Workshop Report: Risk Perception and the Acceptability of Human Exposure to Pesticides

Berlin, 20 December 2017

SAPEA

Science Advice for Policy by European Academies

This Workshop Report has been produced under the auspices of the SAPEA Consortium under Grant Agreement Nr 737432 "Science Advice for Policy by European Academies" (SAPEA) that was signed by the Consortium and the European Commission on 22 November 2016.

This report can be viewed online at www.sapea.info/workshopriskperceptionacceptability

PUBLISHER

SAPEA
c/o acatech
Pariser Platz 4a
10117 Berlin | Germany

CONTACT

SAPEA Communications Office
13 Rue d'Egmont
Brussels 1000 | Belgium

contact@sapea.info

SAPEA

Science Advice for Policy by European Academies

Workshop Report: Risk Perception and the Acceptability of Human Exposure to Pesticides

Berlin, 20 December 2017

Workshop Report 3

About SAPEA

Spanning the disciplines of engineering, humanities, medicine, natural sciences and social sciences, SAPEA (Science Advice for Policy by European Academies) brings together outstanding knowledge and expertise from over 100 academies, young academies and learned societies in over 40 countries across Europe.

Working closely with the European Commission Group of Chief Scientific Advisors, SAPEA provides timely, independent and evidence-based scientific expertise for the highest policy level in Europe and for the wider public.

SAPEA is part of the European Commission Scientific Advice Mechanism (SAM) which provides independent scientific advice to the College of European Commissioners to support their decision making.

The project is funded through a grant from the European Union Horizon 2020 programme running from November 2016-October 2020.

SAPEA comprises the European Academy Networks: Academia Europaea, ALLEA, EASAC, Euro-CASE and FEAM.

For further information about SAPEA visit: www.sapea.info

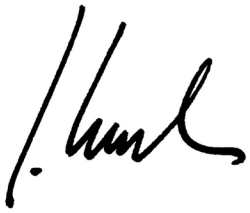
Foreword

The European Commission's Group of Chief Scientific Advisors received from Commissioner Andriukaitis (Health and Food Safety) a request for scientific advice to inform a Regulatory Fitness and Performance Programme (REFIT) evaluation. This REFIT aims to carry out an evidence-based assessment of the current regulatory system for plant protection products (PPPs) and pesticides residues.

A SAPEA (Science Advice for Policy by European Academies) working group of European experts were asked to compile an evidence review report addressing the question 'Could the current EU dual system for approval and authorisation of plant protection products (PPPs) be rendered more effective, efficient, and transparent, and if so, how?'. The SAPEA report informs SAM HLG Scientific Opinion, thus enabling Commissioner Andriukaitis to foster evidence-based policy making in the field of pesticides regulations.

This topic is highly relevant to our society, therefore SAPEA and the Institute for Advanced Sustainability Studies (IASS, Potsdam, Germany) jointly organised a workshop on the 20 December 2017 in Berlin, on the theme of «Risk perception and the acceptability of human exposure to pesticides». This report summarises the outcome of the workshop.

We would like to express our sincere thanks to the scientific experts who have enriched the topic with their contributions, as well as to all participants present. We particularly express our gratitude to Professor Ortwin Renn (Scientific Director, IASS), and his colleagues Viola Gerlach and Joschka Jahn for their close and fruitful collaboration.



Prof. Günter Stock
President of ALLEA &
Member of the SAPEA Board

Table of Contents

Figures

Tables

Executive Summary

The Science Advice for Policy by European Academies (SAPEA) consortium and the Institute for Advanced Sustainability Studies (IASS) organised a joint workshop on risk perception and the acceptability of human exposure to pesticides on 20 December 2017 in Berlin. The objective was to facilitate an exchange of experiences and research results among regulators and natural and social scientists in the field of pesticide regulation. While the distribution of pesticides continues to grow on a global level, society is becoming more sensitive to health hazards and environmental impacts associated with alimentation. Risk perception deviates from statistical data-based risk assessment results, often overestimating the levels of exposure and the severity of risk associated with certain products.

The EU authorisation process for plant protection products and the toxicological risk assessment are based on the premise "that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment", as written in the *EU Regulation N° 1107/2009*. New active substances for plant protection need to apply to the European Food Safety Authority (EFSA), which conducts a comprehensive and periodical evaluation, including separate risk assessments from EU Member States and consultations of experts and the public. The risk assessment approach has four steps:

- *Hazard Classification*: Examines the potential of an active substance to cause harm to human health and the environment.
- *Dose-Response-Assessment:* Determines the probability of harm as a function of dose leading to an assessment of the maximum amount of active substance absorbable by humans.
- *Exposure Estimation*: Estimates the exposure of the population and specific subpopulations (children, operators, workers…) to the active substance.
- *Risk Assessment:* The combination of Hazard Classification, Dose-Response-Assessment and Exposure Estimations determines the risk of an active substance to cause harm to human health and the environment.

