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## Communication inside Risk Assessment and Risk Management (COMRISK): Final report

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## Abstract

A key feature of risk analysis is that risk assessment and risk management should be functionally separated. However, the usefulness of a risk assessment may be limited if the output is not designed to help with risk management decisions. The COMRISK project investigated the communication between risk assessors and risk managers. The overall goal of the project was to identify current practices and challenges in communication between risk assessors and risk managers during the risk analysis process, and thus increase and improve the understanding and the quality of the communication between them. Specific actions to achieve this aim included reviewing of historical food safety cases, analysing risk assessment requests, identifying communication guiding documents, including legislation and agreements, conducting semi-structured interviews with risk assessors and risk managers, and identifying tools for facilitating the communication between risk assessors and risk managers. It was concluded that the usefulness of a risk assessment is strongly dependent on well-defined and mutually recognised risk questions and that scarce or poor communication between risk assessors and risk managers is one of the major reasons when an output from risk assessment fails to support risk management. The communication between risk assessors and risk managers preceding the onset of the risk assessment, when the risk assessment requests with its risk questions are defined, is especially identified as one of the critical points to ensure a risk assessment that is fit for purpose. However, difficulties in understanding were also reported for the communication between risk assessors and risk managers during and after the risk assessment. Lack of communication is seldom a result of formal constraints or agreements nor can it be explained by a wish of the risk assessors or risk managers. Instead, perceived constraints or traditions appear to be possible underlying factors leading to scarce or poor communication between risk assessors and risk managers. It is essential that both risk assessors and risk managers acknowledge the crucial importance of communication between them while at the same time respect their different roles in a risk analysis. According to respondents, the best solution to facilitate the framing of the risk assessment questions is an open dialogue between risk assessors and risk managers to agree on the goal of the assessment and to build trust. Further, the interview results indicate that a formal systematic process may facilitate communication during the risk analysis. Where there is uncertainty, e.g. due to data gaps or issues related to the methodology and models, it should be acknowledged and described properly by risk assessors to risk managers. Training of risk assessors and risk managers may improve the possibility of a timely and fit-for-purpose output. Such a training should give a deeper insight in the risk management process, give a better understanding of the risk managers role, and especially raise the awareness of the importance of the communication between risk assessors and risk managers. To improve the risk analysis process, it is also important that the risk assessor gets feedback regarding how risk assessments have met the needs of the risk managers. The present study also found that aspects of risk communication studied in this project are not extensively discussed in the guidance documents for risk analysis. More research is needed to identify the barriers for a fit for purpose communication.

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**Key words:** Risk Assessment, Risk Management, Risk Communication, Independency

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## 1. Introduction

### 1.1. Background and Terms of Reference as provided by the requestor

Food safety can be improved through risk analysis, which is a structured approach comprising of distinct but interrelated components of risk assessment, risk management and risk communication (FAO/WHO, 2006; Regulation (EC) 178/2002, art. 3(10)). In a food safety risk assessment, risks are scientifically evaluated for their potential to cause adverse health effects resulting from human exposure to foodborne hazards through the process of hazard identification, hazard characterization, exposure assessment, and risk characterization. It provides an integral appraisal of foodborne risks that humans may face and therefore serves as the scientific input for decision making in risk management. Risk managers, on the other hand, are responsible for establishing a risk profile, the weighing of different prevention and risk management options, their implementation, and for monitoring and reviewing. When evaluating different prevention and risk management options, risk managers should take the risk assessment and other health-related aspects into account, besides other socio-economic factors such as trade, environmental aspects, control costs and consumer acceptance and perception.

Within the risk analysis paradigm, the separation of the risk assessment and risk management is important to allow the two components to perform their task independently. According to the Codex Alimentarius (FAO and WHO 2013) "there should be a functional separation of risk assessment and risk management, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest." On the other hand, the increasingly complex global food systems require an effective communication between risk assessors and risk managers as part of the risk communication component of risk analysis. Risk communication is defined as "the interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions" by the Codex Alimentarius Commission (FAO and WHO 2013). An effective communication between risk assessors and risk managers thus ensures that risk assessment focuses to the identified hazards in demand and that the risk assessment is useful and interpretable for risk managers. However, communication between risk assessors and risk managers may conflict with the independency of both risk analysis components and may make the risk analysis less transparent also. Risk communication towards consumers and other stakeholders has been extensively studied (e.g., Frewer et al., 2016) but little is known about the communication between risk assessors and risk managers as part of the risk analysis process.

The overall goal of the COMRISK ("Communication inside Risk Assessment and Risk Management") project was to identify current practices and challenges in the communication between risk assessors and risk managers during the risk analysis process.

To achieve the overall aim of the project, several activities were conducted, being:

- interviews with risk assessors and risk managers were conducted to investigate their daily experiences communicating with their risk analysis counterpart,
- risk analysis requests send to EFSA were described to identify included parameters and those enhancing a valuable risk assessment,
- historical food safety cases were evaluated,
- guiding documents from national food safety authorities and research institutes were investigated for guidance on communication,

- tools that potentially could facilitate the communication between risk assessors and risk managers were reviewed.

COMRISK was financed through a Partnering Grant (GA/EFSA/AFSCO/2017/01-GA05) awarded by EFSA (Call reference: GP/EFSA/AFSCO/2017/01) to the National Veterinary Institute (SVA). Partnering Grants aim to promote capacity building at EU level through joint initiatives between two or preferably more organisations in different Member States, Norway and Iceland, enabling knowledge and expertise transfer and/or exchange within the fields of EFSA`s remit. For the purpose of this grant, Capacity Building is defined as an initiative that leads to the strengthening of food safety risk assessment capacity of national organisations through the transfer or exchange of knowledge, skills, competencies and abilities between partner organisations. Partnering grants aim to promote Knowledge exchange and knowledge sharing between organisations located in different member states. The specific topics of the project were not defined in the call.

## 1.2. Interpretation of the Terms of Reference

This project was a pilot study and therefore hypothesis-generating. An exhaustive description of the current situation or the establishment of best practices was not the scope of this project. In relation to capacity building a goal of COMRISK was to raise awareness of factors that are implicitly or explicitly considered in the communication between risk assessors and risk managers and to identify factors potentially promoting an efficient cooperation between risk assessors and risk managers. This is expected to result in an improved output of the risk analysis process in the participating MS.

## 1.3. Additional information

The leading partners of the chapters in this report were as follows: 3.1 interview analysis in Ruokavirasto, 3.2 evaluation of risk assessment requests in BfR, 3.3 description of historical food safety cases and 3.4 assessment of guidance documents in SVA, 3.5 tools for communication in Wageningen University, and 4-6 synthesis, conclusions and recommendations in SVA. All partners commented on the report.

## 2. Methods

### 2.1. Project workflow

During the first year of the project the work was focused on the collection and reading of written documentation, analysing risk assessment request, as well as the extraction of relevant data needed to set up the questionnaire for interviews. The literature studies were followed up by semi-structured interviews with representatives from risk assessment and risk management bodies.

As kick-off for the second half of the project a workshop with invited risk assessors and risk managers was arranged in connection with the interim meeting in Berlin, Germany on January 29-30, 2019. The second half of the project focused on the processing of interview results and reporting. In this phase, all partners worked together to make a synthesis of information from the activities in year one, with the joint goal to identify theoretical and practical constraints regarding the interaction between the risk assessors and risk managers. In parallel, tools for communication were identified and evaluated how they could facilitate the interaction and possibly overcome some of the constraints. Within the whole project period meetings using telephone conferences took place at least on a monthly level.

### 2.2. Preparation of questionnaire and performing interviews

The questionnaire (Appendix A) prepared within the project consisted of multiple choice, slider rating scale, Likert-scale, and open-ended questions. The questionnaire was similar for both risk assessors and risk managers. The original questionnaire form was in English and it was translated into the native language of each country. The questionnaire was structured to cover the following topics:

- Background questions
- Beginning of risk assessment – identify and describe the issue
- Risk assessment started by request from risk management – defining the risk assessment question
- Ongoing risk assessment project
- Handing over the risk assessment and improving its use

Interviews with the COMRISK questionnaire were conducted in Finland, Germany, the Netherlands, and Sweden. The interviews were conducted by one or two members of the project group in each country. After conducting the interviews, the answers were translated to English and sent to Ruokavirasto where the data analysis was done.

Interview answers were analysed separately for risk assessors and for risk managers. Answers to open-ended questions were categorized into groups according to key-concepts mentioned by the respondents. Because one answer from each respondent could include different key-concepts, it could also have been included in several of these answer categories. In such case the answer from one respondent is included several times in the analysis of that question and thus the percentages do not sum up to 100%.



### 2.3. Evaluation of risk assessment requests

To get a better understanding of the parameters that might be important in a risk assessment request, and therefore should be included in a request to ensure a valuable risk assessment, more than 500 original risk assessment questions (obtained from 182 mandates) were evaluated within the COMRISK project.

The EFSA Register of Questions (RoQ) database was analysed and used as a sole data resource since respective information from the partner countries was partially confidential and the available documents were not comparable with the documents regarding EFSA.

The RoQ database includes all published risk assessment mandates EFSA received since 2003. Information from risk assessment mandates and their related risk assessment questions that were submitted to EFSA with the question type "Article 29 – Scientific opinions" were extracted. This selection led to 1350 risk assessment questions. To ensure the best possible distribution within the different categories as requestors, number of risk assessment questions per risk assessment mandate, units, year of risk assessment request etc., a total of 503 risk assessment questions were randomly selected for further analysis.

The following sub-categories were used within the categories:

- Mandate requestor: European Commission, EFSA's Panel, EFSA, Member States and European Parliament
- Risk assessment questions per mandate: 1-95
- EFSA's Units: animal and plant health, biological hazards and contaminants, feed, food ingredients and packaging, GMO, nutrition, pesticides pesticide residues, Pesticide Peer Review, scientific committee & emerging risks
- EFSA's Output: non-scientific outputs, scientific panel or committee opinions, other scientific outputs, supporting publications
- Food sector area (in the following the official names of EFSA were used): animal by-products, animal diseases, animal welfare, BIOCONTAM - other areas, contaminants in feed, contaminants in food, contaminants in food and feed, data collection and analysis, dietary reference values, EFSA guidance documents, emerging risks, enzymes, feed additives – applications, feed additives – guidance, feed additives – others, flavourings, food additives, food allergens, food and feed consumption, food contact materials, food for specific groups, food hygiene, food manufacturing processes, food-borne zoonosis, GMO generic, GMO notification under directive (EC) 2001/18/EC (GMO), health claims other, micro-organisms, novel foods, NUTRI - other areas, nutrient sources, other substances Reg. 1925/2006, pesticide MRL, pesticide MRL application (Reg. 396/2005 - Art. 10), pesticide PPR panel, plant health, processing aids, RA methodology, SCER - other areas, TSE, upper levels vitamins and minerals
- Reception date - 01/01/2003 – 31/12/2017

Prior to the selection, all risk assessment mandates and risk assessment questions were checked for the availability of the according documents. In case these were missing, the respective mandate was excluded from the selection. Due to the smaller number of risk assessment questions from EFSA, Member states and European Parliament, all risk assessment questions from these requestors were selected and the residual number of risk assessment questions was distributed between risk assessment mandates from the European Commission and EFSA Panels. At least 50% of those selected risk assessment mandates included more than two risk assessment questions and at least 33 risk assessment questions per unit and 13 risk assessment questions per year were selected.



A webinar with all four project partners was arranged to interpret the results of the risk assessment requests in light of the other activities of the project. Moreover, discrepancies due to, for example, structural differences between the respective countries were discussed.

## 2.4. Analysis of historical food safety cases

Four historical food safety cases were evaluated regarding the interaction between risk assessment and risk management. Four incidents were selected based on their differences with respect to (i) agents (chemical, microbiological etc), (ii) type of risk questions, (iii) types of challenges, (iv) time scale, and (v) country involved. The cases selected were:

- Escherichia coli O104:H4 in fenugreek seeds and sprouts made thereof (2011)
- Dioxin in fish/fish meal from fat fish in Baltic sea (2007-2016)
- Phenylbutazone from horse meat fraud (2013)
- Chloramphenicol in pig meat (2012)

A summary description of each incident was prepared based on published literature, personal experience of consortium members and interviews and focused on the interaction between risk assessment and risk management. Thereafter, a webinar was arranged where the project partners aimed to reach consensus regarding the communication challenges identified in the food safety incidents analysed. Before the webinar, participants were instructed to read the brief description of the four type scenarios. In addition, they were asked to come up with, for each scenario, a preliminary answer to the following questions:

- What was the main communication challenge(s) in this incident?
- In what way did (efficient/inefficient) assessor-manager communication contribute to the progress of events (making things better or worse)?
- What is the main take home lesson from the incident, with respect to communication between risk assessors and risk managers?

