SciCom

SCIENTIFIC COMMITTEE
of the Belgian federal Agency for
the Safety of the Food Chain

Guidelines for the opinions of the Scientific Committee

Federal Agency for the Safety of the Food Chain

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Table of content

Appendices

Tables

Figures

1 Introduction

1.1. Scope & Objectives

The aim of this document is to provide a framework for the risk assessments carried out by the Scientific Committee in the areas of food safety, animal health and plant health (phytosanitary risks). The purpose of this framework is to provide a structured and consistent approach in order to:

- ascertain the objectivity of the methodology, particularly regarding the use of data (data sources and investigation results), transparency of the method and description of the limitations related to the validity or availability of data, the variability of results and/or the degree of knowledge (taking uncertainty into account);
- increase the readability of the opinions, amongst others by a consistent use of clear terminology for risk assessment and the application of a logical structure in the opinions;
- increase the transparency and reproducibility of the process leading to the opinion for 3rd parties.

1.2. Abbreviations

DirRisk: Staff Direction for Risk Assessment (i.e. service within the Directorate-General for Control Policy responsible for the administrative and scientific support of the Scientific Committee)
RA: risk assessment
SciCom: Scientific Committee

1.3. Procedures for requesting opinions

The SciCom can be consulted by the Minister or the Chief Executive Officer of the Agency according to three procedures: a formal request (including a rapid procedure), a request for a scientific opinion on a sector guide or a sector monitoring program and a request for an urgent consultation in crisis situations. The SciCom can also self-initiate dossiers ('self referral' dossiers). [1]

(1) http://www.favv-afsca.be/scientificcommittee/opinions/procedures/

2 General framework

Risk analysis follows a structured approach. According to Regulation (EC) No 178/2002 [2] and Codex Alimentarius (Codex Alimentarius, 2015) risk analysis comprises three distinct but closely linked components, namely risk assessment, risk management and risk communication. The World Organization for Animal Health (OIE, 2016) uses a slightly different framework to which an additional component is added, namely hazard identification (see SciCom brochure, 2007 [3]).

Effective communication and consultation with the main interested parties should be ensured throughout risk analysis. There should be a functional separation between risk assessment and risk management to ensure the scientific integrity of the risk assessment, to avoid confusion over the respective responsibilities of risk assessors and risk managers and to reduce the possibility of conflict of interest. However, it is also recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application (Codex Alimentarius, 2015).

In general the risk analysis starts with the identification of the problem typically by the risk manager, continues through the processing of the question and the issuing of an opinion by the risk assessor and ends with the decision of the risk manager. The different steps are shown in Figure 1.

(2) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 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

(3) SciCom brochure (2007) ['Application of risk evaluation on the food chain'] 'Toepassing van risico-evaluatie in de voedselketen' / 'Application de l'évaluation des risques dans la chaîne alimentaire' (http://www.favv-afsca.be/comitescientifique/publications/brochures/)