Assessing the causal and temporal relationships causing risk is very complex and constitutes a severe challenge to human intuition. The uncertainty, inherent in risk assessment, causes irritation about scientific claims and their precision. Risk perception is oriented by simple causality models and the reliance on trust where immediate experience is missing.

Risks are perceived differently according to its origin and characteristics. Social science defined several risk perception clusters of which mainly two correspond to pesticides and pollutants:

- *Pending Risk*: The risk of pending dangers consists in the randomness of its occurrence. Severe harm occurs rarely but unpredictable and it can affect everyone.

- *Creeping Risk*: Creeping dangers are not recognisable by human senses until they cause harm. There can be a long time span between trigger and effect. Humans rely on information by third parties to assess and evaluate the seriousness of risks to which they are exposed.

Individuals tend to avoid these kinds of risk, because of their complexity and uncertainty. Possible risk-benefit trade-offs rely on external information, which is also perceived differently. Individual risk perception is influenced by a set of intuitive heuristics and biases:

- *Availability:* People assess the frequency or probability of an event by the ease with which instances or occurrences come to mind.

- *Representativeness*: The degree to which "A" is similar to "B" leads us to estimate a probability or frequency that is insensitive to base rates.

- *Affect:* Quick, subconscious evaluation of the "goodness" or "badness" of a stimulus.

- *Confirmation bias:* People give greater weight to information that confirms their beliefs and disregard information that disagrees with their beliefs.

- *Motivated reasoning*: People interpret and process incoming information in a way that reinforces their predispositions.

- *Information seeking*: Not everyone is disposed to pay attention to new information.

For successful risk communication, trust is vital. Trust is essential for communicating complex information to society. Only sources considered trustworthy by individuals are able to change their perceptions of risks. Unfortunately, the inherent uncertainty of scientific research and the vast amount of contradicting sources can destroy trust and it is difficult to rebuild it. Modern virtual reality can amplify risk perception and result in a plurality of truth claims, eroding trust.

Risks and uncertainty are perceived differently by risk assessors and the public. Hazard assessments produce clear messages about potential threats and are therefore commonly perceived more trustworthy. Comprehensive and complex risk assessments, on the other hand, include a permanent component of uncertainty and produce ambiguous messages for risk-benefit tradeoffs. Therefore, they are often ignored or considered less trustworthy, albeit they have substantial socio-economic benefits over hazard based approaches, avoiding unnecessary and exaggerated precautions.

The toxicological risk assessment in the EU in its current form produces diverging messages and uncertainty. The underlying uncertainties in the regulatory objectives and assessment procedures leads to an uncertain level of protection provided by the current regulations. The magnitude and impact of uncertainty in risk assessments is rarely transparent and separated from the final decision-making. Therefore, the assessed levels of risk are ambiguous, often resulting in diverging assessment results by different authorities.

Considering the importance of risk perception for successful risk management, the risk assessment process should be sensitive to the perception of uncertainty. They should:

- Avoid diverging interpretations of the assessment results by relating the results to the legally defined regulatory objectives and approaches.
- Quantify levels of uncertainty in risk assessments to avoid ambiguous interpretations.
- Establish a scientific arbitration process to evaluate significant divergence.

Risk communication should react to the mechanisms of risk perception and deliver clear trust-building messages that are:

- Empowering and action-oriented,
- Emphasising benefits,
- Fair and transparent,
- Resolving conflict and approaching divergence and
- Holistic, including multiple “trustworthy” stakeholders.

1. Introduction

The distribution of pesticides continues to grow on a global level, significantly increasing the concentration of pesticides in food and the environment. Nowadays, pesticides are an integral part of our economies and are essential to maintaining current levels of conventional agricultural production. Despite continuous research on pesticides, there are still uncertainties with regard to their effects on human health due to the reliance on animal models with strong extrapolative assumptions, the complex cumulative and synergetic effects of pesticides, and possible biases in assessment methodologies. These uncertainties are perceived differently by scientists and the public. Large sections of society are very concerned about pesticide exposure although statistically it has a record of low risk with respect to human health.

Most toxicological and epidemiological studies demonstrate that in the European Union people live ever safer and more secure lives and enjoy a higher average life expectancy than any previous generation. Apart from old-age diseases like dementia, people are suffering from fewer life-threatening and chronic diseases than their ancestors.

Most people in Europe, however, feel that risks to life and health have steadily grown over time and that in particular environmental health risks caused by chemicals and pollutants have increased in volume and intensity. Nowhere is this discrepancy more evident than for the risks associated with food production and nutrition. Giving credence to popular surveys, food scares top the list of fears and worries shared by the European public. People are highly sensitive to health hazards associated with alimentation and have a keen interest in real and perceived risk assessment. More than 70 per cent are convinced that the dangers associated with food will increase in the future.

Social science research has produced many relevant insights into the process and the mechanisms of risk perception and communication. The intuitive processing of probabilistic information, modes of assigning causality, the lack of trust in institutions and science, and the social amplification by the modern media are major contributors to the discrepancy between risk assessment by scientists and risk perception by stakeholders and the public.