For round 2

- What support do you have for your answers above (references, quotes)?

During the webinar, the moderator recapitulated the incident. Thereafter, a structured discussion took place with the goal to reach a consensus regarding each question, or if that was not possible, a set of alternative answers.

In the first round of discussion, one participant per partner organisation presented the answers from their project team without giving out sources. In a second run, after hearing the answer of the others, the participants were asked to either stick to their first answer or modify it based on what the others had said. In this round, participants were asked to present whatever support they have for their opinion (e.g. conclusions from a report, quotes from interviews). In the final round, the participants were asked to rank the remaining answers. In some cases, the answers converged faster than anticipated and some deviations from the format was allowed.

## 2.5. Identification of procedural constraints and regulations

### 2.5.1. Review of guiding documents

National authorities in the participating countries were requested to provide the project with the documents guiding their interaction with their risk assessing and/or risk managing counterparts and, when applicable, the communication between risk assessors and risk managers. The national authorities were asked to provide:

- Documents describing the risk-analysis process
- Documents describing routines for risk assessment and risk management
- Documents describing the interface between risk assessment and risk management
- Routines and/or agreements for communication with external assessors and /or managers.

It was specified that the project is interested in information on communication in guidance documents at both national and international level as well as agreements and internal procedures and policies. The documents were briefly described by the respective consortium partner since most guidance documents were in the local language. In order to extract the information of interest from the national documents a set of questions was prepared (Appendix B). In addition, SVA analysed documents from CAC, OIE and FAO/WHO which were frequently referred to by the national authorities, either when asked for documents or inside the documents. During the synthesis phase, additional documents were identified which were appended to the list.

### 2.5.2. Webinar: constraints for communication

To summarize the information from the guidance documents, risk assessment requests, and case analysis with respect to potential limiting factors for the communication between risk managers and risk assessors, a webinar was organized with the project partners. The webinar focused on four questions, which were presented by the moderator at the beginning of the workshop.

- Are formal regulations (laws) a limiting factor for the communication between risk assessors and risk managers?
- Are formal agreements between authorities a limiting factor for communication?
- Are informal agreements “unwritten laws” a limiting factor for the communication?
- Based on the statement above, what are the main challenges for an efficient and transparent risk analysis?

During the discussion each participant was asked to present their view. The moderator was driving the discussion forward using prepared “injects”.

## 2.6. Identification of tools for the communication between risk assessors and risk managers

Relevant tools could facilitate the communication between risk assessors and risk managers. Tools were identified based on a previously conducted EFSA-supported project (EFSA/SCOM/01/2013). This review evaluated available tools for the ranking of food-related hazards based on risks for human health (van der Fels-Klerx et al. 2018). The authors briefly outlined the scope, application area, approach followed, and strengths and weaknesses of each tool. The tools were reviewed again but now focussing on their use by risk managers. Eleven categories of tools were evaluated and discussed with all consortium partners in a webinar.

Within the review, Multi-Criteria Decision Analysis (MCDA) was identified as a suitable tool for considering the different dimensions of food safety decision making while considering the interests and priorities of key stakeholders. Risk assessment results are usually very detailed and comprehensive but socio-economic aspects are typically not quantified. In addition, it is often unclear how the risk manager weights the various aspects amongst each other to make a final decision. Such an evaluation can be made using MCDA. To illustrate the usefulness of MCDA to risk management, the method was applied to one of the historical food safety incidents (i.e., dioxin in fish in Sweden and Finland 2007-2015) following the PROMETHEE method (Brans et al., 1986). In short, the method is based on a pairwise comparison of alternative risk management options over each criterion. There are several steps to be followed:

- defining the decision problem and identifying key stakeholders
- identifying the alternatives (list of potential risk management interventions to be compared)
- defining the criteria (the attributes against which the options should be judged) as well as deciding how performance on these criteria will be measured
- constructing a performance matrix: measuring the performance of each option on each criterion, determining the preference functions (deciding how much better an option has to be in a specific criteria in order for it to be preferred to an alternative), and determining the importance of each of the criteria to the decision maker (i.e. preference weights)
- ranking the alternatives (comparing the alternatives within each criterion and producing the overall ranking across the entire matrix)

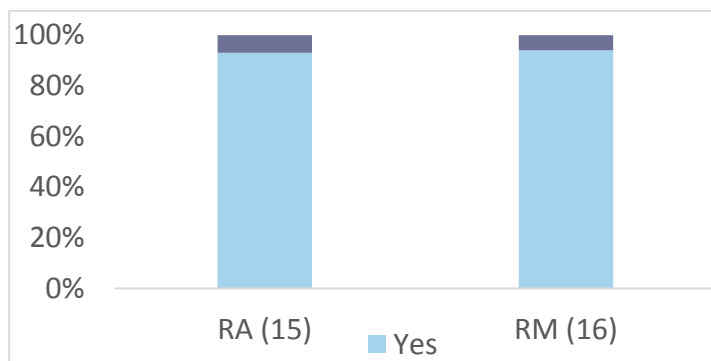
### 3. Results

#### 3.1. Interviews

##### 3.1.1. Interview results

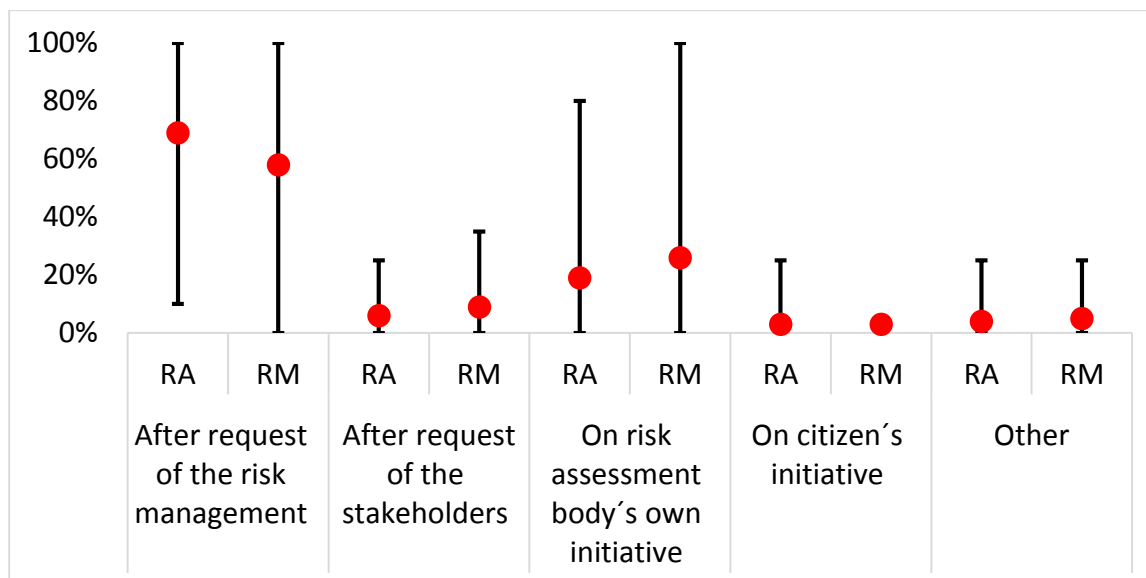
Communication between risk assessment and risk management is a necessity that should cover the whole risk analysis process and should enhance risk communication practice. As defined by Codex Alimentarius, there should be a functional separation of risk assessment and risk management to the degree practicable, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest. This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased and transparent. However, it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application. An open dialogue between risk managers and risk assessors is also critical to build trust in the risk analysis process.

Independency is an essential principle of risk assessment process. The independence of risk assessment was guaranteed according to almost all respondents, for both risk assessors and risk managers (Fig 1). It was asked in an open-ended question how the independency was guaranteed: the respondents mentioned organizational division and separate roles (38% of risk assessors and 40% of risk managers), transparency of the process (38% and 7%), legal determination (25% and 27%), and conduct of risk assessments independently (19% and 33%, respectively). 71% of risk assessors and 80% of risk managers agreed that their country has a national risk assessment policy or strategy.



**Figure 1.** Multiple choice question (yes/no): Is the independence of the risk assessment guaranteed? RA: risk assessors, RM: risk managers.

According to all respondents, risk assessment projects usually start by a request from risk management (Fig. 2). Risk managers use risk assessment mainly for decision making and creating consumer recommendations or instructions for safe use of foodstuffs. Thus, the ultimate goal for the risk assessment process is to get an answer to the question set by risk management and the answer would be in the form that risk managers could use it as such for creating a management decision. When measures that would promote an efficient conduct of risk assessment were asked during interviews, risk managers most commonly mentioned good availability of data (53% of risk managers) and good communication between risk assessors and risk managers (53%). Risk assessors highlighted these as much as 44% and 31%, respectively. Other important things that both parties mentioned were standardised guidance for the risk assessment process and a clear goal of the risk assessment.



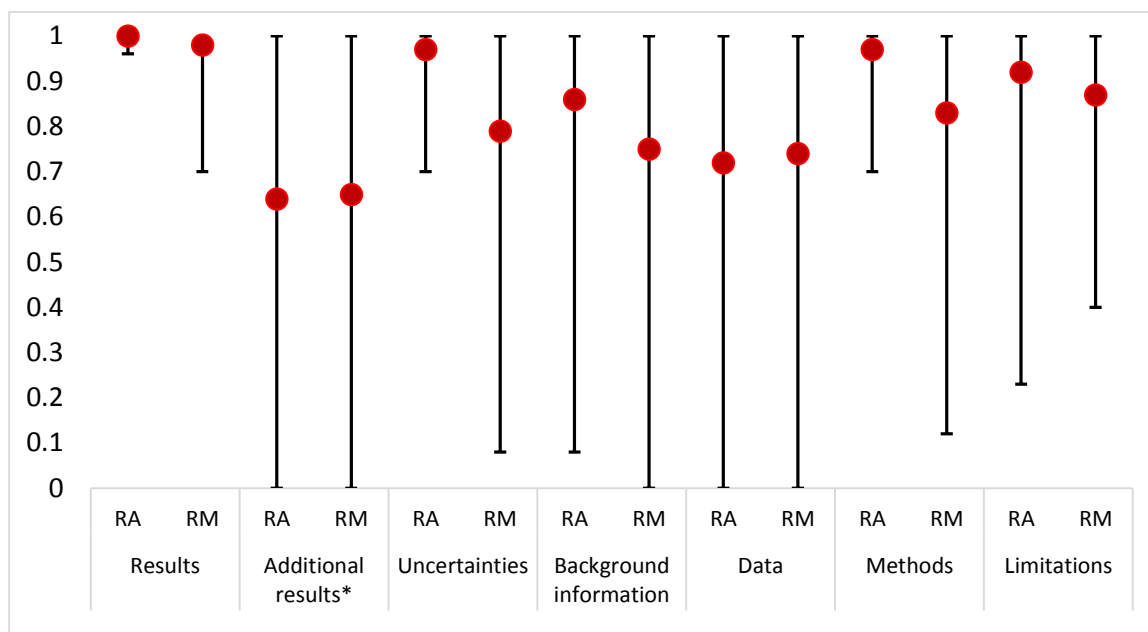
**Figure 2:** Slider rating scale question 0 (never)-100% (always): How do the risk assessment projects start? The mean answer of risk assessors (RA, n=15) and risk managers (RM, n=15) is marked with a dot, and the range of answers with a black line.

According to the interviews, the basic reason why the risk assessment process does not often reach its goal is already seen at the very first step in the process: setting the risk question. When asked, whether risk managers are able to describe their needs for risk assessments clearly and in the way that risk assessors understand what they need, 69% of risk managers found that they were able to do that, whereas 42% of risk assessors agreed. It was also asked if there are problems in mutual understanding when risk managers describe their needs to risk assessors, and most of the respondents agreed to this. When asked with a slider rating scale question (0-100%) how often this occurred, the mean answer for risk assessors was 34% and for risk managers 43%. Risk managers may not have the expertise to set the question by themselves at least for three reasons: 1) risk managers do not know which kind of questions can be answered with risk assessment, 2) the problem, where the answer is needed, is not well-defined and thus perceiving the question is demanding, 3) risk managers do not know what kind of data is available and if it is suitable for answering the risk assessment question. Most of the respondents were saying, that there exist cases with understanding problems. The best solution for how the framing of the risk assessment question could be eased was an open and two-way dialogue between risk assessors and risk managers to understand the goal of the assessment according to 46% of risk assessors and 73% of risk managers.

According to most respondents, the risk assessment questions may change during the process. This can be a sign of poorly phrased questions, but also of the flexibility of the process and an interactive communication between risk assessors and risk managers. The most common reason for a change was that risk assessment questions do not work anymore due to new information available, thus leading to the modification. Other important reasons according to risk assessors were getting the risk assessment question more precise, lack of data and other relevant information, and that the question cannot be answered as such.