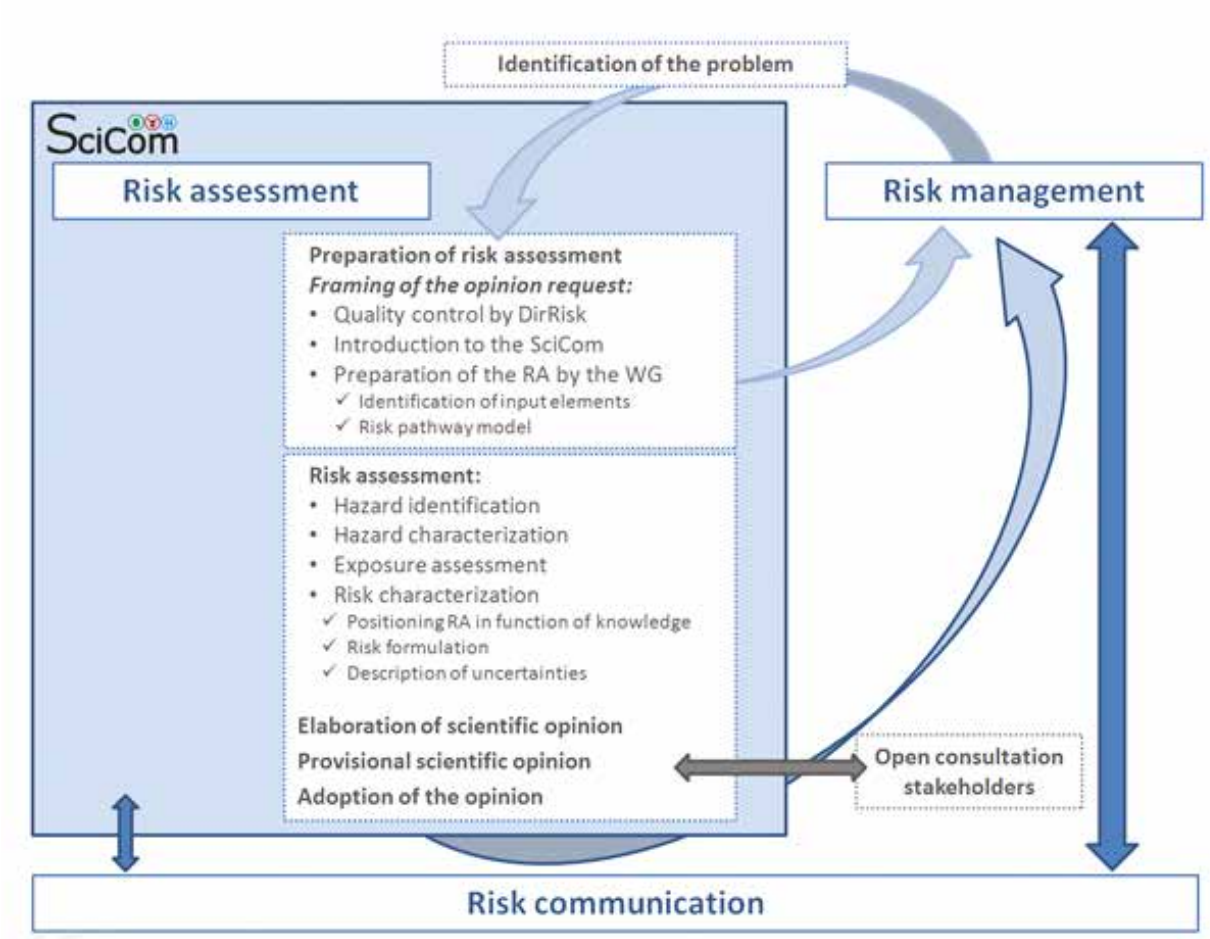

Figure 1. General framework of the risk analysis (RA: risk assessment; WG: workgroup)

3 Guidelines & Recommendations for performing risk assessment

3.1. Identification of the problem

The applicant (i.e. risk manager) may address a question to the SciCom for multiple reasons: to scientifically underpin a control policy plan, a draft royal or ministerial decree or a measure to be taken, to get a state of knowledge on an emerging issue, etc. Therefore, a technical dossier (i.e. opinion request) is compiled containing all supporting information necessary to understand and assess scientifically the request. An explanatory note is added in which the problem is clearly identified and the context is explained. The questions addressed to the SciCom may cover all or part of the different stages of the risk assessment process (hazard identification, hazard characterization, exposure assessment, risk characterization). They may also be related to an evaluation of management measures (e.g. study of one or more scenarios / scenario comparison).
In self-referral dossiers the identification of the problem and the formulation of the terms of reference are carried out by the SciCom itself. Once the terms of references are defined, risk managers are informed and invited to give comments.

3.2. Framing of the opinion request

Following the reception of a request, the relevance of performing a risk assessment is judged and the state of knowledge is identified (pre-existing or performed for the purpose).
At the end of this framing stage, final reference terms and the approach or methodology to be followed are determined. Data collection, initiated upon the reception of the request, is continued throughout the risk assessment process.

3.2.1. Quality control by the DirRisk

Upon receipt of a formal opinion request, the scientific eligibility and the quality of the request is evaluated by DirRisk through the examination of a number of elements (see: Appendix 2. Roadmap fot managing opinion requests (checklist)). Additional clarification can be asked to the applicant.

See SciCom procedures "Requesting an opinion".[4]

(4) http://www.favv-afsca.be/scientificcommittee/opinions/procedures/

3.2.2. Introduction of the request to the SciCom

The request is submitted electronically to the SciCom members and introduced officially at the SciCom plenary session where the work method is discussed and decided. The SciCom might propose to reformulate the request / question(s) during the first meeting of the appropriate workgroup.
In most cases, an ad hoc workgroup is established at the SciCom plenary session (see procedures "Requesting an opinion" [5] & document "Informatie voor leden van de werkgroepen van het Wetenschappelijk Comité"/ "Fonctionnement des groupes de travail du Comité scientifique"). The ad hoc workgroup consists of SciCom members of who a reporter is designated, external experts, observers (experts from the administration representing the questioner) and a file manager (i.e. DirRisk expert).
SciCom members and external experts of the ad hoc workgroup are selected on the basis of their expertise related to the dossier. External members sign a declaration of independency and impartiality. For each dossier, SciCom members as well as external experts must declare either the absence of interests or, where appropriate, the existence of a conflict of interest that might affect their independence and impartiality (declaration of interests). Declarations of interests are analyzed by the SciCom Bureau (composed of SciCom Chair, SciCom Vice-chair and DirRisk Director). Appropriate measures are taken in case of conflict of interests to guarantee the independency of the opinions. Experts with conflicts of interest can be consulted as 'heard experts'. They do not take part in the preparation of the draft opinion nor in the adoption of the opinion at plenary session.

3.2.3. Preparation of the risk assessment by the ad hoc workgroup

At its first meeting, the ad hoc workgroup evaluates the questions and the through-put time and decides upon the work method. The terms of reference (i.e. questions addressed to SciCom or in case of self-referral dossiers formulated by the SciCom itself) are specified during this first workgroup meeting in order to delimit the dossier and to formulate precise questions.

The preparation step involves an examination of the necessary resources with respect to expertise, data and information. (Other elements to be arranged but not directly related to the risk assessment, are listed in Appendix 2. Roadmap for managing opinion requests (checklist).)

In some cases, a reformulation of the question(s) is needed to translate it (them) into a scientific risk assessment question(s) or to split the question into several sub-questions. Framing the question is essential to ensure that the question accurately reflects the problem to be addressed. If the question is not clear, simple, specific, without bias and without ambiguous words, it should be reformulated to provide an adequate answer to the risk manager. If needed, the reporter may decide to feed back to the SciCom plenary meeting to discuss the workgroup's proposals.

(5) http://www.favv-afsca.be/scientificcommittee/opinions/procedures/

This preparatory phase might require further interaction with the applicant, and includes the identification of input elements and the elaboration of a risk pathway model.