To facilitate an exchange of experiences and research results among regulators and natural and social scientists in the field of pesticide regulation, the Science Advice for Policy by European Academies (SAPEA) consortium and the Institute for Advanced Sustainability

Studies (IASS) organised a joint workshop on risk perception and the acceptability of human exposure to pesticides in December 2017 in Berlin.

The first part of the workshop focused on the current EU authorisation system and toxicological risk assessment for pesticides from a (natural) scientific perspective. The sociological dimensions of risk and uncertainty assessment and perception were then addressed, with an emphasis on misperceptions and biases in perceiving complex threats. During the last section of the workshop, the discrepancy between risk assessment and risk perception of pesticides was discussed.

The goal of the workshop was to create a mutual understanding of risk perception mechanisms and to identify ways of better communicating the results of scientific research to society, thereby facilitating evidence-based risk assessment, a better understanding of actual risks, and the processing of risks by governments and regulators.

2. Workshop concept

The workshop was designed to facilitate a mutual exchange between natural scientists, in particular toxicologists and epidemiologists, regulators and social scientists that have specialised in studying risk perception. The organisers felt a need for informing social scientists and regulators about the results and insights from risk assessment studies while, at the same time, natural scientists should gain a better understanding about the patterns of risk perception and the estimation of acceptability by stakeholders and the public at large. The goal was to establish a better evidence-based exchange of information and research results that could help all groups in the regulatory process to understand the underlying scientific assessments as well as the psychological and social mechanisms of processing information about hazards, risks and uncertainty.

The insights from the workshop should assist scientists and regulators alike to include both assessment and risk perception results into their risk management and governance approaches and, in particular, to improve the risk communication efforts sharing information between science, politicians, stakeholders and the public. The ultimate goal is to establish the foundations for a more rational but also responsive risk governance process.

3. Toxicological risk assessment and current authorisation system in the EU

To understand the mechanisms of risk assessment and perception, the first section of the workshop covered current toxicological risk assessment and the authorisation system in the EU. The latter was presented by *Marta Hugas*, chief scientist at the European Food Safety Authority (EFSA). The toxicological risk assessment approach to pesticides in the EU was explained in greater detail by *Susanne Hougaard Bennekou*, senior advisor, toxicologist at the Danish Environmental Protection Agency (EPA) and vice-chair of the Scientific Panel on Plant Protection Products and their Residues at the EFSA.

3.1 Scientific assessment of plant protection products in the EU

The assessment of pesticides and other plant protecting products in the EU follows a strictly regulated and formalised process including several review instances at the national and supranational level, in order to ensure a high level of protection of both human and animal health and the environment, and at the same time to safeguard the competitiveness of the agriculture sector. Following the *EU Regulation N° 1107/2009*, companies requesting market authorisation of a new active substance for plant protection need to submit an assessment-dossier to selected Rapporteur Member States (RMSs), which produce their own comprehensive evaluations of the applicant's dossier and an independent assessment of the new substance. The results are handed over to the European Food Safety Authority (EFSA), which then consults experts from other EU member states and the public. After potential review-loops, the product is then either approved by the EU or rejected.

From the beginning of the process, the application-dossier includes a full report and a summary description of mandatory safety studies for the submitted active substance, a collection of relevant data from scientific peer-reviewed open literature of the past ten years, and studies covering representative uses on a widely grown crop, using at least one plant protection product containing the active substance. The submitted information must be sufficient to evaluate the foreseeable risks, whether immediate or delayed, which the active substance may entail for humans, animals and the environment.

