and Discovery Service
FERA: Food and Environmental Research Agency
FAO/WHO: Food and Agricultural Organization of the United Nations/World Health Organization
FEEDAP: EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
GATT: General Agreement on Tariffs and Trade
GMO: Scientific Panel on Genetically Modified Organisms
JECFA: Joint FAO/WHO Expert Committee on Food Additives
JEMRA: Joint FAO/WHO Meetings on Microbiological Risk Assessment
JMPR: Joint FAO/WHO Meetings on Pesticide Residues
ILO: the International Labour Organization
IPCS: International Programme on Chemical Safety
IPCC: Inter-governamental Panel on Climate Change
IPPC: International Plant Protection Convention
ISPM: International Standards for Phytosanitary Measures
MOE: margin of exposure
MOS: margin of safety
NDA: EFSA Scientific Panel on Dietetic Products, Nutrition and Allergies
NPPO: National Plant Protection Organisations
OGTR: Office of the Gene Technology Regulator
OIE: Office International des Epizooties **(**World Organisation for Animal Health)
PEC: predicted environmental concentration
PNEC: predicted no-effect concentration
OECD: Organisation for Economic Cooperation and Development
PLH: EFSA Panel on Plant Health
PPR: EFSA Scientific Panel on Plant Protection Products and their Residues
REACH: Regulation for Registration, Evaluation, Authorisation and Restriction of Chemicals
RPPO: Regional Plant Protection Organization
SCOEL: Scientific Committee on Occupational Exposure Limits
SPS: Sanitary and Phytosanitary measures
ToR: Terms of Reference

TBT: Technical Barriers to Trade
UNDP: United Nations Development Programme
UNEP: United Nations Environment Programme
UNIDO: United Nations Industrial Development Organisation
UNITAR: United Nations institute for Training and Research
WMO: World Meteorological Organisation
WTO: World Trade Organisation

APPENDICES

A. INTERNATIONAL ORGANISATIONS RELATED TO THIS OPINION

World Trade Organisation (WTO)

The World Trade Organisation (WTO) deals with the global rules of trade between nations. WTO has 153 members, including the European Union, thereby representing more than 97% of the world's population. The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) is an international treaty of WTO, under which the WTO sets constraints on member-states' policies relating to food safety as well as animal and plant health about imported pests and diseases. For the purposes of the SPS Agreement, sanitary and phytosanitary measures are defined as any measures applied:

- to protect human or animal life from risks arising from additives, contaminants, toxins or disease-causing organisms in their food;
- to protect human life from plant- or animal-carried diseases;
- to protect animal or plant life from pests, diseases, or disease-causing organisms;
- to prevent or limit other damage to a country from the entry, establishment or spread of pests.

These include sanitary and phytosanitary measures taken to protect the health of fish and wild fauna, as well as of forests and wild flora. Measures for environmental protection (other than indicated above), protection of consumer interests or the welfare of animals, are not covered by the SPS Agreement. These concerns are addressed by other WTO agreements, i.e., the Technical Barriers to Trade (TBT) Agreement or Article XX of GATT (1994).

The SPS Agreement states that "to harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations". The Agreement names the joint FAO/WHO Codex Alimentarius (CAC), the World Organisation for Animal Health (OIE, Office International des Epizooties), and the International Plant Protection Convention (IPPC) as the relevant standard-setting organization for food safety, animal health, and plant health, respectively.

References:

GATT, 1994. General Agreement on Tariffs and Trade. Available at: http://www.wto.org/english/docs_e/legal_e/06-gatt.pdf (must be read with GATT 1947, available at: http://www.wto.org/english/docs_e/legal_e/gatt47_e.pdf)

WTO (World Trade Organization), 1994. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Available at: http://www.wto.org/english/tratop_e/sps_e/spsund_e.htm.

WTO (World Trade Organization), 1995. Agreement on Technical Barriers to Trade. Available at: http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm

FAO/WHO Codex Alimentarius Commission (CAC)

In the early 1960s, the Food and Agriculture Organization (FAO) of the United Nations and the World Health Organization (WHO) recognized the importance of developing international standards for the purposes of protecting public health and minimizing disruption of international food trade. The Joint FAO/WHO Food Standards Program was established, and the Codex Alimentarius Commission (CAC) was designated to administer the program. CAC has 185 members (184 member countries and European Union as a member organisation). While not officially part of the CAC structure, the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the Joint FAO/WHO Meetings on Pesticide Residues (JMPR), the Joint FAO/WHO Meetings on Microbiological Risk Assessment (JEMRA), and FAO/WHO Expert Consultations (e.g. in safety assessments of foods derived from

biotechnology) provide independent scientific expert advice to CAC and its specialist Committees and Task Forces.