3.2.4. Identification of input elements

During its first meeting, the workgroup analyses the dossier according to the following criteria:

- **Hazards:** relevant hazards are identified or defined by reviewing the available knowledge (scientific articles, reports, communications at scientific conferences, for example);
- **Target population:** may be further specified according to different demographic (e.g. age, species) or spatiotemporal (e.g. region, season) criteria;
- **Scenarios:** a sequence or a combination of particular events in relation to the request, such as the consideration of possible sources, introduction pathways, correlations and different circumstances or events;
- **Effect/consequences:** exposure to a hazard might have several consequences of variable severity, which can be evaluated at an individual, a population or different spatio-temporal levels;
- **Necessary resources:** data sources and availability are considered in terms of usefulness and depending on the timeframe available (deadline for the opinion).

It is useful to list already at this stage, the information and knowledge necessary to conduct the risk assessment and to describe how uncertainty can be accounted for (see 3.2.6).

3.2.5. Elaboration of a risk pathway model

If applicable, it is recommended to elaborate a risk pathway model. The risk pathway model is a tool for structuring the process and to facilitate exchanges among experts to better understand the problem, to identify the parameters to be taken into account as well as the information and data required, to efficiently organize the approach to answer the request questions, to formulate hypotheses, etc. It uses the elements identified in the previous stage of the risk assessment preparation process. The risk pathway model is a description and/or a schematic representation of known or suspected relationships between the different elements identified, according to the scenarios defined or deemed relevant. Some examples of risk pathway models are given in Appendix 3, but the canvas to be used has to be decided case by case.

3.2.6. Accounting for uncertainty

Analysis of uncertainties starts early in the risk assessment process since it plays a role in decisions about whether and how far to refine the overall assessment, and in what way (EFSA, 2015). The uncertainties associated with risk assessment are primarily related to limitations in scientific knowledge and the availability of data, but also to the underlying assumptions of the methodology used for the exposure estimate.
See: 3.3.4. Describing uncertainty.

3.2.7. Expert hearing

During the course of a risk assessment the workgroup may decide to hear (technical) experts from particular stakeholder groups or food chain operators to obtain specific information. Expert hearings have a particular format: the objective is to get the point of view of the stakeholder on a specific issue in order to better underpin the opinion. Heard experts do not take part in the discussion on the draft opinion.

3.2.8. Open consultation

Following a proposal of the ad hoc workgroup, the SciCom can decide to organize an open consultation in order to increase openness and transparency of scientific opinions and also to consider a possible reflection regarding the socio-economic aspects of the (provisional) opinion. The consultation may be done at the end or during the course of a dossier. Practically, it is organized for the members of the FASFC Advisory Committee, but – depending on the case – can be organized for other professional organizations or stakeholders as well, although with exclusion risk managers.
Relevant comments received as well as a short reaction to these comments will be communicated to the consulted parties and made publically available through the SciCom website following the final adoption of the opinion by the SciCom.

The guidelines (exploratory notes and criteria) for organizing such an open consultation are given in Appendix 4. Guidelines 'Open Consultation'.

3.2.9. Quality control of the draft opinion

Two SciCom members who are not members of the ad hoc workgroup, are appointed as 'deep readers' to review the draft opinion before adoption in the SciCom plenary session. Deep readers pay attention to the readability, the clarity, the logic argumentation, the application of a correct terminology and the pertinence of the risk assessment method used.

In case of self-tasking opinions, two additional experts (external experts or SciCom members) are appointed as 'peer reviewers' of the draft opinion. The peer reviewers are chosen based on their technical expertise on the topic of the study. Peer reviewers will also pay attention to the scientific argumentation (see: Appendix 2. Roadmap for managing opinion requests (checklist)).

3.3. Risk assessment

3.3.1. Risk assessment methodology

The definition of "risk" can be approached by the following 3 questions (triplet definition) (Kaplan & Garrick, 1981):

a) What can go wrong? (identifying and characterizing the hazard)
b) What is the probability that it will go wrong? (assessing the exposure)
c) If it goes wrong, what are the consequences? (characterizing the risk)

Generally speaking, a risk assessment comprises the following four steps, particularly if applied to **chemical and (micro) biological hazards** (Codex Alimentarius, 2015; SciCom brochure, 2007 [(6)]):

1. Identification of hazard/introduction pathways
2. Hazard/effect/consequence characterization
3. Exposure assessment
4. Risk characterization

(6) SciCom brochure (2007) ['Application of risk evaluation on the food chain'] 'Toepassing van risico-evaluatie in de voedselketen' / 'Application de l'évaluation des risques dans la chaîne alimentaire' (http://www.favv-afsca.be/comitescientifique/publications/brochures/)

The risk assessment applied to animal diseases (e.g., risk of introduction of an infectious agent in a particular population) may contain an additional step, entry assessment, and may follow an adapted flow. As recommended by the World Organisation for Animal Health (OIE, 2016), the following steps are taken into consideration:

1. Entry (risk) assessment
2. Exposure assessment
3. Consequence assessment
4. Risk estimation

For an infectious animal disease, it is often impossible to describe a dose-effect relationship. In addition, risk assessments concerning animal health hazards often have to be executed within a short timeframe because urgent measures have to be taken to limit the spread of a disease.

The risk assessment applied to phytosanitary hazards may include the following steps (EFSA, 2010; IPPC, 2004):

1. Pest categorization
2. Assessment of potential consequences
3. Assessment of probability of introduction and spread
4. Pest risk estimation

However, SciCom risk assessments related to plant health mostly concerns specific questions involving legislation or the control program.

Comprehensive pest risk assessments have not been asked to the SciCom up till now. These pest risk assessments are mostly undertaken by research groups in the context of thematic research financed by the Contractual Research department of the Federal Public Service Health, Food Chain Safety and Environment.