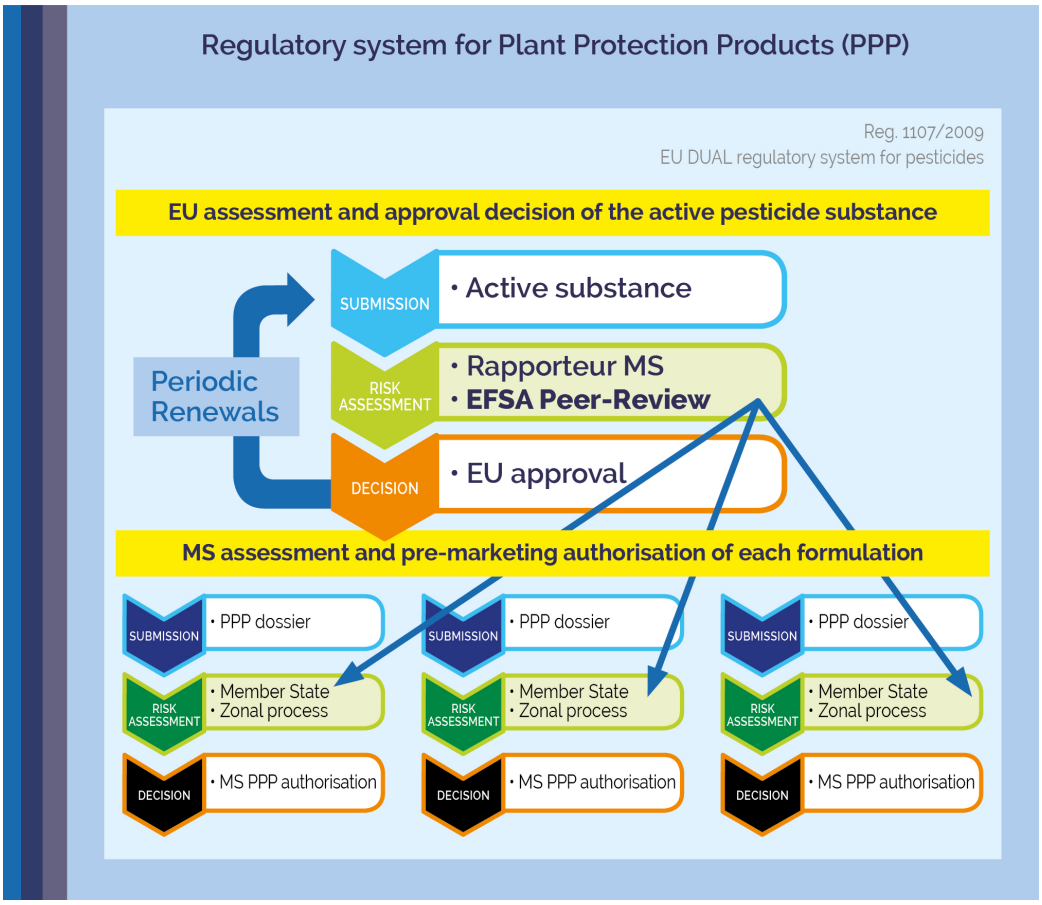


Figure 1: Regulatory system for Plant Protection Products (PPP)

The RMSs check all information in the dossier and, where relevant, correct and amend the applicant's study summaries and evaluations. If the RMSs agree with a particular summary or evaluation they may incorporate the text directly into their reports. They produce a comprehensive independent evaluation of the applicant's dossier and include their own assessment of the safety of the substance.

In the consultation process, the EFSA collects the reports from the RMSs and includes comments, responses and other evidence from EU member states or the public and discusses the results. After reviewing critical concerns and data gaps, the EFSA concludes on the assessment of the product. The final decision of authorising the product is then made by the European Commission.

Complementary to the authorisation process, the Maximum Residual Level (MRL) for the active substance is assessed separately. Applicants refer to an evaluating member state of the EU and the results are handed over to the EFSA for further review and consultation. The EFSA then produces their reasoned opinion on the MRL. The final authorisation is realised by the European Commission, on the EU-level, and by each Member State. Ad-hoc requests about MRL from the European Commission are directly submitted to the EFSA.

Setting the MRL follows some basic principles. The pesticide residuals in food should be as low as possible, and must not represent an acute risk for "extreme consumers" in any Member State. And the MRL may not represent a chronic risk to any of the EU national diets. The EU risk assessment, the most diverse assessment process worldwide, analyses 24 different regional diets. In comparison, the US assessment of pesticides is only based on four different diets.

After the authorisation the EFSA reviews periodically the MRL in the EFSA Annual Report on Pesticide Residues. In the 2015 Report, 43.9% of the probes were inside the MRL, 2.8% surpassed the MRL and in the majority (53.3%) of examined food no residues were found at all.

3.2 Toxicological risk assessment for pesticides in the EU

Toxicological risk assessment in the EU is based on the premise "that substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment", as written in the *EU Regulation N° 1107/2009*. The premise is vague and consequently produces uncertainty about what is acceptable risk for not being harmful to human health.

The risk assessment process in the EU is divided in four parts. The first part consists in identifying the hazard evoked by the examined active substance. Then the health problems at different exposure levels are examined in the Dose-Response-Assessment. In parallel, an estimate of the exposure of the population and specific subpopulations (children, operators, workers…) is determined based on models. The overall risk of the substance is characterised, based on the hazardousness data, for different doses, and the level of exposure.

There is vast data available for the hazard identification and characterisation as determined by specific data-requirements set out in *EU Regulation N° 283/2013* and *N° 284/2013* covering from acute toxicity studies, to local effects, repeat-dose to lifetime chronic/carcinogenicity studies, development effects of fetus in different species, studies on reproduction and more. The bulk of data is coming from guideline compliant animal studies; hence studies are conducted with a minimum of three doses, for up to 50 animals per sex and dose.

From this database the study with the most sensitive adverse effect at the lowest dose in the most sensitive species is chosen as the basis for setting human health-based reference values. As an example, as depicted below, in a 90-day rodent study, the NOAEL (No observed adverse effect level) is determined for effects on liver weight which is the highest dose of the active substance, not causing adverse effects. This result is then extrapolated by assessment factors to establish human "no-effect-levels" (human health-based reference values) established for the purpose of dietary and non-dietary risk assessment.