At the end, risk assessment answered the exact question posed by risk management rather well, but not completely. The main reasons for the answers not being exactly in line with the questions were traced back to the unsuccessful risk question setting and secondly, to lack of data. Sometimes information needed or requested have not been provided in the final risk assessment. In those cases, the missing information has been quite well justified and risk management has accepted the reason for missing information, according to both parties. It was asked in a slider rating scale question which

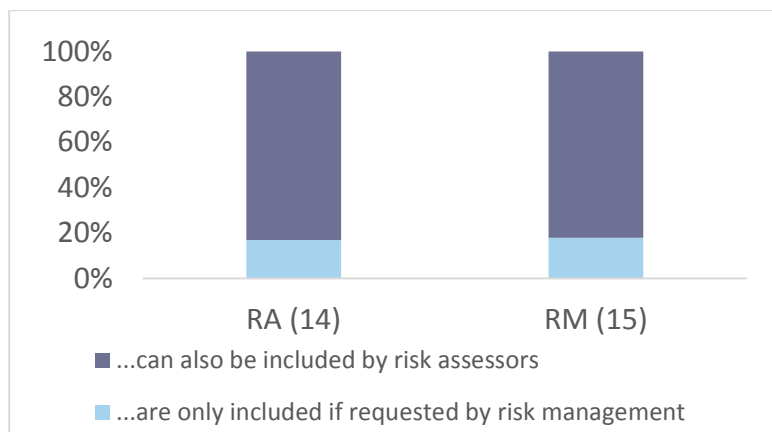
parts of risk assessment are communicated to the requestor. The mean answers about communicated parts of both risk assessors and risk managers were similar, but a remarkable variation within groups was observed (Fig. 3).



**Figure 3:** Slider rating scale question 0 (never)-1 (always): Are following items communicated to the requestor? The mean answer of risk assessors (RA, n=15-16) and risk managers (RM, n=14-16) is marked with a dot, and the range of answers with a black line. \*Additional results: results not directly answering to the risk assessment question but produced in the process.

When asked in a slider rating scale question (from 0=never to 1=always) if communication between risk assessors and risk managers is required for interpretation of the risk assessment results, the mean answer of all respondents was 0.6. In an open-ended question asking for details that particularly needed further assistance, most commonly mentioned answers were about understanding the scientific details of the risk assessment report (79% of risk assessors and 44% of risk managers) and understanding its results (50% and 50%, respectively).

Most respondents (81%) agreed that a risk assessment may include risk management options. The respondents mentioned evaluating the effectiveness or the impact of management decisions, recommendations for specific actions, effect of changes in legislation, comparison of strategic options and scenarios for acceptable exposure levels and corresponding measures as possible risk management options. Most respondents also thought that management options can be included by risk assessors, and not only when requested by risk management (Fig. 4).



**Figure 4:** Multiple choice question: When risk management options can be included in the risk assessment, they... RA: risk assessors, RM: risk managers.

The impact of uncertainty of risk assessment results to risk management was asked in an open-ended question. Most important impact according to 33% of risk managers and 30% of risk assessors was the impairment of value of risk assessment in decision making. Other impacts mentioned were difficulties to choose the adequate risk option (40% of risk assessors and 13% of risk managers) and difficulties to estimate the effectiveness of the chosen option (27% of risk managers).

The respondents were asked to give an example of a case where the communication between risk assessors and risk managers worked in an optimal way and to describe the reasons leading to success. According to risk managers, the main reason was a well-working communication during the whole risk assessment process (71%). According to risk assessors, a clearly formulated risk assessment request (67%) and a quick agreement about the direction of the risk assessment (50%) were the main reasons. In addition, a smooth ongoing risk assessment process (33% of risk assessors and 7% of risk managers), knowing each other roles in the process (17% and 7%), and a well-expressed answer (17% and 7%) were mentioned among other things.

It was also asked to give an example of a case where the communication between risk assessors and risk managers did not work in an optimal way and to describe the main challenges in this situation. According to risk managers, the main reasons for the challenges were the lack of communication (46%) and a disagreement about its results (31%). Shared reasons mentioned by both risk assessors and risk managers were different priorities (22% of risk assessors and 23% of risk managers), unclear roles (22% and 8%), challenges in the communication (11% and 15%), and problems related to staff (22% and 8%, respectively). According to risk assessors, also unclear formulation of the risk assessment question, lack of time, and challenges with the data were mentioned.

The level of understanding of risk assessment among risk managers can impact the formulation of risk questions. Therefore, some risk assessment training tailored to risk managers might help in improving the dialogue.

### 3.1.2. Limitations of the interview study

The process of conducting the interviews was also reviewed and several aspects to improve the questionnaire and the interviews were identified. The need for a harmonized way of conducting the interviews in different countries by several interviewers and analysing the answers was found necessary.

The questionnaire was relatively long because it was covering the whole risk analysis process. During the interviews and while analysing the answers, it turned out that some of the questions were either



less useful, difficult to answer or out of the exact scope of this study. Thus, according to this pilot study we can recommend a modification of the questionnaire for interviews if it will be used again. Secondly, the interviewers need to be trained with the questionnaire to conduct interviews in a harmonized way. Thirdly, it is important to get a mutual understanding of the interviewing method and the way the answers are going to be given, and how precisely answers are going to be translated. Using a recorder and a common web-based questionnaire form to save the answers during the interviews is recommended.

### 3.1.3. Insights for risk communication

Due to the limitations of this interview study material, strong and specific recommendations cannot be made; only rather preliminary recommendations or tips for general use to support risk managers and assessors are formulated. More research is needed to identify the barriers for communicating effectively. However, the obtained results can help developing approaches based on best practices and underlying further research needs on risk communication capacity building in food safety among risk assessor and risk managers.

- The mandate given by risk managers to risk assessors should be as clear as possible. It is encouraged to do this in written. The document could be non-public, for internal use only. It would be recommendable to have data sources available. The mandate should be explained by the risk managers to the risk assessors in a personal meeting.
- The risk assessment policy established by risk managers in advance of risk assessment, in consultation with risk assessors could contain also principles of risk communication, taking into account the roles of risk assessors and risk managers, while guaranteeing their independence. This could be a national or EU -level public document.
- An open and transparent two-way dialogue is important. Openness and transparency are crucial to good risk communication practice. This also enhances comprehensibility, effectiveness and usability of risk assessment. The two-way dialogue preferably should be done by personal communication (phone or physical meeting). A physical meeting should at least be held at the start and end of the assignment, and in case of a large assignment also half-way.
- Where there is uncertainty, such as outlining any data gaps or issues related to the methodology and models, it should be acknowledged and described properly, by risk assessors to risk managers. This understanding is essential to maximize the effectiveness of communication. Risk managers should take the responsibility of the decision they are making, being aware of the uncertainty it includes. It is important to communicate early, often and regularly. Ensure enough time for risk communication.
- Risk assessors and risk managers need to build and maintain a trustful relationship as it is essential for an effective risk communication. Trust can be easily eroded or lost through ineffective or inappropriate communication. Listening and seeking understanding together helps to build trust.
- Collect regularly feedback (e.g. after every risk assessment process) about risk communication from both parties; risk assessors and risk managers. Fine tune risk communication according to it.

## 3.2. Evaluating risk assessment requests

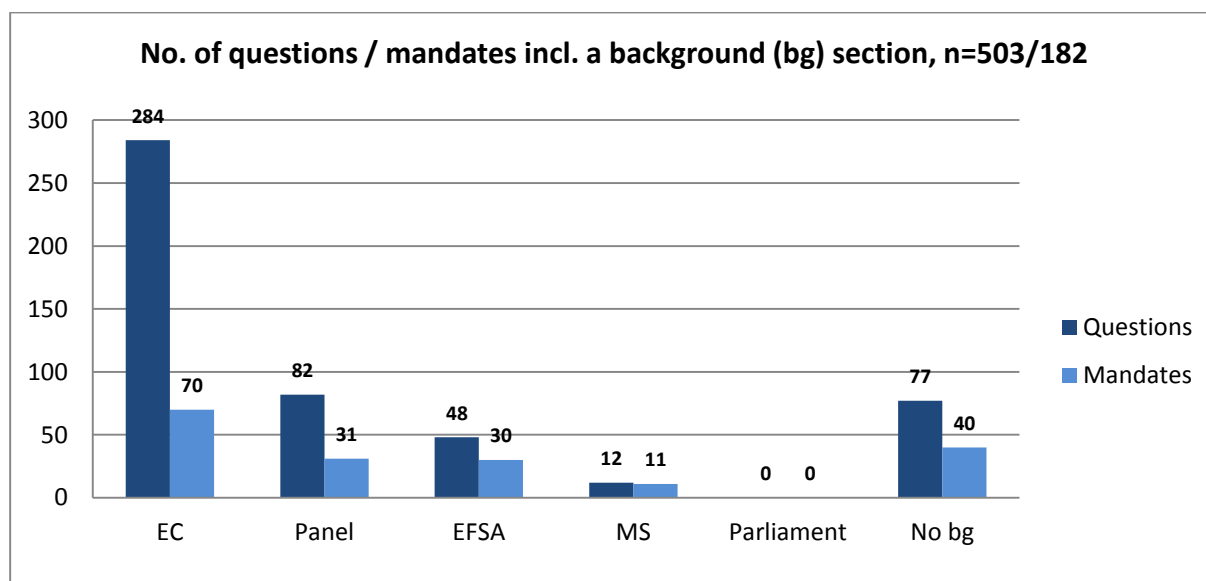
Besides general knowledge on structural and scientific parameters of more than 500 risk assessment questions (obtained from 182 mandates), it was investigated whether management strategies have been already requested in the frame of the mandate. Further, causal relations based on the background of the requestor and other parameters were evaluated.

### 3.2.1. Structure

In EFSA's scientific advice by its scientific committee regarding approaches to enhance EFSA's responsiveness to urgent questions, it is stated that risk assessment requests should contain clearly defined terms of reference including the scope of the request and a relative background (European Food Safety Authority 2007). That is why all analysed mandates were screened to see whether they contain at least one of these contents.

#### Background (BG)

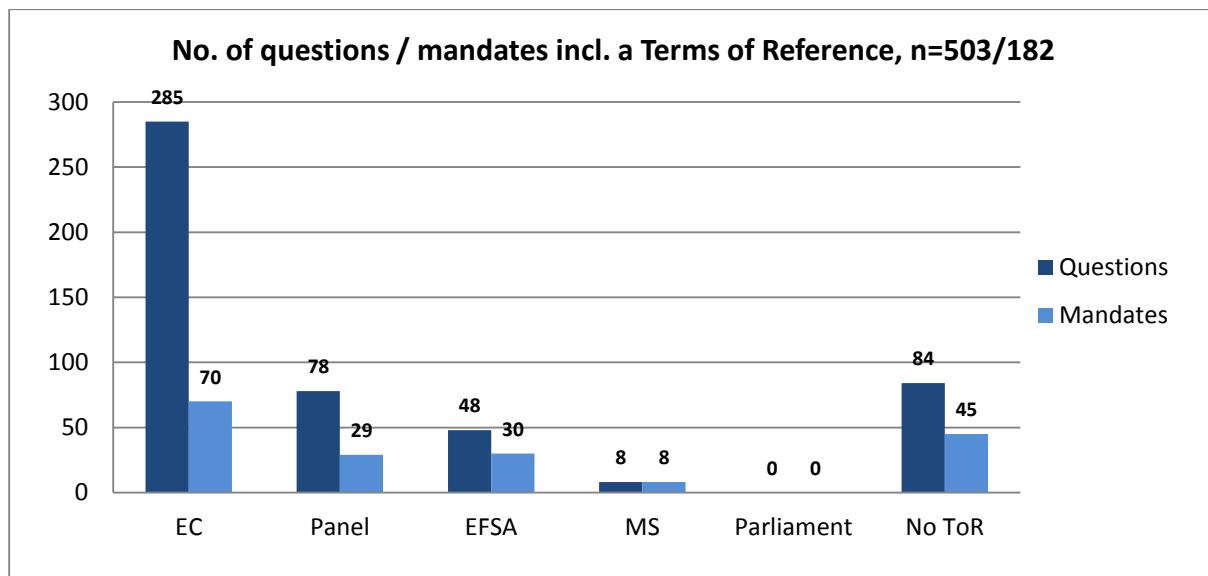
The analyses of the 182 selected mandates revealed that 142 of those include a background section. Of those, 70 were submitted by the European Commission (Fig. 5). From the remaining 40 mandates that did not include a background, 27 originated from the European Commission (data not shown).