Rapid pest risk assessments ("quick scans") are performed by DirRisk experts according to a special procedure developed by the Agency. This simplified pest risk assessment is used in case of risk of introduction of harmful organisms into the Belgian territory. The risk assessment includes gathering information on the localization of the pest, its harmful properties, the host plants and the risk of introduction, establishment and spread. These "quick scans" are validated by (SciCom) experts in phytosanitary plant diseases and plant pests.

The use of the risk assessment steps listed above for chemical and microbiological hazards, animal diseases and phytosanitary hazards can be adapted to the specific nature of the question(s). Moreover, it is clear that the risk assessment should be performed using an appropriate methodology fit-for-purpose and according to the state of knowledge, the results of the risk assessment preparation step, the timeframe and the expertise mobilized. Ideally, the risk assessment is entirely evidence-based. However, it rarely occurs that all data necessary to conduct the risk assessment are available and/or that the available data are all of sufficiently high quality (weight of evidence). To indicate to risk managers the quality of information at disposal for performing the risk assessment, the approach used for assessing the risk and based on the degree of knowledge about the likelihood of

occurrence or exposure and on the degree of knowledge about the outcomes, is presented by means of a scheme (Figure 3; see 3.3.3.). Besides this schematic indication of the risk assessment approach, assumptions made and uncertainties affecting the risk assessment outcome are described as well (see 3.3.4.).

3.3.2. Risk formulation

Generally, the risk assessment should be non-biased, excluding any element related to risk management. An important endpoint of the risk assessment is the formulation or description of the risk assessment, namely the expression of the risk level.

When the risk assessment is based on quantitative data, often formulations can be used such as: "The exposure of the [average] population does not exceed X% of the [toxicological reference dose, such as the acceptable/tolerable daily intake or ADI/TDI, the acute reference dose or ARfD]", or "On a yearly basis, the probability of becoming ill, is x persons out of 100,000".

In some cases, however, it can be chosen to characterize the risk by means of a scale in order to clarify the risk assessment outcome. As such, the risk can be scaled from 'very low' to 'high', based on a combination of a 'likelihood assessment scale' and a 'consequence assessment scale' (Figure 2). The choice for a 'likelihood assessment scale' and a 'consequence assessment scale' is case-dependent, and has to be decided and argued by the ad hoc workgroup. Some examples of possible definitions or formulations for the 'likelihood assessment scale' and the 'consequence assessment scale' are given in Appendix 5.

		Consequence assessment			
		Marginal	Minor	Medium	Major
Likelihood assessment	Highly likely	Low	Moderate	High	High
	Likely	Low	Low	Moderate	High
	Unlikely	Very low	Low	Moderate	Moderate
	Highly unlikely	Very low	Very low	Low	Moderate

Figure 2. Risk matrix used to classify the level of risk

3.3.3. Positioning of the risk assessment in function of the knowledge

In order to indicate the relation between the uncertainties and the risk assessment performed, it is important to clearly distinct the concepts of "risk", "uncertainty", "ambiguity" and "ignorance", which are illustrated in Figure 3. The scheme in this figure starts from a known hazard, i.e. a) what can go wrong from the triplet definition. The vertical and horizontal axes concern respectively b) what is the probability that it will go wrong and c) what are the consequences if it goes wrong from the triplet definition.

The scheme should not be viewed as a choice between four separate domains, but should be viewed as a continuum. The risk as such can only be assessed when a certain minimum knowledge is available about both the likelihood (probability of occurrence) and the consequence(s). It should be clearly communicated to risk managers when this minimum knowledge is absent, in order to give them the opportunity to apply the precautionary principle (see Article 7 of Regulation (EC) No 178/2002 [7]). The line between a valid risk assessment and the presence of too much uncertainty is not always clear and is additionally related to the hazard in question.

(7) Regulation (EC) of the European Parliament and of the Council of 28 January 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

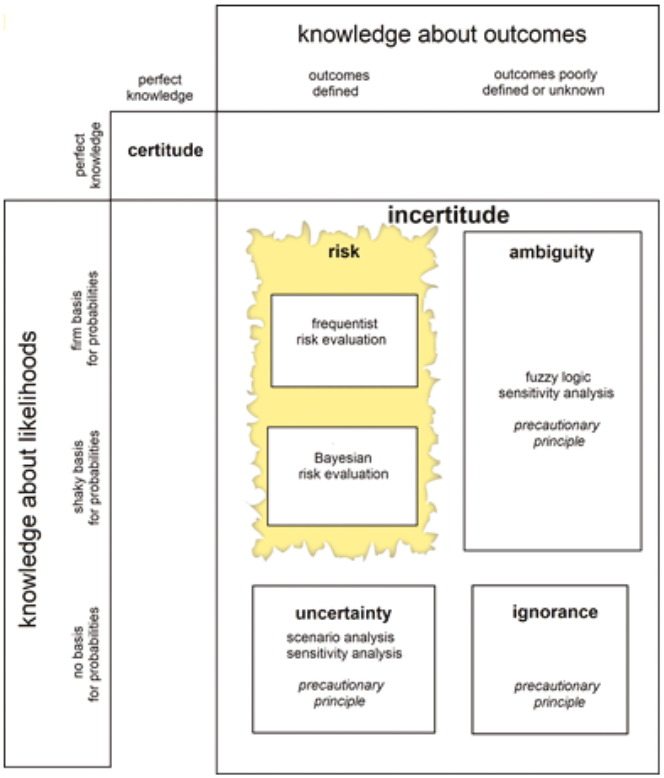

Figure 3. Relation between (lack of) knowledge and method to assess the risk. (after Stirling, 2008 & 2007) [(8)]