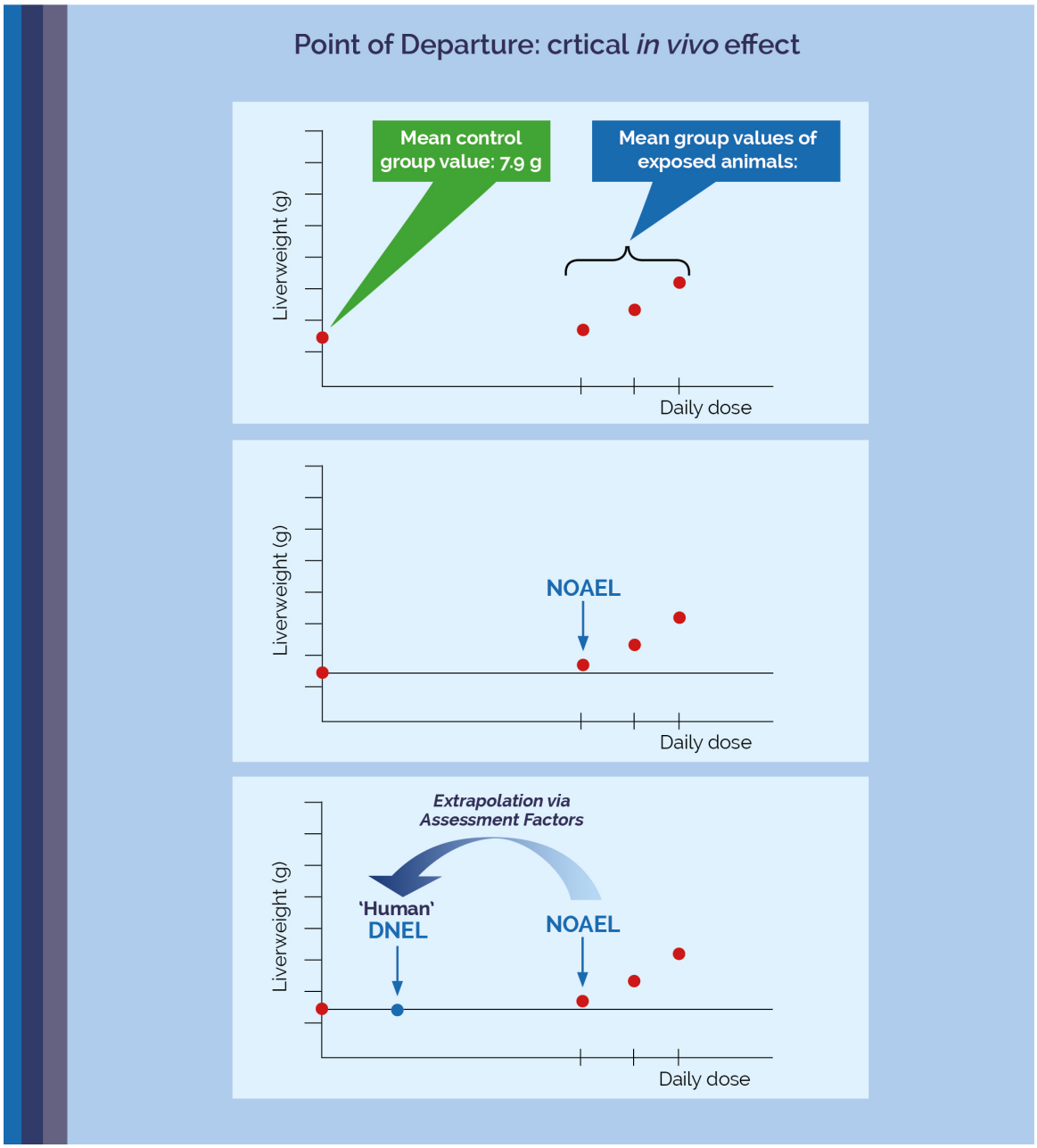


Figure 2: 90-Days rodent study to determine the human "No-Effect-Level"

3.3 Uncertainties in the current toxicological authorisation system

The current system of toxicological risk assessment and authorisation is perceived in very different ways. Current approaches assessing the safety of chemicals and pesticides on humans may deliver ambiguous results and receive rather negative evaluations. The process is very resource and time consuming and has limited relevance as predictor of adverse effects in some cases. Academia, industry and regulators agree that the sensitivity and specificity of animal-based safety testing too often leads to wrong predictions of human adversities and there is a call for a risk assessment based on biological mechanisms. To aid this goal, the OECD has developed the AOP (adverse outcome pathway) framework which is a way to organise knowledge for the purpose of regulatory decision making. An AOP is an analytical construct that describes a sequential chain of causally linked events at different levels of biological organisation that lead to an adverse health or ecotoxicological effect (see figure below). Having AOPs will in the future allow a better integration of different types of data in risk assessment outputs and ultimately facilitate the transition from risk assessment based on in vivo animal data to non-animal data.