**Figure 5:** Number of mandates including background (bg) per requestor

#### Terms of reference (ToR)

137 of the 182 mandates included a Terms of reference (ToR) section (Fig. 6). The distribution of mandates including a ToR section per requestor was similar to those including a background section (Fig. 5). 27 of the remaining 45 mandates that did not include a ToR section were submitted by the European Commission, one by EFSA, nine by Member States, six by one of EFSA's panels and two by the European Parliament (data not shown).



**Figure 6:** Number of mandates including a Terms of reference (ToR) per requestor

### 3.2.2. Management strategies

The analysis of the 182 mandates revealed that only nine included a request for management strategies. Seven of these nine mandates were submitted by the European Commission, the remaining two mandates originated from one of EFSA's panels (Table 1). From these nine mandates three concerned the animal and plant health unit, two GMOs, two the Scientific Committee & Emerging risks unit, one Food ingredients and packaging, and one biological hazards and contaminants (data not shown).

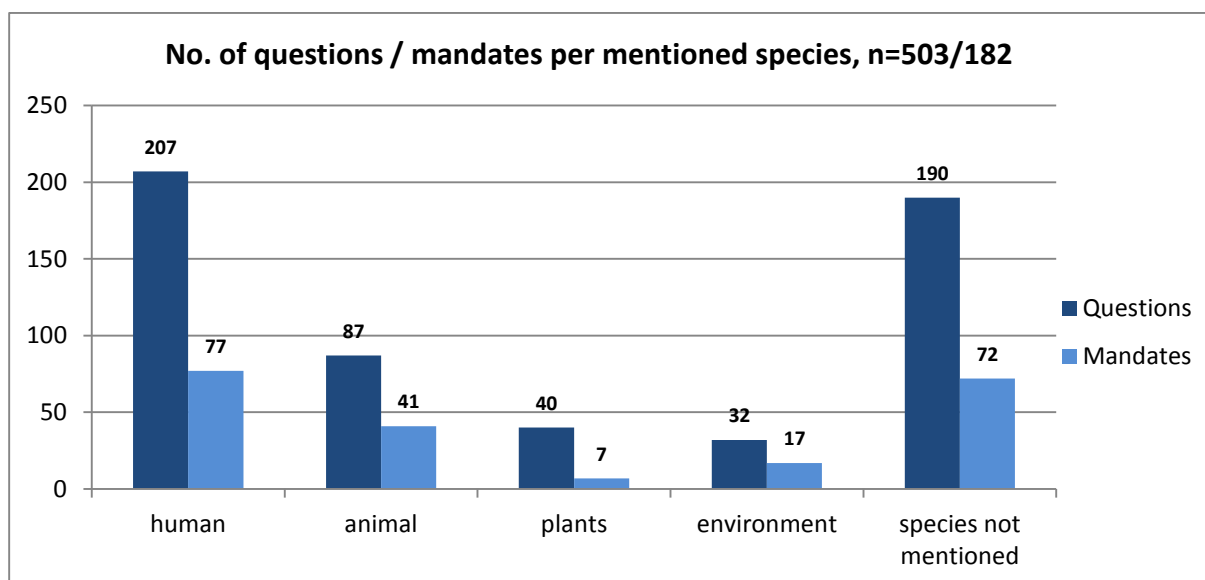
Evaluation of the mandates also showed that three mandates already proposed a potential risk management strategy (Table 1). One of each of those mandates was submitted by the European Commission, an EFSA's Panel or the European Parliament. In mandate M-2009-0144 for instance, the European Commission proposed to include *Ambrosia spp.* seeds in the annex of Directive 2002/32/EC on undesirable substances in animal feed to reduce their presence in bird feed (European Commission 2002).

**Table 1:** Number of questions / mandates mentioning risk management (RM) strategies, n = 503/182

	RM strategy requested		RM strategy proposed	
	Questions	Mandates	Questions	Mandates
<b>EC</b>	40	7	3	1
<b>Panel</b>	3	2	2	1
<b>EFSA</b>	0	0	0	0
<b>MS</b>	0	0	0	0
<b>Parliament</b>	0	0	1	1
<b>No RM</b>	460	173	497	179

### 3.2.3. Mentioned species

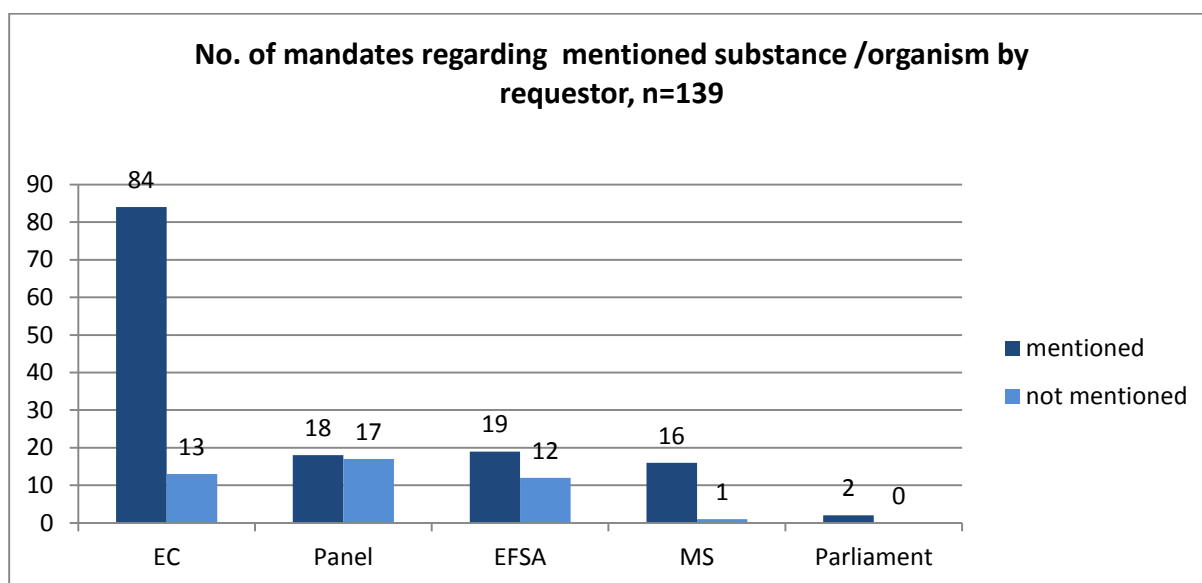
Within the selected 503 questions, 190 did not mention an affected species. These questions originated from 72 mandates. Many of these mandates regarded an update of guidance documents, guidance for applicants and updates of former scientific opinions (Fig. 7). From those mandates without mentioning of the affected species, 31 originated from the European Commission, 21 from EFSA, 16 from one of EFSA's panels and four from Member States. Many of the remaining 110 mandates mentioned more than one affected species (24 mandates). A great number of these mandates regarded human health (77 mandates) and animal health (41 mandates; Fig 7).

**Figure 7:** Number of questions per mentioned species

### 3.2.4. Concerned substance/organism

Within the selected 503 questions, 164 did not specify the concerned substance or organism to be evaluated. These questions originated from 43 mandates. Similar to chapter 3.2.3 many of these mandates regarded guidelines, updates of former scientific opinions, and also general welfare (Fig. 8). From those mandates not mentioning the concerned substance or organism, 13 were submitted by the European Commission, 12 by EFSA, 17 by one of EFSA's panels and one by a Member State. Also 22 of those 43 mandates did not mention a specific species.

Most of the 139 mandates that mention a specific concerned substance or organism to be evaluated originate from the European Commission (84 mandates). There was no noticeable difference detectable in the origin of the mandates between Panel (18 mandates), EFSA (19 mandates) and Member states (16 mandates). Both analysed Parliament mandates mentioned a specific organism.



**Figure 8:** Number of questions/mandates mentioning the concerned substance or organism per requestor

### 3.2.5. Insights regarding risk assessment requests

The evaluation of 182 risk assessment requests showed that only 5 % of them included a request for risk management strategies. In 1.7 % of the analysed risk assessment requests management strategies were already proposed. Risk management strategies are therefore predominantly not part of the risk assessment requests received by EFSA.

Regarding important parameters included in risk assessment requests, analysis showed that a large number of these requests have a similar structure. 75 % of the mandates included sections dedicated to the background and the terms of reference that included the scope of the request. Since the scope of the risk assessment requests sent to EFSA varies, it appeared difficult to determine the important parameters for every risk assessment request. For example, no species was specified if the scope is a general request or an update of guidance documents.

In 2007, EFSA published a scientific advice by its scientific committee regarding approaches to enhance EFSA's responsiveness to urgent questions. There it was stated that risk assessment requests should contain clearly defined terms of reference including the scope of the request. Also, a relevant background should be included as well as a deadline for EFSA's response (European Food Safety Authority 2007).

Since 75 % of the risk assessment requests received by EFSA already contain a terms of reference and a background section, it appears that EFSA's scientific advice is already noted by the requestors (European Food Safety Authority 2007). Since 68 % of all the risk assessment requests received by EFSA in the years from 2003 to 2017 have ended in a journal publication, the general structure of the requests appeared to be good.

For future risk assessment requests, it should be stated that a uniformly structured mandate including a cover letter, background and, especially, a terms of reference section in the risk assessment request is important. This will result in a mandate that will support the risk assessor better to provide the information needed by the requestor.

### 3.2.6. Webinar on Risk assessment requests

The main focus of the webinar was the presentation of the data regarding the descriptive and structural parameters of risk assessment requests that were sent to EFSA. Additionally, results from the questionnaire were included in the presentation and evaluated with regards to the findings from the analysis of the risk assessment requests. Findings and discrepancies between the risk analysis process at European level (EFSA risk assessment requests task 2.1) and national level (questionnaire) were discussed.

The analysis showed large differences in the number of questions in the analysed years between 2003 and 2017. Discussions with the COMRISK consortium led to the notion that political and electoral cycles could be important in relation to the number of questions. Especially the animal and plant health unit had particularly high numbers of questions in 2014 and 2017. A hypothesis generated within the discussions of the webinar was that specific outbreaks could be responsible for these numbers. For example, there were African Swine Fever outbreaks in Europe both in 2014 and 2017.

The analysis of the risk assessment requests sent to EFSA showed that management strategies are predominantly not part of risk assessment requests. Data obtained with the interviews, however, revealed that 60 % of the interviewees encountered information on management strategies in risk assessment requests. 50 % of those even encountered proposed management strategies. These results lead to the understanding that the inclusion of management strategies in a risk assessment request is more common on a national level compared to the requests that EFSA received.

## 3.3. Description of historical food safety cases

For each of the four food safety cases relevant information about the communication was summarized and based on that preliminary set of challenges for communication between risk assessors and risk managers were listed for each of the cases (Table 2). During the workshop in connection with the COMRISK midterm meeting in Berlin an additional casework was conducted (MCDA) based on the dioxin in fish crisis incident.

Table 2. Summary of properties and challenges related to the four food safety incidents.

Incident	Properties	Communication challenges
<i>E. coli</i> O104:H4 in fenugreek seeds and sprouts made thereof (2011)	<p>Ongoing outbreak</p> <p>Risk assessors investigate the origin of the Hemolytic–uremic syndrome outbreak.</p> <p>The outbreak investigation points out foods with increased risk.</p> <p>Initial “risk estimates” comes with large uncertainty</p> <p>Different risk managers (central/local, between countries) take different precautionary measurements</p>	<p>Did local risk managers misunderstand scientific evidence and its associated uncertainty? (Spanish cucumbers being on the “suspected list” based on epidemiological data was misinterpreted and understood as if the organism was detected).</p>
Dioxin in fish/fish meal. Sweden & Finland (2007-2015)	<p>When EC set limits for dioxin (EC (no) 2375/2001) fat fish from the Baltic region were above limits. Sweden and Finland got a temporary derogation</p> <p>In 2007 the NFA, and other authorities, was commissioned to evaluate the derogation.</p> <p>Based on assessment of dioxin hazard and health benefits, the assessment did not judge a continued derogation as beneficial. Government decides to ask for permanent derogation, taking into account the consequence assessment from the board of fisheries. The decision has been controversial.</p> <p>In Finland, the decision to continue the derogation was based on the decreasing trend of Baltic fish consumption as well as the results of national risk-benefit assessment and risk assessment. The fish in the Gulf of Finland had lower dioxin levels than measured in Sweden, and the portion size was also smaller in Finland than in Sweden. Thus, the decision and the fish consumption recommendation have not been found controversial in Finland.</p>	<p>How can we support rational and transparent decision making when consequences are on very different scales (health, economy, traditions, local production etc)?</p>
Phenylbutazone through from horse meat fraud. (2013)	<p>Large scale fraud where horse meat was sold as beef</p> <p>Horse DNA was found in beef burgers</p> <p>Investigations in 15+ MS, at least 7 affected.</p> <p>Phenylbutazone is used for non-food-producing horses. May be fatal to humans.</p> <p>During the scandal EFSA conducted RA.</p> <p>Phenylbutazone in meat is a very low concern risk</p> <p>Despite this massive recalls and huge financial losses.</p>	<p>What is a balanced response when the main concern is ethics rather than food safety?</p>
Chloramphenicol in pig meat in Sweden (2012)	<p>Broad spectrum antibiotics</p> <p>Banned in food production due to side effects</p> <p>Detected in urinary samples from slaughter ready pigs</p> <p>Low levels detected in meat</p> <p>Media response, restrictions to farm</p> <p>No indication of illegal use or accidental contamination</p> <p>Tracing points at natural contamination of feed in field, by actinomycetes</p>	<p>What is a balanced response when trace levels of a “zero-tolerance” substance are detected and there is no suspicion of crime?</p>



### 3.4. Webinar on historical food safety cases

During the webinar the following challenges, consequences and take-home lessons were identified regarding the communication between risk assessors and risk managers during the four food safety cases studied in the project.