(8) In the strict or formal sense,

- "risk" is a condition under which both (i) a comprehensive set of all possible consequences is defined and (ii) a discrete set of probabilities across the array of outcomes is resolved;
- "uncertainty" applies to a condition under which there is confidence in the completeness of the defined set of consequences, but where it is acknowledged to exist no valid theoretical or empirical basis for the assigning of probabilities to these consequences;
- "ambiguity" is a condition under which it is not the probabilities but the possible consequences themselves that are problematic. This might be the case even for events that are certain or have occurred already;
- "ignorance" is a condition that applies in circumstances where no basis exists for both the assigning of probabilities (as under uncertainty) and the defining of a complete set of consequences. It is thus impossible to rank the options and to fully characterize them. Under a state of ignorance, it is always possible that there are effects (consequences) which have been entirely excluded from consideration. It differs from uncertainty, which focuses on agreed known parameters (like carcinogenicity). It differs from ambiguity in that the parameters are not just contestable, under characterized, or undetermined in their relative importance but are uncontrolled or at least partly unknown.

The term "incertitude" is introduced opposed to "certitude" to avoid confusion with the strict definition of the term "uncertainty" as used here.

3.3.4. Describing uncertainty

Communication of the risk assessment results includes communication of uncertainty. Describing inherent uncertainties within an assessment supports the transparency of the assessment.
Uncertainty covers all limitations related to the information and knowledge gathered during the risk assessment process. The degree of uncertainty can, at least in principle, be reduced on the basis of knowledge.
As already mentioned at 3.2.6., uncertainty should be accounted for already at the beginning of the risk assessment as well as throughout the whole risk assessment process. An approach for identifying uncertainties, is to systematically check each component of the assessment step whether any uncertainty can be recognized.

The main sources of uncertainty and their impact on the decisions taken in the risk assessment process, as well as the resulting conclusions are described. The uncertainties can be described qualitatively or by means of quantitative estimations.

Information sources on uncertainty analysis are given in appendix 6.

3.4. Proposition and evaluation of risk management options

The SciCom can be asked to consider risk management options based on the evaluation of the risk. The assessment performed by the SciCom involves an estimation of the consequences of one or more management options (e.g. by means of "what if" scenario's). The SciCom is however not involved in the choice of management options, their implementation and their monitoring, which fall within the risk managers decision.

4 Format of the scientific opinion

SciCom's scientific opinions are developed according to a standardized outline showing the different stages of the realization of the collective, scientifically based expertise and results. While maintaining coherency in the structure of the final document, the structure can be customized accordingly to the request, e.g. by adjusting the subchapters.

The scientific opinion consists of the following main parts:

4.1. Summary

A short note is given on the background of the question(s), the issue, the methodology followed, the results obtained and the conclusions made. The summary contains the key elements of the opinion allowing the reader to be rapidly informed about the message.

4.2. Reference terms

Corresponds mainly to "framing of the question" and includes following contextual elements:

- the questions formulated in the opinion request, with reference to related previous opinions;
- legal provisions (e.g., regulatory standards or guidelines);
- the methodology or rationale followed (input elements, e.g., available expertise, sources of data and investigations conducted, approach of exposure estimation, hypotheses made);
- definitions & abbreviations used in the opinion.

4.3. Introduction / background

Outline of the issue, reason of the opinion request, …

4.4. Risk assessment

If applicable, reference is made to the risk pathway model giving a structured presentation of the process followed (see 3.2.5.). In this part, the different risk assessment steps are elaborated (see 3.3.1.). In some cases, a full risk assessment is not requested and this section may be adapted following the needs of the opinion request.

4.5. Uncertainties

Uncertainties, constraints and assumptions having an impact on the risk assessment result should be explicitly mentioned.
In order to keep the communication clear, only those uncertainties that most affect the risk characterization/estimation, are described together with their impact on the resulting conclusions. Additionally, reference is made to the scheme (given in annex of the opinion) in which the risk assessment approach followed is positioned in function of the available knowledge (see 3.3.3.) pointing out where in the scheme the opinion is situated.

4.6. Conclusions

Formulation of conclusions in response to the questions, including –if applicable- a discussion of the effectiveness of the various risk management options.
If no conclusive results are obtained or if opinions diverge, this is mentioned and argued.

4.7. Recommendations

In certain cases, results or conclusions may lead to recommendations, including additional scientific research to be done or a listing of possible risk management options.

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Appendix 1. Glossary

Based on definitions from: (1) Codex Alimentarius, 2015; (2) European Science & Technology Observatory (1999); (3) OIE, 2016; (4) EFSA, 2010.