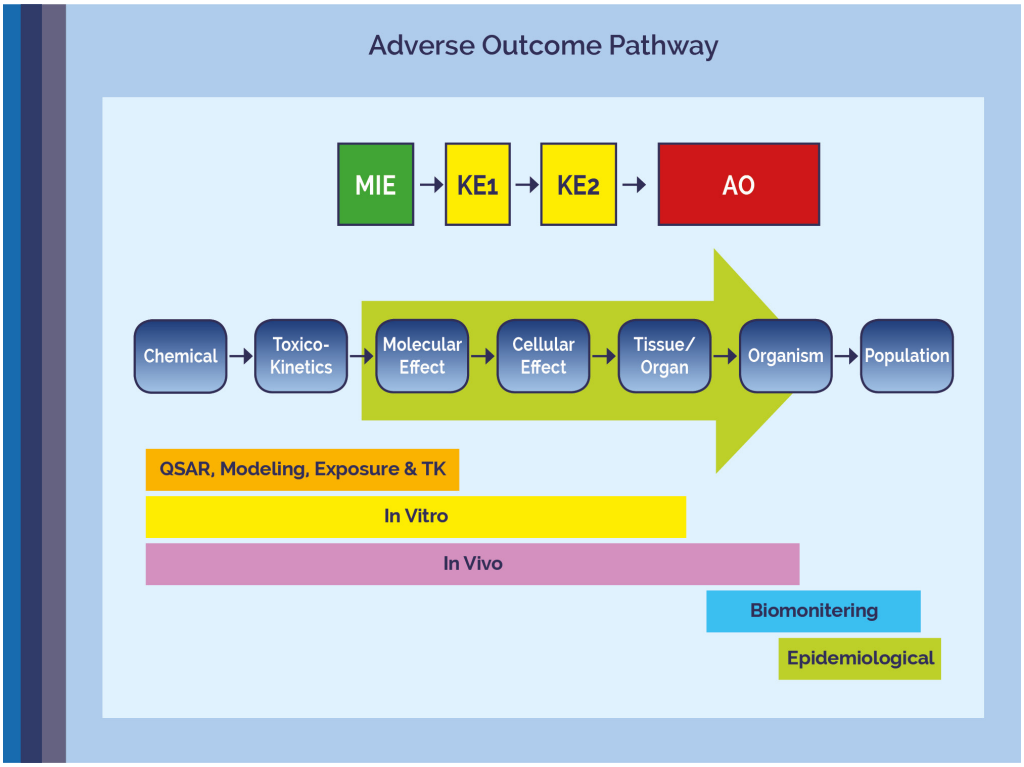


Figure 3: Adverse Outcome Pathway (AOP)

Disregarding the rational uncertainty in the assessment process, the public perception of the toxicological risk assessment in the EU is very different from case to case.

In 2013 the EFSA assessed the pesticide risk for bees and advised to restrict plant protection products containing neonicotinoids (Clothianidin, Imidacloprid, Thiamethoxam), because they were identified as harmful for Europe's honeybee population. This decision received wide acceptance in society.

Based on the same assessment approach, the EFSA concluded that Glyphosate is unlikely to be carcinogenic to humans, even though small uncertainties can never be dispelled. This decision was shared transparently with the public, but received very negative reactions and provoked a public debate. Considering the more than 8000 outputs the EFSA produced in the last 15 years, the public reaction to Glyphosate was unique and cannot be explained on a rational, evidence-based level.

4. Risk and uncertainty perception

After the presentation of the EU pesticide risk assessment system and cases of contradictory perception of risks, the social science perspective on risk and uncertainty perception was presented. Professor *Ortwin Renn*, Scientific Director at the Institute for Advanced Sustainability Studies (IASS) Potsdam (Germany), introduced the field of sociological risk research and risk perception. *Katherine McComas*, Professor of Communication at Cornell University (USA), then highlighted the heuristics and biases concerning risks.

4.1 Risk perception orientations and clusters

Social science research has shown that human behavior is guided by perceptions, not by scientific "facts". Nonetheless, these perceptions are not arbitrary. They follow consistent patterns and rationales that are comprehensively studied by social science research.

Knowledge about risk is limited and opens the gates to conflicting interpretations of reality. Assessing the causal and temporal relationships between potential triggers and effects for human health is very complex and constitutes a severe challenge to human intuition. Besides, risk assessment involves a permanent component of uncertainty about these complex relationships. This causes irritation about scientific claims and their precision, especially when the understanding for stochastic probabilities and modeling is limited. People seem to handle uncertainty in different ways and interpret scientific uncertainty as an indicator for ignorance or lack of hard evidence. It is hard to understand to most people that the characterisation of uncertainty is not a sign of scientific weakness but a major step forward towards improved precision when compared to the old-fashioned way of reporting only the means of a probability distribution. In addition, people follow different rationales when making trade-offs between risks and benefits. While some people are very sensitive to risk and downplay potential benefits to society, for others possible benefits outweigh risks or they even ignore risks completely. Another problem about risk assessment is the ambiguity of the results, producing competing interpretations of the same data depending on the value that people assign to what they consider safe or unsafe.