- ***E. coli* O104:H4 in fenugreek seeds and sprouts made thereof (2011)**

- **Main challenge:** A major problem was the erroneous statement about Spanish cucumbers being the source of the outbreak. The cucumbers were on the suspect list, based on epidemiological indications. However, when pointed out by local authorities, it was claimed that the pathogen had been isolated. Our interpretation is that local risk managers, not necessarily familiar with epidemiological investigations, misunderstood and overinterpreted information. In combination with time pressure and the severity of the outbreak, the lack of coordination and communication between authorities resulted in the misunderstanding whereas the correction – especially in public media - took time.

**How did efficient/inefficient communication affect the outcome:** Inefficient communication, a result of a lack of a coordinated approach, made the outcome worse by prolonging lead time to respond to the crisis.

- **What is the main take home lesson from the incident?**

The need for coordination (task force-type for this kind of situation) and the importance of double-checking that information from risk assessment is not misunderstood. The first may contribute to the latter.

- **Dioxin in fish (2007-2016)**

- **Main challenge:** The decision is based on a mix of health effects (risks and benefits) and other non-risk assessment-related factors which are on very different scales (health, economy, traditions, local production etc.)
- **How did efficient/inefficient communication affect the outcome:** There was an efficient communication between risk assessors and risk managers, but a non-transparent management decision was made which resulted in uncertainty (lack of information) on how the weighing of different factors was done. This resulted in distrust between authorities and caused a communication problem towards the public. The slight differences in the risk assessments and management decision between Sweden and Finland contributed to the communication problem towards the public.
- **What is the main take home lesson from the incident?** The experience from the communication varied between the countries. There may be a need for improvement in transparency of the risk analysis process, including the risk management. There should be a clearer communication between risk managers and risk assessors about aspects that need to be considered from the beginning. There is also a need for coordination between countries when results of risk analysis are presented, for the sake of maintaining trust.

- **Phenylbutazone through from horse meat fraud (2013)**

The case was discussed at EU level, without focusing on a Member State.

- **Main challenge:** There was no risk assessor-risk manager communication challenge. Rather, the real challenge with this case was the fact that it concerned food fraud of which the actors were not used to deal with.
- **How did efficient/inefficient communication affect the outcome:** The crisis was managed with a well coordinated approach, and clear information with all the MS together. Information was distributed to member states. However, Member States were not prepared for such a large -scale fraud.
- **What is the main take home lesson from the incident?** There is a need for a plan to deal with food fraud in every country including the communication between risk assessing and risk managing bodies.

- **Chloramphenicol in pig meat (2012)**

- **Main challenge:** The legal basis of the zero-tolerance level gives no room for contextualization. Timing was also an issue as it occurred just before Christmas.
- **How did efficient/inefficient communication affect the outcome:** There was efficient communication between risk assessors and risk managers. Both the risk assessing and risk managing authorities knew that the problem was caused by the zero-tolerance. An ad hoc group was created to minimize the economic consequences.
- **What is the main take home lesson from the incident?** It is necessary to be prepared for holiday season crises. The crisis team proved useful for managing the situation. a trend towards lower limits of detection there should be a review of applicability of zero-tolerance legal basis for contexts where no crime is suspected.

### 3.5. Assessment of guiding documents

Guiding documents were collected from the participating countries following requests to risk assessing and risk managing organizations. The documents included laws, guidance documents from international organisations, such as the CAC procedural manual (FAO and WHO, 2019), and agreements between authorities. The documents provided by each partner are listed in a spreadsheet {3.1A List of regulatory documents}. In most of the documents little (or no) information was given relating to the communication between risk assessors and risk managers. As the documents were in different languages, the content of were analysed using a questionnaire. The form used to extract information, and the summary of the information concerning risk-communication are found in appendix B and C respectively.

The documents identified, point out that risk assessment and risk management are separate tasks. The documents do not suggest that there are strong formal constraints preventing efficient communication between risk assessors and risk managers. In general, the description in the national documents is not very extensive and there are differences between authorities and countries when it comes to how detailed the protocols for communication are. The meaning of functional separation is well described in the FAO food safety analysis (FAO 2017)

“In practice, “functional separation” means that risk managers and risk assessors have different jobs to do, and they each need to do their own jobs. Risk managers must avoid the temptation to “guide” the risk assessment so that it supports a preferred risk management decision, and risk assessors must assemble and assess the evidence objectively, without being influenced by risk management concerns such as economic benefits of an activity, costs of reducing exposure or consumer perceptions of risks.”

The documents from (FAO and WHO 2006) and Codex Alimentarius commission (CAC) (FAO and WHO. 2019) stressed the importance of strong communication between risk assessors and risk managers and CAC describes risk analysis as an iterative process where the two parts have a frequent communication. This is also stressed in the “General food law” (EC 178/2002).

The guiding documents all agree that the dialogue leading to setting the risk question is part of risk management. In EFSA’s guidance on health risk-benefit assessment (reference) it is stated that “Problem formulation is the responsibility of the risk-benefit manager and preferably should be conducted in dialogue with the risk-benefit assessor to ensure that the outcome, i.e. the formulated Terms of Reference, is appropriate for the risk-benefit management goals (EFSA 2010), In the FAO generic framework for risk management (FAO/WHO 2007), the process of identifying the appropriate risk question(s) is part of the “Preliminary risk management activities” and it is stressed that During this preliminary phase, good risk communication is important. It should be noticed that “problem formulation” does not unambiguously refer to a risk management activity. In the PROMETHEUS 4-step approach for evidence use in EFSA scientific assessments (EFSA 2018), problem formulation refers to the first step of the risk assessment, where the problem formulated by the risk manager is further assessed and sub problems are identified.

### 3.5.1. Webinar constraints and regulations

During the discussion each participant was asked to present his view. During the discussion the moderator was driving the discussion forward using prepared “injects”.

#### **Question 1: Are formal regulations (laws) a limiting factor for the communication between risk assessors and risk managers?**

Participants from all project partners stated that there are no formal constraints for interactions between risk assessors and risk managers in their country. The CAC procedural manual (FAO and WHO. 2019) is often referred to but that document states that there should be a functional separation. It does not exclude that the same person performs the two tasks. In the “EU Food Safety Almanac” published by the BfR (2017), each country of the EU provides an overview of public institutions in the area of food and feed safety (BfR 2017). In the Netherlands, law prescribes that the risk assessment activities of the Netherlands Food and Consumer Product Safety Authority should be independent, but in practice it is not a limiting factor. Typically, the parties work together, and the formal separation do not put constraints to communication. However, although risk assessors and risk managers are in different organizations and buildings, this does not impose a constraint for interacting.

#### **Question 2: Are formal agreements between authorities a limiting factor for communication?**

Again, there does not seem to be formal agreements preventing interactions. In Sweden there is a formal agreement between SVA and the board of agriculture. This agreement regulates how things should be done but rather serves to facilitate the communication than constraining it. In the Netherlands there is a Front Office receiving requests. This virtual institute forwards the questions to the right risk assessing institute depending on the topic. This adds an additional step, which, for the

better or worse, makes the process more structured, but does not constrain the communication with the risk manager.

In response to an inject asking whether risk assessors may, for example, take part in a cost benefit assessment, it was noted that it might be allowed in all, but rarely takes place. Nevertheless, in Germany the BfR is not including cost-benefit analysis in risk assessment outputs. However by law it is not strictly defined that risk assessors are not allowed to assist in, conduct or include a cost-benefit analysis within risk assessment or its output. Furthermore, it was noted by all consortium partners that risk assessors may not have the experience and competence for such an analysis additional to a traditional risk assessment. In Finland, cost-benefit analyses have been part of projects, but then they have been conducted in other institutes than Ruokavirasto.

### **Question 3: Are informal agreements and “unwritten laws” a limiting factor for the communication?**

This does not seem to be the case, in general. In Sweden, at SVA management strategies inclusion is about the risk question. The interviews suggest that risk assessors inside the Swedish National Food Agency may be more reluctant to discuss management strategies and avoids giving advice as part of their assessments. They may however include the as scenarios for calculation e.g. reduction of risk.

## **3.6. Tools for communication**

### **3.6.1. Review of tools**

Effective tools are required to facilitate the interaction between risk assessors and risk managers since the final decision of the risk manager depends on how the risk assessment results are interpreted. The procedural manual of Codex Alimentarius Commission (2013) states that risk communication should:

- Promote awareness and understanding of the specific issues under assessment during the risk analysis;
- Promote consistency and transparency in the formulation of risk management strategies;
- Provide a basis for understanding the proposed risk management decisions;
- Improve the overall effectiveness and efficiency of the risk analysis;
- Strengthen working relationships among participants;
- Raise public understanding of the decision-making process for enhancing public trust and confidence in food safety along the supply chain;
- Promote the appropriate involvement of all interested parties; and
- Promote information exchange regarding the concerns of stakeholders about food safety risks.

In light of these purposes for communication, the suitability of available risk analysis tools (van der Fels-Klerx et al., 2018) for the interaction between risk assessors and risk managers is discussed.

## 1. Risk assessment

Risk assessment, which consists of hazard identification, exposure assessment, hazard characterization, and risk characterization, aims at estimating the risk for human health associated with the presence of certain hazards in food products, and in relation to total food consumption. As van der Fels-Klerx et al. (2018) stated, risk assessment is the most precise method to estimate risks as it systematically organises and analyses all available scientific and technical information while considering variabilities and uncertainties. However, this tool is only one of the three components of a risk analysis process. As stated above, risk managers need to consider several other dimensions in food safety decision making (e.g. economic impact, consumer acceptance and perception, costs of implementing a certain intervention, public health benefits, ...) on top of public health risk. Risk assessment is a basis for decision making but should be complemented with other (socio-economic/ecological) dimensions. A more precise risk assessment improves a transparent decision making by risk managers, but it provides only partial information and does not provide a full basis for understanding the risk management decisions proposed. Risk assessment has limitations associated with data and uncertainties. The communication of uncertainties to risk managers is also difficult.

## 2. Comparative risk assessment

This tool estimates the number of deaths that would be prevented if the current distributions of risk factor exposures were changed to a hypothetical alternative distribution. It has been applied to study the impact of dietary factors on disease mortality. It is measured in population attributable fractions (PAFs) using information on: (a) effect size of the causal diet-disease relationship (relative risk estimate), (b) optimal or theoretical minimum-risk exposure distribution, (c) dietary risk factor exposure distribution in the population and, (d) total number of disease-specific deaths (including non-fatal events) in the population. This method also does not consider other aspects of decision making such as public health benefits, economic impact, environmental impacts, consumer acceptance and perception, etc. The tool is useful for priority setting and policymaking, but the huge uncertainties for the different risk factors make the tool less reliable to risk managers.

## 3. Risk ratio method

It is a measure where estimates of exposure are divided by estimates of effect (e.g. Hazard Index: Estimated Daily Intake divided by Acceptable or Tolerable Daily Intakes). It requires quantification of the amounts of the hazard consumed (either the dose or the concentration) and their effect on human health. It has often been applied to rapidly screen and rank the risk of different chemical compounds (e.g. pesticides). The outputs of risk ratio methods are easy to understand and to communicate to risk managers. This tool can provide necessary, but insufficient, information for risk managers for making food safety management decisions. Other dimensions of food safety management decision making, beside public health risk, are not considered for making food safety risk management decisions by risk managers. Moreover, the lack of toxicological reference values for emerging chemical hazards (e.g. nanomaterials) limits the use of this tool. The tool does not account for uncertainty and variability.