Consequence assessment	Consequence assessment consists of describing the relationship between specified exposures to a hazard and the consequences of those exposures. A causal process might exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. It describes the potential consequences of a given exposure and estimates the probability of them occurring. This estimate may be either qualitative or quantitative. (3)
Entry assessment	Entry assessment consists of describing the biological pathway(s) necessary for an importation activity to introduce pathogenic agents (hazards) into a particular environment, and estimating the probability of that complete process occurring, either qualitatively or quantitatively. It describes the probability of the 'entry' of each of the hazards 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.(3) This definition that applied first for importation, can be adapted for an introduction of pathogenic agents in an animal population.
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. (1)
Hazard	A biological, chemical or physical agent in a food (product), or in an animal/plant product or a condition of an animal/plant with the potential to cause an adverse effect. (1) & (3)
Hazard characterization	The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents (hazards) which may be present in food. (1)
Hazard identification	The identification of biological, chemical, and physical agents (hazards) capable of causing adverse health effects and which may be present in a particular food or group of foods. (1)
Ignorance	A precise technical concept which is as well-founded in probability theory as the concept of risk and which refers to a situation under which it is possible neither to assign probabilities nor even to define all possible consequences. (2)
Incertitude	A term introduced (after Stirling) to encompass the formal concepts of 'risk', 'uncertainty', 'ignorance' and 'ambiguity'. (2) – see point 3.3.3, Figure 3.
Pest (harmful organism)	In the context of plant health, "pest" and "harmful organism" are considered equivalent terms and refer to any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products. (4)
Pest categorization	Used in the context of plant health, and comparable with hazard identification. (4)
Precautionary approach	An approach of risk management which directly addresses the problems of multidimensionality, incommensurability and ignorance, displaying properties such as a broad framing, inclusion of multiple perspectives, humility about knowledge, an openness to alternatives, consideration of benefits as well as placing the proof burden on advocates of a technology (rather than the sceptics) and emphasizing the rights of wider society (rather than those of industry). (2)
Precautionary principle	The adoption of a precautionary approach as an explicit formal element in the design of conventions, treaties, legislation, institutions or other statutory instruments associated with the management of a risk. (2) As such, it concerns a risk management decision.

Risk	The likelihood of the occurrence and the likely magnitude of the biological and economic consequences of an adverse event or effect to animal, plant or human health. (3)
Risk analysis	A process consisting of three components : risk assessment, risk management and risk communication. (1)
Risk assessment	A scientifically based process consisting of different steps (see 3.3.1.).
Risk characterization	The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment. (1)
Risk communication	The interactive transmission and exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions among risk assessors, risk managers, risk communicators, the general public and other interested parties. (3)
Risk estimation	Risk estimation consists of integrating the results from the entry, the exposure and the consequence assessment to produce overall measures of risks associated with the hazards identified at the outset. It takes thus into account the whole of the risk pathway from hazard identified to unwanted outcome. (3)
Risk management	The process, distinct from risk assessment, of identifying, selecting and implementing measures that can be applied to reduce the level of risk. (3)
Risk matrix	A table with several categories of likelihood for its row, and several categories of consequence for its columns; a tool used by risk assessors for combining qualitative scores. (4)
Uncertainty	A precise technical usage of the term 'uncertainty' to mean a situation under which it is possible to define all possible consequences but where there is no basis for the confident assigning of probabilities. (2) The inability to determine the true state of affairs of a system; may arise in different stages of risk assessment due to lack of knowledge and to natural variability. (4)

More definitions can be found in:

- SciCom brochures 'Application de l'évaluation des risques dans la chaîne alimentaire'/'Toepassing van risico-evaluatie in de voedselketen' (2007) & 'Terminologie en matière d'analyse des dangers et des risques selon le Codex alimentarius'/'Terminologie inzake gevaren-en risicoanalyse volgens de Codex alimentarius' (2005) (http://www.favv-afsca.be/scientificcommittee/publications/brochures/).
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- OIE - World Organisation for Animal Health. (2016). Terrestrial Animal Health Code. Glossary. http://www.oie.int/international-standard-setting/terrestrial-code/access-online/

Appendix 2. Roadmap for managing opinion requests (checklist)

1. Quality control of opinion requests

Upon receipt of the formal opinion request, the DirRisk investigates different elements of the dossier:

- whether it belongs to the field of SciCom competencies;
- whether the dossier is administratively and technically compliant;
- whether the question has a scientific content;
- whether the question is clearly and adequately formulated;
- whether there is a risk for conflict of interest for the members of the SciCom;
- whether the complexity of the question requires further consultation with the applicant in view of a timely delivery of an opinion.

2. Introduction of a dossier at the plenary session

- Context and terms of reference;
- Adequate formulation of the question in terms of risk assessment?
- Identification of the expertise required for treating the dossier;
- Proposition of composition of the workgroup and appointment of a dossier reporter;
- Is there a risk for conflicts of interest of the workgroup members?
- Appointment of 2 'deep readers' (= 1 Dutch member = 1 French member of the SciCom outside the workgroup to review draft opinion with respect to e.g. readability, clarity, logic argumentation, correct terminology and pertinence of used method);
- Self-tasking opinions: appointment of 'peer reviewers' (= 2 experts, preferentially 1 Dutch + 1 French).

3.1st meeting workgroup

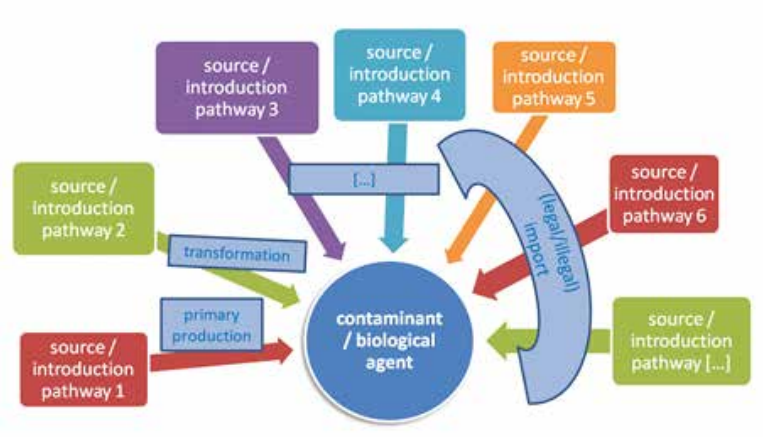
- Declaration of independence & impartiality received from all external workgroup members?
- Declaration of interest received from all SciCom and workgroup members?
- Working language to use (English or Dutch/French)?
- Terms of reference (formulation of the question; e.g. (sub-)questions to be answered); is further clarification needed?
- Identification of input elements: inventory of resources, incl. scientific expertise, availability of data, bibliographic resources;
- Elaboration of a risk pathway model: strategy / approach to be followed (incl. e.g. scenario analysis or a roadmap with different steps for reaching the advised objective);
- Is it possible to follow the risk assessment framework (rationale) as laid down in the framework document?
- Open consultation? Stakeholder hearing appropriate?
- Tasks & timeframe.