Risk perception is oriented by simple causality models that normally attribute causality according to the proximity in time and space. Everything that is closely related in time and space is seen as the most likely cause for observed negative effects. However, in complex

systems this intuition is rarely true. Many triggers are distant from the local cause (i.e. a flood caused by climate change induced by emissions of carbon dioxide in a distant country) or unrelated to events that precede the experience of harm (i.e. a cancer incident with a latency periods of more than 10 years). Particular in relations with risks from pesticides, most people rely on trust since immediate experience is missing. However, in a plural society with a broad variety of opinions on toxicity people have a hard time deciding whom to trust. They cannot judge the truthfulness of all the competing risk assessments. In this dilemma, they even demand zero risk (there is nobody one finds trustworthy) or they rely on peripheral cues that are not related to the content of the respective claims. This leads to a feeling of insecurity and often amplifies anxieties. These anxieties are often further amplified by the modern virtual reality and the resulting experience of internet users being faced with a broad and confusing plurality of truth claims.

Risk is perceived differently, depending on the type of risk. There are five dominant clusters to cope with risks.

The five semantic images of risk perception

1. Pending danger (fatal threat)
Artificial risk source Large catastrophic potential Inequitable risk-benefit distribution Perception of randomness as a threat
2. Stroke of Fate
Natural risk source Belief in cycles (not perceived as a random event) Belief in personal control (can be mastered by oneself) Accessible through human senses
3. Personal thrill (desired risks)
Personal control over degree of risk Personal skills necessary to master danger Voluntary activity Non-catastrophic consequences
4. Gamble
Confined to monetary gains and losses Orientation towards variance of distribution rather than expected value Asymmetry between risks and gains Dominance of probabilistic thinking
5. Creeping danger
(Artificial) ingredient in food, water or air Delayed effects; non-catastrophic Contingent upon information rather than experience Quest for deterministic risk management Strong incentive for blame

Table 1: The five semantic images of risk perception

In the context of pesticides, only two of the five are of crucial importance: the risk of pending danger and the risk of creeping danger.

The risk of pending danger refers to a risk category where the worst outcome is catastrophic but the probability of that catastrophe occurring extremely small. Large-scale accidents and industrial disasters belong to the category of pending dangers. Their occurrence is not very probable but when it occurs the consequences are severe. The mechanisms behind are complex and unfamiliar, so that there is hardly any time for warning or emergency measures. Since the probability distribution follows stochastic reasoning, it is not excluded that the worst case could happen any time. For most people this randomness of its occurrence is the most frightening element of this risk class. In many cases (for example nuclear power) people find such a risk not acceptable because in theory the major catastrophe could occur at any time. The low probability is often ignored or downplayed. In the case of pending danger, risk aversion is the most frequent response to this kind of risks for the society.

Another relevant risk cluster refers to creeping dangers. Such risks operate mostly in the background and cannot be detected by human senses. Creeping dangers raise additional fears because they affect people without them being aware of the risk. Many pesticides and chemicals belong to this risk type. People do not smell, taste or see them, but once they accumulate on the body they can cause negative health impacts such as cancer. Since people cannot detect them personally, they rely on information from other parties to warn them. However, as stated above, people are exposed to a wide variety of warnings from many actors in society. So, whom can they trust? Risks tend to be amplified if people feel insecure about whom to trust and which of the many warnings is accurate and relevant.

4.2 Heuristics and biases assessing risk

Besides the different types of perceived risks, individuals often assess risks relying on heuristic principles or "rules of thumb". These influence the risk perceptions and the reaction to third party information.

The availability heuristic influences how people perceive the frequency or probability of an event to occur. The easier an event comes to mind, the likelier people tend to evaluate its occurrence. This can lead people to overestimate the occurrence of infrequent yet highly "available" risks, such as the occurrence of fatal shark attacks.

The representativeness heuristic means that people imply similar events to have similar risks. For example, when individuals see workers managing pesticides wearing hazardous materials

suits, it may lead them to think that pesticides pose risks similar to nuclear waste or other very toxic contexts, where workers also wear hazmat suits. This can lead to over- or under-estimating risks.

Another important heuristic is the affect heuristic, which is an immediate feeling of whether something is positive or negative. This evaluation happens subconsciously prior to more elaborative and mindful judgements and can influence how individuals view risks. Research has shown, for instance, that individuals generally feel more negative about human generated risks than natural risks and therefore generally consider them worse than natural risks.

It is difficult to communicate information that contradicts people's heuristic assessment of risks, because individuals have biases, limiting their acceptance for new information. The fact that we give greater weight to information that confirms our beliefs and discount information that disagrees with our beliefs, is called the confirmation bias. In addition, individuals interpret and process information in a way that reinforces their predispositions. They like to avoid cognitive dissonance.

Another point is that not all people are seeking information and will pay attention to your messages. Individuals tend to follow advice and acquire risk information, if they recognise a gap in their knowledge, if they believe it is important for their social environment, if they consider the information available and if they believe that they can do something to solve the problem.