CAC has adopted a collection of international food safety standards, called Codex Alimentarius. A number of Directives and Regulations of the European Union refer to Codex Alimentarius, JECFA etc.

References (including some relevant FAO/WHO documents prepared under Codex Alimentarius scientific advice):
CAC, 1999. Principles and guidelines for the conduct of microbiological risk assessment. CAC/GL 30-1999.
CAC, 2003. Principles for the risk analysis of foods derived from modern biotechnology. CAC/GL 44-2003. ftp://ftp.fao.org/codex/Publications/Booklets/Biotech/Biotech_2003e.pdf
CAC, 2006. Guidelines on estimation of uncertainty of results. CAC/GL 59-2006.
CAC, 2009. Guidelines on analytical terminology. CAC/GL 72-2009.
CAC, 2011. Procedural Manual, Twentieth Edition. Joint FAO/WHO Food Standards Pprogramme. ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_20e.pdf
FAO/WHO, 1995. Application of risk analysis to food standards issues, Report of the Joint FAO/WHO Expert Consultation, Geneva, Switzerland, 13-17 March 1995, WHO/FNU/FOS/95.3. World Health Organisation. http://www.who.int/foodsafety/publications/micro/march1995/en/index.html.
FAO/WHO, 2003. Hazard characterization for pathogens in food and water. Guidelines. Microbiological Risk Assessment Series, No. 3.
FAO/WHO, 2008. Exposure assessment of microbiological hazards in food. Guidelines. Microbiological Risk Assessment Series, No. 7.
FAO/WHO, 2009. Risk characterisation of microbiological hazards in food. Guidelines. Microbiological Risk Assessment Series, No. 17.

World Organisation for Animal Health (OIE)

The OIE (Office International des Epizooties) is the intergovernmental organisation responsible for improving animal health worldwide, and is the WTO reference organisation for standards relating to animal health and zoonoses. The OIE publishes two codes (Terrestrial and Aquatic) and two manuals (Terrestrial and Aquatic) as the reference for WTO members. The *Terrestrial Animal Health Code* and *Aquatic Animal Health Code* respectively aim to assure the sanitary safety of international trade in terrestrial animals and aquatic animals, and their products. The codes originally addressed animal health and zoonoses, but have expanded to cover animal welfare and animal production food safety. The OIE regularly updates its international standards as new scientific information comes to light.
More on http://www.oie.int

References:
OIE, 2011. Terrestrial Animal Health Code.

FAO International Plant Protection Convention (IPPC)

The WTO's SPS Agreement identifies the IPPC as the reference organization developing International Standards for Phytosanitary Measures (ISPMs). These are standards, guidelines and recommendations recognized as the basis for phytosanitary measures applied by WTO members. Standards in themselves are not regulatory instruments but come into force once countries establish requirements within their national legislation. The IPPC is a treaty for international cooperation in plant protection administered through the Secretariat located in FAO's (Food and Agriculture Organization of the United Nation) Plant Protection Service. A Regional Plant Protection Organization (RPPO) is an inter-governmental organization functioning as a coordinating body for National Plant Protection Organizations (NPPOs) on a regional level. There are currently nine RPPOs, one of which is the European and Mediterranean Plant Protection Organization (EPPO).
(More on https://www.ippc.int/index.php?id=1110589&L=0)

References:
IPPC, 2011a. Framework for pest risk analysis. International standards for phytosanitary measures. ISPM No. 2.
IPPC, 2011b. Glossary of phytosanitary terms. International standards for phytosanitary measures. ISPM No. 5.
IPPC, 2011c. Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms. International standards for phytosanitary measures. ISPM No. 11.

International Programme on Chemical Safety (IPCS)

The International Programme on Chemical Safety (IPCS) is a joint venture of the United Nations Environment Programme (UNEP), the International Labour Organization (ILO), and the World Health Organisation (WHO). The overall objectives of the IPCS are to establish the scientific basis for assessment of the risk to human health and the environment from exposure to chemicals, through international peer review processes, as a prerequisite for the promotion of chemical safety, and to provide technical assistance in strengthening national capacities for the sound management of chemicals. The opinions developed are used by the Committees (e.g. JECFA, JMPR, JEMRA) that provide independent expert advice to CAC. As a joint IPCS/OECD project, internationally harmonized generic and technical terms used in chemical hazard/risk assessment were developed (IPCS, 2004).