## 4. Scoring method

It is a semi-quantitative scoring of both exposure and effect of a foodborne hazard on human health, followed by their multiplication/addition. It considers both exposure and severity (or effect) endpoints. Endpoints for exposure include chemical transformation properties (e.g. degradability), release, frequency of detection, and dose concentrations. Endpoints for effect include acute toxicity, carcinogenicity, or reproductive toxicity. The endpoints are classified semi-quantitatively, e.g., using scores from 1 to 3. Then, the scores are multiplied (added), and classified into different categories. The method allows the inclusion of stakeholder perceptions in assigning the scorings and the

importance (to each stakeholder) of each model variable. The outputs of scoring methods are easy to understand and communicate to risk managers. However, its results are very sensitive to the multiplication factors, which makes the tool less reliable. Although the tool provides an overview of food safety risks by considering the preferences of stakeholders, the method is not rigorous. Other dimensions of food safety decision making, beside public health, are also not considered, which makes the tool less relevant for risk management.

## 5. Cost of illness

This method estimates the (societal) costs of a particular illness or injury in a given time frame by aggregating the direct health and non-health costs and indirect non-health costs associated with a given food safety risk. The results are easy to understand and to communicate. However, as van der Fels-Klerx et al. (2018) stated, the method has limitations associated with missing data and failure of the approach to adequately include non-working members of society (e.g. infants and elderly) and quality of life impacts, which makes the method less important for risk managers. Although the process appears highly transparent, the cost coefficients and incidence data may be derived from inadequate data, which limits the reliability of the results for decision making. Although this method provides basic information for cost-effectiveness analyses of interventions and for prioritizing food safety risks, besides illustrating the economic impact of a food safety risk, it does not provide any information on the other dimensions of food safety decision making.

## 6. Health adjusted life years (HALY)

HALYs are nonmonetary health indices, where an individual's health status is evaluated on a severity scale (usually between 0 to 1) and this health score is multiplied by the duration of that health state. HALYs aggregate the quality and quantity of life years. The two most common HALYs are quality-adjusted life years (QALYs) and disability-adjusted life years (DALYs). In QALY approach, each health states are valued between 0 (death) and 1 (perfect health). The QALY loss associated with food safety risk is measured as the difference between QALYs with and without the risk. On the other hand, DALYs measures the number of years of healthy life lost due to mortality and morbidity associated with food safety risks. Death, the worst possible health state, is assigned a disability weight of 1 and 0 represents perfect health. The burden of disease in a population is measured by taking the prevalence or the incidence multiplied by the corresponding DALY loss for each case. Both DALYs and QALYs can be used to assess the cost-effectiveness of food safety interventions; cost/DALYs prevented or cost/QALYs gained. Moreover, since HALYs are standardized health indices, they can be used to compare different diseases or food safety risks. HALY methods are often used for microbiological hazards and improve food safety decision making. However, the methods are not commonly used for assessing the risk of chemical or physical hazards. These measures can be used for reporting risk assessment results and provide large and easy to understand information for risk managers. However, they should be complemented with assessments regarding other dimensions of food safety management (economy, society, environment, etc.).

## 7. Risk matrix

Risk matrices, like the scoring methods, use scoring of both exposure and effect endpoints. In the risk matrices, exposure and effect endpoints are not aggregated by multiplication or addition but are presented in a risk ranking matrix with effect on the one axis and exposure on the other. Then, exposure (likelihood of occurrence) may be scored as certain, likely, possible, unlikely and rare. Likewise, effects can be scored as insignificant, minor, moderate, major and severe. Then, risk classes are assigned to the combinations of likelihood and effects, for example, as low, moderate, high and extreme. Compared to other methods (e.g. risk assessment), this method provides less information for risk managers. However, this method can be used to visualize both the effect and the exposure of



a hazard. It also facilitates discussions amongst stakeholders regarding the risks of various hazards. The interpretation of the different likelihoods is often difficult (e.g. what is an 'unlikely' exposure? what is a 'minor' consequence). The definitions of the different scores are crucial. Otherwise, the tool is very intuitive and easy to understand. It can be used to communicate results from individual risk assessments. However, the results from this method should be complemented with assessments regarding other dimensions of food safety management.

## 8. Flow charts/decision trees

Flow charts are based on a set of clearly defined questions or criteria. By following these, the hazards can be classified into different categories (e.g., negligible, low, medium and high) with respect to their risk for human health. These methods can be used to get a qualitative indication about the risks associated with food safety risks. Compared to other methods (e.g. risk assessment), this method provides less information for risk managers. Moreover, these methods do not provide information on other dimensions of food safety decision making (e.g. consumer acceptance and perception, economic impact, etc.).

## 9. Stated preference techniques

By eliciting the preferences of individuals (citizens and households), food safety risks can be prioritised. When aggregated they show society's preferences for food safety risk preference. Since stated preference techniques consider the concerns and perceptions of society, the outcome produced may be different from that produced by experts on technical grounds alone. These techniques can be used to incorporate societal preferences in food safety decision making. The techniques quantify preferences of individuals for food safety risks in which multiple trade-off decisions must be made among several criteria. However, they do not provide a public health risk analysis that is based on a rigorous process using technical data. Moreover, other dimensions of food safety risk management are not considered in this tool. The method can be used to determine consumers' preferences / risk perceptions and subsequently use it to put risk assessment into perspective (e.g., to lower risk perceptions by consumers when there is no real hazard).

## 10. Expert judgement

Expert judgment-based methods can be used to produce a systematic and transparent ranking of risks by citizens, stakeholders or other experts. These methods can provide input in cases where crucial data is missing, and a decision needs to be made. They also provide a means of engaging the general public in evaluative and decision-making processes and of incorporating societal preferences for different alternatives. The method facilitates communication between risk assessors and risk managers besides engaging stakeholders in the decision-making process. The method could also be useful for making urgent decisions, e.g. during crisis management. However, as van der Fels-Klerx et al. (2018) noted "unless judgement-based methods are planned and executed well, there is a danger that they will be biased and unreliable". This method is often used to fill data gaps in a normal risk assessment.

## 11. Multi-Criteria Decision Analysis

Food safety-decision problems are often multi-criteria in nature. Public health, technological, economic, social and political factors are commonly considered during decision making. MCDA is a powerful methodology for evaluating competing alternatives on multiple, often conflicting, criteria. It is a method for objective and transparent risk management, by integrating value judgments as well as objective, quantitative measurements. It also allows for incorporating the preferences of stakeholders.



MCDA method is officially recognised by FAO and WHO for risk analysis. FAO (2017) developed a guideline for applying MCDA in food safety analysis for selecting risk management options (interventions) and for risk ranking and prioritisation of food safety issues.

The definition of MCDA by the Institute of Medicine and the National Research Council (2010) by itself implies the relevance of MCDA for risk communication. They defined MCDA as “an approach used to systematically structure and model decision problems in multiple dimensions, with the goal of achieving a well-considered and -justified decision, and to provide a transparent explanation of the decision’s basis”. This definition implies that MCDA facilitates communication between risk assessors and risk managers. The method is also suitable for reporting uncertainty and variability as it allows for conducting a sensitivity analysis. Decision scientists use deterministic or stochastic approaches of modelling by using point-estimate values and probability distributions for describing model inputs, respectively. The stochastic approach enables to account for uncertainty and variability of inputs, where insight into the level of robustness is gained. The growing public pressure for transparency in risk management practices requires reporting of the uncertainties associated with technical risk assessments, on which risk management decisions are founded.

MCDA is a relevant tool for risk managers as it enables to balance multiple criteria (e.g. public health, economy, environment) while incorporating the preferences of stakeholders in a transparent manner. The process of MCDA analysis by itself facilitates communication between risk assessors and risk managers (e.g. it initiates discussion during the development of alternatives/interventions and criteria, derivation of weights, etc.). The method is likely not suitable for food safety crisis situations, because conducting a MCDA is rather time-consuming and requires quantitative (or semi-quantitative) information regarding multiple criteria. It is therefore deemed more appropriate for strategic food safety decisions. The suitability of MCDA for (strategic) food safety risk analysis is illustrated with an application to the Swedish food safety incident of dioxins in fish (next section).

### 3.6.2. Application of multi-criteria decision analysis in dioxin risk management

#### Defining the decision problem and identifying key stakeholders

The European commission has set a maximum limit for dioxin concentration in fish products with Regulation EC 2375/2001 in 2001 (replaced by Regulation EC 1881/2006). The dioxin concentration of wild caught salmon and Baltic Sea herring often exceeds the proposed maximum limit. Sweden and Finland opposed the European commission’s maximum limit on fish products by stressing the socio-economic and cultural importance of fishing in the region, the contribution of some fish products (e.g. herring) in the national diet, and the health benefits of consumption of fatty sea fish. As a result, they were granted two separate temporary derogations from the maximum limit for the periods of 2002 to 2006 and 2007 to 2011. The exemption allows the sales of wild-caught fishes and Baltic Sea herring within their domestic, other EU countries with similar exemptions and/or outside the EU markets. The second derogation was set to end on 31 December 2011.

To make the derogation permanent or to end it, the Swedish government commissioned the National Food Agency (NFA) and the Board of Fisheries to analyse the consequences on human health and on the fishery and local businesses, respectively. The risk assessment by the NFA (Livsmedelsverket, 2011) concluded that maintaining the derogation can, in the worst case, result in thousands of children and women in reproductive age facing the risk of exceeding the tolerable dioxins intake limit. The benefit analysis stated that the nutritional benefit from eating Baltic Sea herring and wild caught salmon (with high levels of dioxins) could be achieved by eating herring and farmed salmon from other regions of Sweden (with low levels of dioxins) or by importing fish. On the other hand, the industry impact assessment by the Board of Fisheries (Fiskeriverket, 2011) indicated that ending the derogation would most likely have large consequences for local fisheries, which in turn may impact

local related businesses, like processing and tourism. There are thus different conflicting criteria that need to be evaluated.

The NFA, Board of Fisheries, Local Businesses, and Consumers were identified as the four key stakeholders in the Swedish risk management of dioxins in fish.

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### Identifying the alternatives

Three alternatives were assumed:

- Reference system: no derogation (follow the EU maximum limit)
- Derogation in combination with consumer information (e.g. intake recommendations and warnings to high-risk consumers)
- Derogation: permanent exemption from the EU maximum limit, without providing any consumer information (e.g., without a diet advise).

**Table 3:** Preference/criteria weights for the different stakeholder groups

Stakeholders	Public health risk (DALYs/year)	Public health benefit (DALYs/year)	Socio-economic impact (3-point score)	Consumer perception & acceptance (5-point score)
Human health experts	90	10	0	0
Board of fisheries	0	10	50	40
Local businesses	12	18	65	5
Consumers	35	20	0	45

**Table 4:** Hypothetical performance/scoring matrix for the Swedish incident of dioxins in fish

Alternatives	Public health risk (DALYs/year)	Public health benefit (DALYs/year)	Socio-economic impact (3-point score)	Consumer perception & acceptance (5-point score)
Reference system	0.00	0.00	High	Very low
Derogation with consumer information	10.00	500.00	Moderate	Very high
Derogation	23.00	688.00	Low	Moderate
Objective	Minimize	Maximize	Minimize	Maximize
Preference function; threshold	U-shape; 0	U-shape; 0	U-shape; 0	U-shape; 0

### Defining the criteria

Risk management alternatives were evaluated on public health risk (DALYs lost per year), public health benefit (DALYs prevented per year), socio-economic impact (3-point score: low, moderate and high), and consumer perception and acceptance (5-point score: very low, low, medium, high, very high).

### Constructing a performance matrix

Preference weights for the different stakeholder groups were retrieved during a workshop with risk assessors and risk managers in connection with the COMRISK midterm meeting in Berlin. Preference weights were determined by dividing workshop participants into 4 groups. Each group represented one of the stakeholder groups and was requested to collectively provide preference weights by dividing 100 points among the 4 criteria (Table 3).

Normally, the scores (for each alternative over each criterion) should be generated based on scientific literature and/or expert knowledge elicitations. Suppose the following hypothetical scoring matrix is generated for each alternative over each criterion (Table 42). Furthermore, a "U-shape" preference function and an indifference threshold of zero for all stakeholder groups was assumed for all criteria. In these pair-wise comparisons, any positive difference in scores for two alternatives results in a higher ranking for the alternative with the higher score on that criterion. Complete rankings are based on the aggregation of all criteria with a preference weight assigned to each criterion and the calculation of a net outranking flow for each alternative under consideration. This calculation includes two components: the degree to which an alternative outranks other alternatives (positive flows) and the degree to which an alternative is outranked by other alternatives (negative flows). The alternative with the highest net flows (i.e. positive flows minus negative flows) is preferred.

## Ranking the alternatives

The analysis was conducted in PROMETHEE MCDA software (Decision Lab 2000 Software) to rank the risk management alternatives. The results of the net-flows (Table 5) showed that for the NFA, the best alternative was the reference system, which is to end the exemption or the derogation. However, for the Board of Fisheries and for Local Businesses, the preferred alternative was the derogation. For Consumers, the best alternative was derogation with consumer information. The overall rank, which is the best alternative for all stakeholder groups, was derived by scaling (normalising) the net flows for each stakeholder group using the maximum net flow for each alternative. Accordingly, derogation with consumer information was the best alternative for all stakeholder groups (Table 5), assuming that all stakeholders are equally important. The best risk management alternative resulting from this hypothetical MCDA exercise agreed with the strategy chosen by the Swedish Government in 2012 (Ur N2016\_05005).

