European Food Safety Authority

Transparency in Risk Assessment – Paper from Bart Sangster

Introduction

The different activities involved in dealing with risk are captured in the term ''Risk Analysis''. In Risk Analysis three different phases are distinguished; Risk Assessment, Risk Management and Risk Communication. Risk Assessment (RA) allows us to understand risk in terms of hazard and probability; Risk Management (RM) captures the process that results in a decision on how to manage the risk. Risk Communication (RC) is a prerequisite for allowing the risk management decision to be communicated to the various stakeholders and lead to the legitimacy of that decision.

EFSA has Risk Assessment in its remit as well as Risk Communication. EFSA was created to advance the European Consumer's confidence in food. Transparency in the process of Risk Assessment will allow the consumer to understand how risk is being assessed as well as the validity and thus credibility of the outcome. It will allow Risk Managers to take better-informed decisions and will enable Risk Communication. Since a lack of credibility of the current processes was one of the reasons for creating EFSA there is a need for a critical assessment for opportunities for improvement.

Risk Assessment

In Risk Assessment scientific data on hazards serve as input for the process in conjunction with exposure data. Before these scientific data can be used an assessment has to be made regarding their validity. In an ideal world this should be done based on criteria that have been formulated in advance. Scientific studies that generate data that are going to be used in a risk assessment process differ from each other not only by their subject of study but also regarding their scientific robustness[1].

The Risk Assessment process aims at relating exposure of humans to a particular agent[2], or a mixture of agents, to (adverse) effects. Both the quantity of the effect (severity or amount) or effects and the probability of occurrence should be part of the outcome of the Risk Assessment-process. Given the nature of this process each Risk Assessment implies a certain level of uncertainty. Making the inclusion- and exclusion-criteria for studies whose data have been used in a given Risk Assessment part of the final report is a prerequisite for understanding the level of (un)certainty of the outcome. Similarly in using exposure data making visible what assumptions were part of the exposure assessment will also help the user of a Risk Assessment to appreciate the level of (un)certainty that is involved.

EFSA could add value by asking the Scientific Panels to make their inclusion and exclusion criteria explicitly part of their assessment as well as the assumptions that form the basis of the exposure data that have been used. This and a transparent description of the Risk Assessment process a.i. the line of reasoning will allow the Panel to make an assessment of the level of (un)certainty regarding the outcome of the RA process an integral part of their report.

[1] Number of samples, sensitivity and specificity of methods etc but also recent versus old study.
[2] Agents can be chemical (vitamin, stabiliser or residue), biological (bacteria, viruses, moulds, insects etc) or physical (temperature, metal pieces, give aways)

Risk Management
Risk Management that starts from a Risk Assessment that includes the level of (un)certainty involved will allow a better understanding of the risk associated with a given use of an ingredient, process or product. A better understanding of hazard as well as likelihood will enable a better-informed decision and therefore a better protection of public health.

Risk Communication
In analogy with risk management a better understanding of risk will facilitate the communication about a given risk. The transparency that is introduced by adding inclusion and exclusion criteria, the assumptions behind exposure data and making explicit the level of (un)certainty associated with each Risk Assessment outcome will increase credibility with the European consumer.

Improving Transparency in Risk Assessment
Risk Assessment is not always easy. Assessing what is valid and what not and understanding the science and the logic thus allowing the Panels to translate exposure in to effect and public health risk often is difficult. The public and the risk managers could benefit from understanding these difficulties and how they have been dealt with by having them made an integral part of the reports of the Scientific Panels. It could very well be that allowing the public to be part, in a passive sense, of these deliberations could add to transparency. Making meetings public allowing listening and on looking as is currently already being done with the Management Board meetings by means of web streaming could be a way forward. The public and other interested parties could also be allowed a more active role in hearings for interested individuals, interested scientists, media, NGO's, Industry and national Authorities. Allowing the Panel to be challenged about the data that were used, the logic that was applied etc. before the Risk Assessment is finalised could improve quality, transparency and credibility.

A different approach to Risk Assessment is critical to EFSA's success. Making it happen will not be easy since it implies a fundamentally different way of working for scientists that are accustomed to the present modus operandi of the Committees. We are under tremendous pressure to get started and the huge workload looming over the horizon could prevent us from introducing the step changes that are needed to serve public health in the EU properly. Changing EFSA's approach to Risk Assessment will allow us to meet the expectations of many, in particular the European Consumer. It will allow us to add value to the National Authorities and be accredited the leadership role our founding fathers wished us to attain.