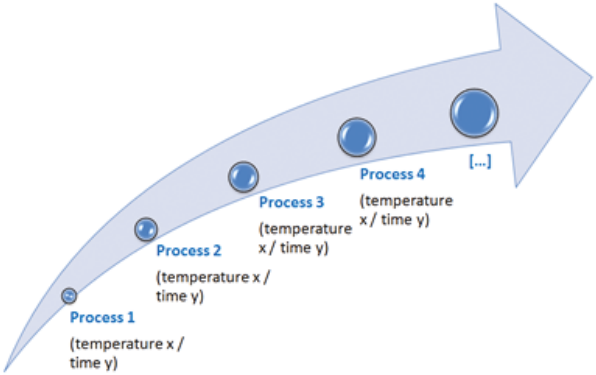
4.'State of the art' at plenary session

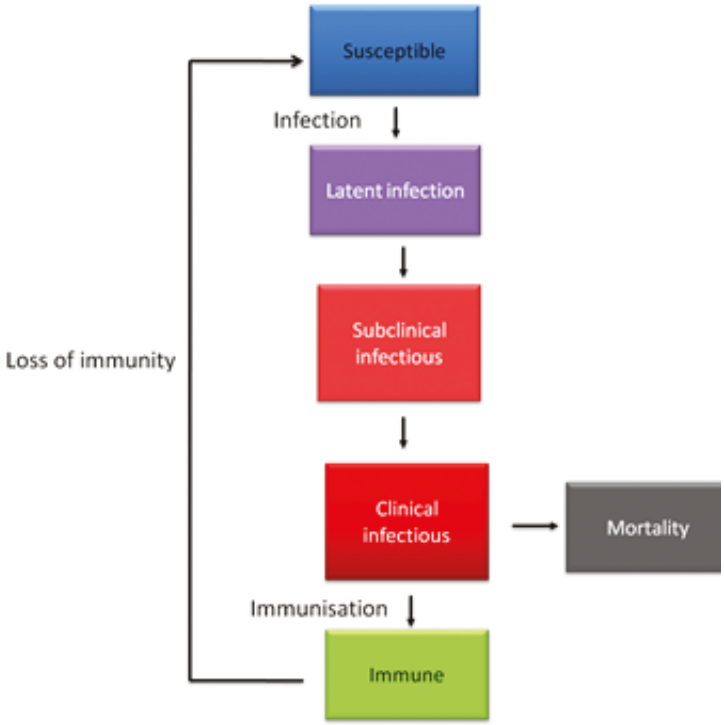
If applicable:

- Further discussion of opinion request formulation (e.g., when further modification took place after dialogue with applicant);
- Proposition of workgroup regarding participants open consultation / stakeholder meeting;
- Current dossier situation;
- Presentation of the draft opinion;
- Confirmation of the persons designated as 'deep reader' or as 'peer reviewer'.

Appendix 3. Examples of risk pathway models







Appendix 4. Guidelines 'Open Consultation'

OBJECTIVES

It is the objective to hold a consultation (for practical reasons) among the members of the FASFC Advisory Committee, and – depending on the case – among members of other professional organizations or among stakeholders concerned (but excluding risk managers) and only for particular opinions (see next point for proposed criteria) in order to increase openness & transparency of scientific opinions and to consider a possible reflection regarding the socio-economic aspects of the opinion outcome.

TIME LINE

> decision to have a consultation round at start up or during the course of a dossier
> adoption of 'provisional' opinion by SciCom without publication of the opinion
> consultation round amongst the Advisory Committee members (stakeholders concerned) (± 3 weeks)
> formulation of response and where applicable, adaptation of provisional opinion
> approbation of response to remarks and the 'final' opinion by SciCom
> sending response to Advisory Committee (stakeholders concerned) & publication of response + final opinion

CRITERIA

A consultation of stakeholders will usually be considered for opinions resulting from a self tasking study, which covers a more general issue and which can arouse a specific interest of stakeholders (socio-economic interest).
The decision for organizing a consultation round, depends on the available through-put time, resources in terms of personnel and means, and will be taken by the SciCom after informing the management of the FASFC.

EXPLANATORY NOTES

[Proposed text:]

In order to increase openness and transparency but without compromising the independent position of the Scientific Committee, the stakeholders of the FASFC, namely the <members of the Advisory Committee, members of professional organization X, stakeholders Y> are invited to communicate their comments on the following (provisional) scientific opinion:

<title SciCom opinion>

The <members of the Advisory Committee, members of professional organization X, stakeholders Y> are invited to submit comments and pertinent scientific information by means of the electronic form available on this page / in annex of this mail by <date deadline>.

The Staff Direction for Risk Assessment (X, dossier manager) and the workgroup (Y, dossier reporter) will assess all relevant comments which are submitted in line with the criteria below. The comments will be further considered by the Scientific Committee and taken into account where these will enhance the scientific quality or understanding of the document. Relevant comments received as well as a short reaction to these comments will be communicated to the <members of the Advisory Committee, members of professional organization X, stakeholders Y> and made publically available through the website following the final approbation of the opinion by the Scientific Committee.