**Disclaimer:** *This MCDA exercise reflected a hypothetical situation. The conclusions drawn regarding the best decision in this specific case, are not based on scientifically derived input data and do therefore not represent any formal position or representation of the COMRISK consortium. This hypothetical exercise was only included to illustrate the usefulness of the MCDA method to facilitate decision making by risk managers.*

**Table 5:** Net-flows of alternatives and standardised scores

Alternatives	Human health experts	Board of Fisheries	Local businesses	Consumers	SUM
Reference system	0.80	-1.00	-0.76	-0.30	
Derogation	-0.80	0.60	0.71	-0.15	
Derogation with consumer information	0.00	0.40	0.05	0.45	
Derogation	-0.80	0.60	0.71	-0.15	
<i>Normalised scores</i>					
Reference system	1.00	-1.67	-1.07	-0.67	-2.40
Derogation with consumer information	0.00	0.67	0.07	1.00	1.74
Derogation	-1.00	1.00	1.00	-0.33	0.67

## 4. Synthesis

The communication between risk assessors and risk managers at the time of defining the mandates with its risk questions might be one of the critical points to ensure a risk assessment that is fit for purpose. Nevertheless, many interviewed risk managers and risk assessors stated problems with their mutual understanding resulting in less useful risk assessment. In addition, the German national research council recommends paying more attention to the formative stages of risk assessments which includes the rigorous preparation of the scoping and problem formulation (National Research Council 2009).

Risk managers work in a generalist mindset, which is natural and fit for purpose since risk management is multidimensional in nature. Risk assessment on the other hand, is reductionistic and focuses on answering specific questions with the highest possible precision. It is vital to acknowledge and accept this fundamental dichotomy. The risk manager, who is responsible for defining the mandate/fixing the risk question (FAO and WHO. 2019), thus must be aware of which type of questions the risk assessor is able to work with. The risk assessor, on the other hand, must have an adequate understanding of the actual problem for which the risk assessment is needed. The results from the interviews, as well as from the guiding documents, indicate that the framing of mandates and phrasing of risk questions is best done in a dialogue between the risk manager and risk assessor. This way the risk assessor gets to understand the goal of the assessment and the risk manager will be aware of limitations and possibilities of the risk assessment. Also, the communication at the point of handing over the risk assessment was stressed, to ensure a correct interpretation and best use of the risk assessment.

Based on the interviews, it is evident that lack of two-way dialogue, and understanding of the different roles, sealed with an agreed mandate and set of questions, can reduce the usefulness of the final output for the risk managers. When dealing with a professional risk manager, trained in the generic risk management framework, this may not be an issue. But in practice, as illustrated in the historical food safety incidents, the risk manager may represent a political institution (such as the ministry in the Swedish dioxin case) or be a generalist at a local authority (as in the E coli o104:H4 case) with little (or insufficient) risk analysis experience. In those cases, it is common observation that the risk assessor must facilitate the risk manager with formulating the right risk questions.

Risk analysis may take place at very different levels of society and degree of complexity. Consequently, the time and resources that can be spent will also vary. It was noticed in the CAC manual (FAO and WHO. 2019) that it is stressed that "every step should be thoroughly documented. However, the interviews indicate that both risk assessors and risk managers prefer informal communication during the risk assessment process. Time is a limiting factor for gaining sufficient amount of communication according to both risk assessors and risk managers. This conflicts with the ideal of a fully transparent and documented process, which was also recognised in the Prometheus project (EFSA 2019) where it is noted that "*the protocol methods are tailored to address the trade-off between applying extensive/formal approaches and delivering an assessment that is fit-for-purpose and timely*". Nevertheless, irrespectively of the complexity of the risk question, and the timeframe, there are, however, three stages in the risk analysis process where communication between risk assessors and risk managers may be of extra importance.

**Initiation of risk assessment:** Formulation of the mandate at the initiation of the risk assessment is, as pointed out above, the most critical step where communication is needed. This is true even in the simplest possible risk analysis scenario. Omitting this step will lead to an uncertainty of the task to solve by the risk assessor and will introduce a high probability of a suboptimal risk assessment. The

results from the interviews identified several factors that may facilitate or interfere with this dialogue. Having a dialogue when initiating a risk assessment is not extensively discussed in the guidance documents for risk analysis.

**During the risk assessment:** Once the risk assessment is initiated, the degree of interaction may vary. In some cases, there is no further need for interaction but in general checkpoints are recommended. According to most respondents, the risk assessment questions may have to be changed during the process, which is already a sign of both flexibility of the process and an existing interactive communication between risk assessor and risk manager. The most common reason for a change was that risk questions no longer were fit for purpose due to new information leading to the need of modification. Other important reasons according to risk assessors were getting the risk question more precise, lack of information and suitable data, and that the question cannot be answered as such.

**Handing over the risk assessment:** The interview results stress the importance of communication at the time of delivering the risk assessment to ensure that the results are correctly understood. At this point some risk managers commented that they often want to double-check that the inference of the results on the management decision is correct, that is that there are no misunderstandings regarding the expected consequences of the intended management decisions. The interviews and the studies of the historical food safety cases support the view that feedback from risk managers, e.g. in the form of a management report, is important for improving the risk analysis process and for maintaining and strengthening a trustful relation. For instance, in Sweden, lessons learned from failed communication have resulted in written agreements between SVA and the board of agriculture and between the different functions of the NFA to ensure that misconceptions are sorted out before a risk assessment is initiated and that the output is correctly understood.

Whereas a “strict separation” between risk assessment and risk management is sometimes mentioned in discussions, we have not found any formal constraints that would prevent an efficient communication, neither at EU nor at MS level. We also searched for guidance documents and agreements between authorities without finding any significant constraints. In most of the national documents little (or no) information was given relating to the communication between risk assessors and risk managers (Appendix C). When organisations from Finland, Germany, Sweden, and the Netherlands were asked to provide the guidance documents that regulate their work most would refer to the OIE and/or CAC guidelines (FAO and WHO, 2019). In conclusion, the guidance documents all stress that communication between risk assessors and risk managers is crucial, and that risk analysis is an iterative process.

Despite this, the interview results show that insufficient communication between risk assessors and risk managers during the risk analysis process is the most commonly mentioned reason why risk assessments do not meet the needs of the risk assessment request. It is evident that there exist perceived constraints that might play a role in the lack of sufficient communication.

Speculated reasons for such perceived constraints might be:

- Misinterpretation of guidelines
- Confusion concerning definitions



- Differences in interpretation of guidelines between countries and organisations
- Heritage from old practices

During the workshop it became evident that the same guidelines are interpreted differently between countries and organisations. There may exist confusion between expressions like “functional separation”, “organisational separation” and “strict separation” and it is speculated that some perceived constraints reflect a heritage from past attempts to create a system with strictly separated risk assessment and risk management (EU Food Safety Almanac 2017). The “General Food Law” (Regulation 178/2002) created a European food safety system, in which responsibility for risk assessment (science) and risk management (policy) are kept separate. However, various levels of separation were implemented, as for example “formally separated”, “institutionally separated”, “no (strict) institutional separation”, “some institutional separation”, “in-house separation”, or “separated functionally” (EU Food Safety Almanac 2017). It is obvious that the procedures for keeping risk assessment and risk management separated differs between countries and organizations and this also includes the communication between risk assessors and risk managers.

As mentioned above, it is vital that all risk analysis parties should recognise and respect their different roles and have trust in their counterpart. Communication at the time of defining the mandate and at the time of handing over the results are the most critical stages for the outcome and these are also the stages when the practical implementation of the separation of roles leave the most room for interpretation since they, formally, takes place within the risk management process. The webinars identified that risk assessors may hesitate to contact the risk manager, even when they feel that help would be needed. This was mainly out of respect for their counterpart. Comments made during the interviews further indicated that the risk of misunderstandings and unfit risk questions increased when risk assessors and risk managers did not have the same knowledge and speak the same professional language. The risk for misunderstanding is much reduced if the parties know each other and when the persons are confident in their respective roles. This stresses the value of an established and trustful relation between parties and that new persons get an appropriate introduction and mentorship.

The quest for tools to enhance the communication identified multi-criteria decision analysis (MCDA) as an approach to evaluate risk management alternatives in a transparent and objective manner. MCDA originates from the field of operation research and has been applied in many fields outside those of food safety (e.g., Mardani et al., 2015). Within the field of food safety, the MCDA concept is advocated by FAO (2017) but has yet found only limited applications. In this project, the method was illustrated by applying it to the food safety case of Dioxin in fat fish in the Baltics using hypothetical performance scores. While promising for supporting risk management, there are still some open questions regarding how MCDA could be implemented at EU and MS level and fitted into the risk analysis process. Performing an MCDA requires skills and training that are currently not widespread among risk assessors and risk managers. Additional experts (i.e., beyond the traditional risk managers and risk assessors) and information are needed to execute an MCDA. It is therefore not likely that it will conflict with the functional separation of risk assessment and risk management. Moreover, the method seems more suitable for strategic food safety decisions. Quantification and weighing of different criteria can be time consuming and such time may not be available in a food safety crisis. To define and weight the different criteria within a MCDA, there must be an active discussion among risk assessors, risk managers and other stakeholders. MCDA is therefore expected to build trust among parties, enhance mutual understanding, and result in a transparent evaluation of multiple criteria that will support complex food safety decision making problems.

## 4.1. Outlook

The results from the interviews stress the importance of the dialogue preceding the onset of the risk assessment and identified several factors that may facilitate or interfere with this communication. This aspect of risk-analysis is not extensively discussed in the guidance documents for risk analysis. To the best of our knowledge there is not a lot of attention for risk communication in the training of risk assessors. While defining mandates and risk questions is part of risk management by definition (FAO/WHO 2007, EFSA 2010), the COMRISK consortium suggests that the training of risk assessors should give a deeper insight in the risk management process, give a better understanding of the risk manager's role, and especially raise the awareness of the importance of the communication between risk assessors and risk managers for achieving a timely and fit-for-purpose output.

The training should also pinpoint the challenges that may be faced in the communication between risk assessors and risk managers and should suggest strategies for managing them. EFSA might support this by organizing risk communication courses and the European Commission could include these aspects in the BTSF courses. A basic training in risk analysis could also be offered to new staff at risk assessment and risk management bodies at national level. Developing such courses and training instructors at national level, could be supported by EFSA and/or EC by financing professional risk communication trainings.

## 4.2. Impact of COMRISK

The main impact of the project is an increased awareness of the importance of the communication between risk assessors and risk managers before, during and after conducting a risk assessment, in particular, in the participating organizations and countries but also, to some extent, at EU level. The project has also identified topics that need further investigation. In particular we have identified that the communication during the planning phase is sparsely studied and deserves more attention.

The project has also initiated further cooperation and strengthened the network between the partners which is expected to result in future research projects.

The project has been presented as a poster at the third EFSA conference in Parma 2018 and as a webinar at the EFSA Communications Expert Network in March 2019. Nationally, COMRISK was presented at the National Risk Assessment Day in Helsinki, Finland 2019 (Ruokavirasto: Mikkilä A: Riskinarvioinnin ja -hallinnan välistä viestintää etsimässä (oral presentation). National Risk Assessment Day, Helsinki 7.11.2019) and at internal seminars at BfR.

Upcoming activities that are expected to increase the project's impact include dissemination events, follow up projects and scientific publications. A poster abstract has been submitted to the "Discipline(s) of Risk Science conference" in Espoo, Finland in June 2020 (Joutsen S, Siekkinen K-M, Mikkilä A, Suomi J, Tuominen P. Challenges of risk communication in food safety and proposals for improvement. The Discipline(s) of Risk Science conference. Espoo, Finland June 2020). A proposal for a follow up project (ComCeptRisk) has been submitted by BfR to the EU Risk Assessment Agenda (EURAA). SVA, together with Wageningen University, is preparing a grant application for the Swedish research council FORMAS where concepts from COMRISK, including MCDA, will be further developed. Scientific publications are under preparation focusing on results from the interviews, analysis of risk assessment requests and on the application of MCDA to food safety scenarios.

## 5. Conclusions

### General conclusions

It is essential that both risk assessors and risk managers acknowledge the importance of communication between them. Scarce or poor communication has been identified as one of the major reasons for the risk assessment not meeting the need of the risk manager. Insufficient communication is seldom a result of formal constraints or agreements nor can it be explained by a wish of the risk assessors or risk managers. Instead, perceived constraints or traditions appear to be possible underlying factors.