References:
IPCS, 1987. Principles for the safety assessment of food additives and contaminants in food. Environmental Health Criteria 70. WHO. http://www.inchem.org/documents/ehc/ehc/ehc70.htm
IPCS, 1989. Glossary of terms on chemical safety for use in IPCS publications. WHO/ICS/89.27.
IPCS, 1994. Assessing human health risks of chemicals: Derivation of guidance values for health-based exposure limits. Environmental Health Criteria 170. WHO. http://www.inchem.org/documents/ehc/ehc/ehc170.htm
IPCS, 1996. Principles and methods for assessing direct immunotoxicity associated with exposure to chemicals. Environmental Health Criteria 180. WHO.
IPCS, 1999. Assessing human health risks of chemicals: Principles for the assessment of risk to human health from exposure to chemicals. Environmental Health Criteria 210. WHO. http://www.inchem.org/documents/ehc/ehc/ehc210.htm
IPCS, 2004. IPCS risk assessment terminology. Part 1: IPCS/OECD key generic terms used in chemical hazard/risk assessment. Part 2: IPCS glossary of key exposure assessment terminology. WHO. http://www.inchem.org/documents/harmproj/harmproj/harmproj1.pdf
IPCS, 2008. Uncertainty and data quality in exposure assessment. Part 1: Guidance document on characterizing and communicating uncertainty in exposure assessment. Harmonization Project Document No. 6. WHO.
IPCS, 2009. Principles for modelling dose-response for the risk assessment of chemicals. Annex I: Terminology. Environmental Health Criteria 239. WHO. http://whqlibdoc.who.int/publications/2009/9789241572392_eng.pdf
IPCS, 2009. Principles and methods for the risk assessment of chemicals in food. Environmental Health Criteria 240. Annex 1: Glossary of terms. FAO/WHO.

Intergovernmental Panel on Climate Change (IPCC)

The Intergovernmental Panel on Climate Change (IPCC) is a scientific body for the assessment of climate change, established by the United Nations Environment Programme (UNEP) and the World Meteorological Organisation (WMO). It is open to all member countries of the United Nations (UN) and WMO. Currently 194 countries are members of the IPCC. It reviews and assesses scientific, technical and socio-economic information produced worldwide relevant to the understanding of climate change. As thousands of scientists from all over the world contribute to the work of the IPCC, guidance notes have been prepared to assist in the consistent treatment of uncertainties. The aim is to ensure a common approach and language that can be used for developing expert judgments, and for evaluating and communicating the degree of certainty in findings of the assessment process.
More on: http://www.ipcc.ch/index.htm

References:
IPCC, 2005. Guidance notes for lead authors of the IPCC fourth assessment report on addressing uncertainties. WMO and UNEP.
IPCC, 2007. Climate change 2007: The physical science basis. Summary for policymakers. IPCC WG I Fourth Assessment Report. WMO and UNEP.
IPCC, 2010. Guidance note for lead authors of the IPCC fifth assessment report on consistent treatment of uncertainties. WMO and UNEP.

Organisation for Economic Cooperation and Development (OECD)

OECD is an intergovernmental organisation with 34 member countries, and the European Commission as a non-voting participant. The work of the OECD related to chemical safety is carried out in the Cooperative Chemicals Assessment Programme. The terminology document (OECD, 2003) was produced as a joint project with IPCS on the harmonization of hazard/risk assessment terminology within the framework of the Inter-Organisation Programme for the Sound Management of Chemicals (IOMC; current participating organizations: FAO, ILO, UNEP, UNIDO, UNITAR, WHO, World Bank, OECD, and UNDP as observer).

References:
OECD, 2003. Descriptions of selected key generic terms used in chemical hazard/risk assessment. ENV/JM/MONO(2003)15, OECD Environment, Health and Safety Publications Series on Testing and Assessment No.44.

EU RISK ASSESSMENT SYSTEM

In addition to the three non-food Scientific Committees (SCs) managed by DG SANCO (SCCS, SCHER, SCENIHR), the EU Risk Assessment system includes, the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), The European Chemicals Agency (ECHA), the European Centre for Disease Control and Prevention (ECDC), the European Environment Agency (EEA) and the Scientific Committee on Occupational Exposure Limits (SCOEL), managed by DG Employment. The SCs do not appear to have general glossaries but some key definitions are explained in the opinions. Some of the opinions of the SCs are presented in a format and language which can be easily understood by non-specialists. The reader can choose between three layers of complexity with the first layer being the most simplified version and the third being the scientific opinion itself. The first layer contains "glossary terms" which sometimes include risk assessment terms. The EMA and ECDC do not appear to have public source of (risk assessment) terminology.