A submission will not be considered if it:

- is submitted after the deadline set out in the call;
- is presented in any other form than the instructions and template provide for;
- contains comments which do not relate to the contents of the document;
- contains complaints against institutions, personal accusations, irrelevant or offensive statements or material;

Additionally, the following information should be considered:

- Repeated comments received from the same contributor will appear only once;
- Comments submitted by individuals acting in a personal capacity will be published anonymously;
- Comments submitted formally on behalf of an organization will appear with the name of the organization.

Appendix 5. Examples for defining the risk matrix scales

The criteria listed in the tables below are illustrative and will depend on the circumstances of the specific case.

Table 1. Examples of the rationale for the likelihood assessment scale

Scale	Probability of occurrence [1]	Prevalence [2]	Contribution [2]
Highly unlikely	Only in very rare circumstances	Low analytical detection and standard not exceeded; very low prevalence.	Limited contribution because the food product(s) is (are) insignificantly consumed and/or other food products account for an important part of the overall exposure to the hazard under consideration.
Unlikely	In some limited circumstances	Standard is exceeded a few times or else regular analytical detections but no exceeding of standard; standard value in case of insufficient information (low probability of prevalence).	Average contribution, standard value when insufficient information.
Likely	In many circumstances	Regular exceeding of standard or else frequent analytical detections and standard exceeded a few times (average probability of prevalence).	Substantial contribution because the food product(s) is (are) significantly consumed and/or contribute(s) substantially to the overall exposure.
Highly likely	Expected in most circumstances	Frequent analytical detections and exceeding of standard (high probability of prevalence).	Very substantial contribution because the food product(s) is (are) very significantly consumed and/or is virtually the exclusive source of overall exposure.

based on :

(1) OGTR Australia (2013)

(2) Maudoux et al. (2006):

"The prevalence is used to indicate to what extent the hazard occurs and may harm the population (sample matrices). For diseases, this parameter is specifically used to estimate the seriousness of the hazard according to the probability of the introduction of the pathogen onto the national territory or/and of the risk of spreading from the primary outbreak(s) that has(have) been identified. The prevalence is the first component of population exposure and takes into account the frequency of exceeding a standard and, if necessary, the frequency of analytical detections (presence below a limit value).";

"Contribution is the second component of exposure. Starting from the principle that the overall exposure of an individual to a hazard results from many sources of contamination, the contribution represents the relative importance the population (sample matrices) account(s) for in the risk related to this hazard."

Table 2. Examples of the rationale for the consequence assessment scale

Scale	Injury / disease [1]	Harmful effect of the hazard [2]
Marginal	Minimal or no (increase in) illness/disease	Not harmful or negligibly harmful (in particular for parameters which are not directly related to food safety, animal disease or plant disease).
Minor	Minor (increase in) illness/disease that is readily treatable	Probably harmful (especially for parameters that are indicators of the hygiene of foodstuffs; standard value applied in the absence of more specific indications).
Medium	Significant increase in illness/disease that requires specialized treatment or Serious illness/injuries usually requiring hospitalization; treatment is usually available; prevention may be available	Seriously harmful (for toxic agents, infectious agents or agents which cause moderate symptoms of gastro-enteritis).
Major	Significant increase in severity of illness/disease, generally not treatable or Deaths or life-threatening illness/injuries; treatment or prevention is not usually available	Very harmful (notably for toxic agents and agents provoking infections at a small infectious dose and/or with high mortality rates).

based on :

(1) OGTR Australia (2013)

(2) Maudoux et al. (2006):

"These scores (i) are based upon the available scientific information; (ii) take into account harmful effects both on public health and animal and plant production (e.g. economic impact); (iii) intervene in establishing a program aimed at detecting the presence of the hazard. In the case of multi-residue analyses (combination of analyses) the score for the combination equals the maximum score for the analyses (hazards) of which it is composed."

Appendix 6. Information on uncertainty analysis

ANSES (2016). Prise en compte de l'incertitude en évaluation des risques: revue de la littérature et recommandations pour l'Anses (Rapport d'étape). https://www.anses.fr/fr/system/files/AUTRE2015SA0090Ra.pdf

BfR (2015). Guidelines on uncertainty analysis in exposure assessment. http://www.bfr.bund.de/cm/350/guidelines-on-uncertainty-analysis-in-exposure-assessments.pdf

ECHA (2012). Guidance on information requirements and chemical safety assessment. Chapter R19: Uncertainty analysis. https://echa.europa.eu/documents/10162/13632/information_requirements_r19_en.pdf

EFSA (2016). Guidance on uncertainty in EFSA Scientific assessment – EFSA Scientific Committee. [Revised draft for internal testing]. https://www.efsa.europa.eu/sites/default/files/160321DraftGDUncertaintyInScientificAssessment.pdf EFSA (2006). Guidance of the Scientific Committee on a request from EFSA related to Uncertainties in Dietary Exposure Assessment (Request No EFSA-Q-2004-019). The EFSA Journal (2006) 438, 1-54. http://www.efsa.europa.eu/en/scdocs/doc/438.pdf

European Science & Technology Observatory (1999). On science and precaution in the management of technological risk. Volume 1. A synthesis report of case studies. (p. 61). http://ftp.jrc.es/EURdoc/eur19056en.pdf

Hart A., et al. (2010). Development of a framework for evaluation and expression of uncertainties in hazard and risk assessment. Research Report to Food Standards Agency, Project N° T01056. http://www.food.gov.uk/sites/default/files/676-1-1148_T01056_Final_Report_for_Web.pdf

Kettler S., et al. (2015). Assessing and reporting uncertainties in dietary exposure analysis – Mapping of uncertainties in a tiered approach. Food and Chemical Toxicology 82, 79-95.

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