The communication is enhanced by an established and trustful relationship between the risk assessor and the risk manager as well as by a solid understanding of the roles, duties and background knowledge of the other part.

A formal systematic process for communication during the risk analysis may be a tool for transparency and respect for the different roles in the chain of risk assessment through risk management. A systematic process should contain important key elements, including a few decision points, and not be overly complicated. The process should be used to set a minimal level of communication between risk assessor and risk manager within the risk analysis process, not to limit communication between them. A key element is the risk question. Any risk assessment fit for purpose is dependent of well-defined and mutually recognised risk question. It is generally recommended to apply an iterative process where risk assessors and risk managers together define the risk question(s) and the assessment request.

Different tools exist for the presentation and visualization of risks and their associated uncertainties. When conducted in addition to a (traditional) risk assessment, MCDA is considered the most promising tool for this since it incorporates multiple criteria (e.g., public health, economy, environment) and preferences of stakeholders in a transparent and objective manner.

### Defining the risk question(s)

- An effective communication between risk assessors and risk managers will improve usability of the risk assessment output. The communication is essential to ensure that the risk question(s) in the risk assessment request will be possible to answer in a way that meets the requirements of the risk manager and that risk assessors have a clear understanding of the challenges risk management faces.
- To document the risk assessment request including the specific risk question(s) (e.g. in a standardised form) before proceeding with the risk assessment is good routine. This will bring clarity and, subsequently, will result in more useful risk assessments.

### Carrying out the risk assessment

- It is good advice to include checkpoints during the risk assessment process to evaluate that the risk question is still relevant.

### Handing over of the risk assessment

- When the risk assessment is handed over to the risk manager it is important to allow room for discussions to ensure common understanding of the results. It is proposed to arrange a meeting in association with the handing over, physical or over the internet. This meeting may need to be followed up in an iterative manner.

## Feedback from risk management

- To improve the output of future risk assessments it is important that the risk assessor gets feedback regarding how the risk assessment fulfilled the needs of the risk managers. It may also be useful for the risk assessors to learn how the results of the risk assessment were used and what management action were taken. The feedback is important for a continuous improvement of the risk assessment process.

## 6. Recommendations

Based on the conclusions above this project has identified several activities that could strengthen the communication between risk assessors and risk managers in the European Union and the member states.

EFSA could support the work in the member states by arranging training activities, or support EC's BTSF -training activities, to raise the awareness about the importance of communication between risk assessors and risk managers and to increase the understanding of the tasks and challenges each party faces. EFSA could organise:

- A joint course for risk assessors and risk managers focusing on communication and the formulation of risk assessment requests and risk questions and in the interpretation of risk assessment results and the evaluation of management strategies based on risk assessments.
- Risk assessment courses for risk managers
- Risk management courses for risk assessors
- Activities should be encouraged that (i) support the communication between risk assessors and risk managers and (ii) raise the awareness that risk communication is not only about one-way information aimed at the public and also stressing the difference between communication for dialogue and communication for influencing.
- Exercises and training in risk communication. It is desirable that all persons involved in risk assessment and risk management activities have a basic training in risk analysis, especially the risk communication.
- Networking activities related to risk communication bringing risk assessors and risk managers together for building trust and to facilitate communication

### Project level – future research

- The semi-structured interviews have been an important source of information and insight for this pilot project. It was noted that the mere existence of the project, and the search for subjects to interview, has contributed to raising the awareness of the communication between risk assessors and risk managers.
- The most promising follow-up project would be an interview study based on a refined questionnaire and involving a larger number of member states (and candidate countries).
- The COMRISK consortium has submitted a follow-up project proposal "COMmunication while separation - ConCEPTs inside RISK Assessment and Risk Management (ComCeptRisk)" into the EURAA (Risk Assessment Agenda) in September 2019.
- Comparison of the format of Risk assessment requests on a national level within the four member countries of the current COMRISK consortium or even within a larger number of member states.
- MCDA in practice. Decision makers need an objective and transparent framework to balance the outcome of risk- and benefit assessments with other legitimate factors. The theoretical framework of MCDA is presented in FAO reports and numerous scientific publications in other areas, but the question remains how this method can be efficiently implemented in the risk analysis process while maintaining the functional separation between risk assessment and risk management.

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## Glossary

For this document several terms were defined more in detail than currently available in literature. Therefore, existing terms were adapted by the authors using information obtained from BfR (2010), EFSA (2014, 2018) and FAO (1997).

### Mandate

An authoritative order or command

*Upon receipt of a mandate EFSA allocates a mandate number (e.g. M-2018-0012) and at least one EFSA risk assessment question number (e.g. EFSA-Q-2009-12345). For further info see RAW.*

### Register of Questions (RoQ)

An online database by EFSA

*A database by EFSA that contains information on risk assessment questions asked by submission of mandates to EFSA by the EU regulatory authorities on food and feed safety issues within EFSA's remit. The Register of Questions*

*(<http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin?12&panel=ALL>)*

*provides information on the progress of mandate and its risk assessment question(s) as it/they move(s) through the risk assessment process by using a defined Risk Assessment Workflow (RAW).*

### Risk Assessment Workflow (RAW)

EFSA's main task to carry out scientific risk assessments is described in detail here

<http://registerofquestions.efsa.europa.eu/roqFrontend/wicket/page?8-1.ILinkListener-guideLnk>

In general, three main entities are involved in the workflow and are illustrated in (Fig. 9).

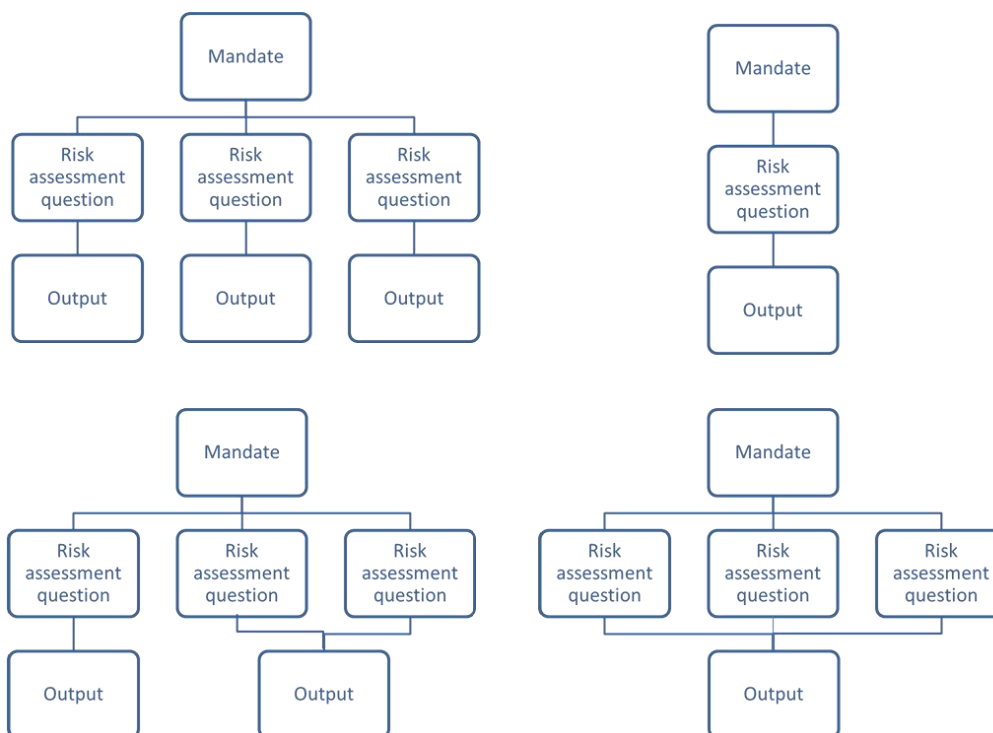
The workflow begins with a **mandate** (from the Commission or Member State or by an internal mandate). It is defined by an official letter. The mandate contains the reference to the risk assessment questions that EFSA must reply to. If several Panel/Units work on the same mandate then at least one risk assessment question will be created for each Panel/Unit, a single risk assessment question may not be related to more than one Panel/Unit.

A **risk assessment question** or risk question can be further divided into risk assessment sub-questions within a Panel/Unit, but this information is not made public. Nevertheless, there also can be internal risk assessment questions as part of the mandate, which are EFSA internal entities.

A risk question describes a risk, which results in a mandate to be submitted at e.g. RoQ. For further info see "Question (Q)"

At the end an **output** is produced. This is an opinion, statement, guidance or report that EFSA produces for the mandates that are received. The output is identified by a number (e.g. EN-1046). Each output can be related to one or more risk assessment questions, but it is not possible to have several outputs for the same risk assessment question, but for the same mandate.

**Figure 9:** Examples of the possible relations between the Risk Assessment Workflow (RAW) entities (adapted from EFSA 2018):



### Question (Q)

A sentence in an interrogative form, addressed to someone in order to get information in reply.

*As the term question can be used meaning different aspects of the risk analysis process, the project consortium decided, that questions related to the RoQ, RAR, RAW or PF are named in the following **risk assessment questions**. Questions that are part of the questionnaire/interview and – of course the common meaning without relation to a specific kind of questions are further called **questions**. Nevertheless, before a mandate can be formulated, a question (**request formulation**) about the possible risk has to be defined, discussed and specified for submitting a mandate. This kind of questions is in the following named **risk questions**.*

### Risk assessment request (RAR)

*In this report RAR refers to **the process in which a mandate is submitted and divided in risk assessment questions**. RAR not include further steps of the standard RAW nor the PF itself.*

### Risk assessment

The analysis of a risk by means of scientific methods. This includes:

- Identification of a possible risk source (“hazard identification”), i.e. the biological, chemical or physical agent which could have adverse health effects must be identified;
- Characterization of the hazard potential (“hazard characterization”), i.e. the qualitative and/or quantitative evaluation of adverse health effects that could arise from the risk source, if necessary, under consideration of a dose-response relationship;

- Depending on the request, an assessment of human exposure (“exposure assessment”), i.e. the qualitative and/or quantitative evaluation of the intake of an agent with regard to the relevant routes of exposure in individual cases (intake through food intake, breathing or skin contact);
- Finally, a characterization of the actual risk (“risk characterization”), i.e. the qualitative and/or quantitative evaluation of the frequency and severity of adverse health effects in a certain segment of the population under consideration of uncertainties related to the assessment

### **Risk Assessor**

A risk assessor is evaluating existing and emerging risks associated with food and feed safety. It collects and analyses data and provides scientific advice to support decision-making by risk managers.

### **Risk communication**

It is a purpose-specific exchange of risk information and opinions between stakeholders. Stakeholders include members of politics, science, public bodies, associations, non-governmental organizations and the mass media as well as individual citizens. Risk communication with all stakeholders – including knowledgeable target audiences – should follow the key basic rules of transparent, comprehensible and useful risk communication.

### **Request formulation**

*The process of formulating the scope and questions for a RAR. A risk question has to be formulated before submission. For further info see “Question (Q)”.*

### **Risk management**

The process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.

### **Risk Manager**

*Institutions responsible for risk management are for example the European Commission, Member State authorities and the European Parliament. They are responsible for making decisions or setting legislation about food safety.*

### **“Risk assessment question”**

See “Question (Q)”

### **Risk question**

See “Question (Q)”

### **Problem formulation (PF)**

The Initial step in the scientific assessment process

*In this report it may refer to (i) an activity during the preliminary risk management activities where the scope of the RA is defined or (ii) the first step of the RA where the original mandate is translated into a scientific question and split in as many sub-questions as needed.*

## Abbreviations

BfR	German Federal Institute for Risk Assessment
BG	Background
BIOCONTAM	Scientific Panel on Biological Hazards
BTSF	Better training for safer food
CAC	Codex Alimentarius Commission
DALY	disability-adjusted life years
E.coli	Escherichia coli
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organization
GMO	Genetically modified organism
HALY	Health adjusted life years
MCDA	Multi criteria decision analysis
ML	Maximum limit
MS	Member states
NFA	National Food Agency of Sweden
NUTRI	EFSAs Nutrition Unit
OECD	Organisation for Economic Co-operation and Development
OIE	World Organisation for Animal Health
PAF	population attributable fraction
PPR	Plant Protection Products
PROMETHEUS	Project "PROmoting METHods for Evidence Use in Scientific assessments"
QALY	quality-adjusted life years
R&D	Research and Development
RA	Risk Assessment
RAA	Risk Assessment Agenda
RM	Risk Management
RoQ	Register of Questions
SCOM	System Centre Operations Manager
SVA	National Veterinary Institute of Sweden
TERA	Project "Transparency and engagement in risk assessment"
ToR	Terms of Reference
WHO	World Health Organisation

Appendices A-C are available on the online article under “Supporting information”.

**Appendix A – Questionnaire**

**Appendix B – Information to obtain from guiding documents**

**Appendix C – Summary information from guiding documents**