European Chemicals Agency (ECHA)

ECHA is an agency of the European Union with the task of implementing the EU's chemicals legislation. The mission of ECHA is to: manage all REACH (Regulation for **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals) and CLP (Regulation on **C**lassification, **L**abelling and **P**ackaging of chemical substances and mixtures) tasks by carrying out or co-coordinating the necessary activities; ensure a consistent implementation at Community level; provide Member States and the European institutions with the best possible scientific advice on questions related to the safety and the socio-economic aspects of the use of chemicals. ECHA has a web-based "Guidance on Information Requirements and Chemical Safety Assessment", which includes, among others, glossary of terms with definitions for e.g. "hazard", "hazard assessment", "exposure assessment" and "risk".

References:
ECHA, 2008. Guidance on information requirements and chemical safety assessment. http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm?time=1261490244
ECHA, 2008. Guidance on information requirements and chemical safety assessment. Part E: Risk characterisation
ECHA, 2008. Guidance on information requirements and chemical safety assessment. Chapter R.20: Table of terms and abbreviation (http://guidance.echa.europa.eu/public-2/glossary.htm?lang=en)
ECHA, 2008. Guidance on information requirements and chemical safety assessment. Chapter R.19: Uncertainty analysis

European Environment Agency (EEA)

EEA is an agency of the European Union with the task to provide sound, independent information on the environment. Currently, the EEA has 32 member countries. EEA's mandate is: to help the Community and member countries make informed decisions about improving the environment, integrating environmental considerations into economic policies and moving towards sustainability; to coordinate the European Environment Information and Observation Network (Eionet). EEA has extensive web-based glossary that includes risk assessment terms (Environmental Terminology and Discovery Service (ETDS) http://glossary.en.eea.europa.eu/).

References:
EEA, 1998. Environmental Risk Assessment – Approaches, Experiences and Information Sources. Environmental issue report No 4 (http://www.eea.europa.eu/publications/GH-07-97-595-EN-C2)

B. GLOSSRAY

The Scientific Committee has not prepared an extensive glossary for this opinion, but the following is an example of terms that might occur in a stand-alone glossary of a scientific output.

Term/Acronym	**Definition used in this Scientific Opinion (source of term definition in brackets unless the term is specifically defined for this opinion)**
CAC	Codex Alimentarius Commission
FERA Report	A report commissioned by EFSA to the Food and Environmental Research Agency (FERA) to analyze 219 opinions issued by the Scientific Committee and Panels and published in 2008, 2009 and early 2010 in order to recommend possible ways of improving the expression and communication of risk and/or uncertainties within the Scientific Opinions. The report was published in 2010.
International standard setting organizations	International standard setting organizations named in the SPS agreement for food and feed safety, animal health and plant health are CAC, IPPC and OIE.
International standards, guidelines and recommendations	International standards, guidelines and recommendations as defined in SPS Agreement: (a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice; (b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics; (c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and (d) for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the Committee (SPS Agreement Annex A: Definitions)
IPPC	International Plant Protection Convention
ISPM	IPPC's approved International Standard for Phytosanitary Measures. E.g. ISPM 02: 2007 Framework for pest risk analysis (originally adopted in 1995, revised in 2007)

OIE	Office International des Epizooties ; International Office of Epizootics World Organisation for Animal Health
Risk Assessment	Definitions developed by different international standard-setting organisations are presented in Table 1
Scientific Opinion	EFSA can issue Scientific Opinions at the request of the European Commission, European Parliament, Member States, or on its own initiative or as foreseen in relevant sectoral legislation. Scientific Opinions are prepared by the Scientific Committee or a Scientific Panel. These scientific outputs are adopted by the Scientific Committee or one or more of the Scientific Panels (EFSA definition for scientific outputs – http://www.efsa.europa.eu/en/riskassessment/scdocdefinitions.htm)
Scientific Output	Scientific Outputs of EFSA are publications adopted or endorsed by Scientific Committee, EFSA Panels or EFSA and published in the EFSA Journal. EFSA's scientific outputs can be classified in broad categories: 'Opinions of Scientific Committee/Panel'; and 'Other Scientific Outputs'. The scientific outputs find their legal basis in Chapter III of the founding regulation 178/2002, specifically in Article 28 to Article 40.
SPS Agreement	The Agreement on the Application of Sanitary and Phytosanitary Measures (the "SPS Agreement") entered into force with the establishment of the World Trade Organisation on 1 January 1995. It concerns the application of food safety and animal and plant health regulations. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations. (http://www.wto.org/english/tratop_e/sps_e/spsund_e.htm)