The multiple information channels, from official and unofficial sources, make it difficult to discern between relevant and irrelevant, trustworthy and untrustworthy science. Individuals are more likely to seek and accept information from sources they feel they can trust. However, in the modern media society it is increasingly difficult for people to discern between allegedly trustworthy and non-trustworthy sources of information.

4.3 Trust and risk commmunication

Trust is essential for communicating complex information to the society. Only sources considered trustworthy by individuals are able to change their perceptions of risks. Unfortunately, the inherent uncertainty of scientific research and the vast amount of contradicting sources can destroy trust and leave people in the dark about the decision whom they can trust. Risk communication has to tackle this problem since the lack of trust is a major impediment in being regarded a liable and effective communicator. Trust building is

asymmetric, which means it is easier to destroy trust than to build it. Negative events are more noticeable than positive events and sources of bad news tend to be viewed as more credible than sources of good news. Distrust tends to perpetrate distrust.

Individuals base trust judgements on whether they think regulatory and scientific risk managers share their values, which determines whether they cooperate with the risk manager. Besides shared values, people consider fairness as an indicator for trustworthiness. When viewed as unfair, e.g. nontransparent or interest-driven, communication processes can heighten concerns about risks and destroy trust. An increased attention to fairness is essential to maintain or rebuild trust in risk management institutions. Trust in sources does not only affect the likelihood people believe new information, but also the severity of the assessed risks. Individuals may perceive risks as greater or lower than the statistics would suggest, depending on trust.

Effective risk communication has to accept that risk perception is a reality for itself, which needs to be considered when managing risk and designing policies on risk regulation. One objective of risk communication is to enlighten society, making people able to understand risks and benefits and to change their behavior positively. Risk communication should also contribute to trust-building, assisting risk management agencies to generate and sustain trust. And finally, it could be instrumental for resolving conflicts by involving major stakeholders and affected parties to take part in the risk-benefit evaluation.

In order to accomplish these objectives, risk communication has to consider the purpose of communication, the risk and benefit trade-offs and be explicit about the remaining uncertainties. On the audience level, communicators have to consider the various audiences and the risk perception patterns that can be associated with each type of audience, as well as available communication channels. Risk-benefit communication needs excellent recorded management and follow-up programs and evaluations.

Possible clues to build trust could be joint campaigning with other trustworthy institutions, inform the respective audience about past performance to deal responsibly with risks, and comprehensive communication about the risk assessment and managing process.

5. Implications of risk perception on risk assessment

The workshop provided participants with the opportunity to discuss the implications of risk and uncertainty perception on risk assessment and communication. In several break-out sessions, the main challenges in communicating food and agriculture risks to policy makers, stakeholders, and consumers were discussed. Furthermore, the participants reflected on possible helpful and rewarding risk communication strategies as opposed to unsuccessful or even detrimental risk communication.

The last section of the workshop was guided by *Ragnar Löfstedt*, Professor of Risk Management at King's College London (UK), who presented various implications of the perception and communication of risk or hazard assessments, and by *Andy Hart*, Professor of Risk Analysis Practice at Newcastle University (UK), who addressed uncertainty in pesticide risk assessment, outlining options for improving the regulatory assessment of pesticides, taking account of uncertainty and resolving divergences in scientific assessment.

5.1 Problems of communicating uncertainty

Communicating risk of food and agriculture bears obstacles for policy makers, stakeholders and consumers. Multiple actors are involved in risk communication, resulting in conflicting messages that make it difficult to build trust and transfer reliable information. Cultural differences, including the language, between those seeking for information and risk managers cause additional problems that need to be addressed by risk communicators.

Different channels of communication are used by different social groups, enforcing perception biases in society. While social media have become increasingly important nowadays, many groups still rely on traditional media. As a result of different information from different sources, researchers are not considered impartial, but often seen as biased members of different parties. Some researchers are framed as ideology-driven and others are suspected to work on demand for non-governmental organisations (NGOs) or the chemical industry. This makes it even more difficult to build a trustful relationship between risk managers and the targeted audiences.

The greatest obstacle for trust in risk communication seems to be uncertainty. All guidelines of large risk communicating institutions, like the World Trade Organization (WTO) or the World

Health Organization (WHO), recommend communicating uncertainty transparently. The intention is to create trust by revealing all used information. However, uncertainty undermines the perception of expertise, which is an essential factor for trust in risk communicators.

The official risk communication on nuclear energy traditionally ignored uncertainty and presented an unambiguous position towards possible risks for the society. The Chernobyl incident in 1986 therefore came as a surprise for most people and destroyed trust in nuclear energy forever. A more transparent communication of uncertainties may have been a better strategy. An example for the other extreme was the public reaction towards the Bovine Spongiform Encephalopathy (BSE), commonly known as the mad cow disease. The risk of BSE was perceived to be very high and resulted in exaggerated prevention measures.

Successful risk communication needs clear messages. Communicators should engage trust by focusing on benefits, without ignoring the uncertainties. Being more honest with perception goals seems to be more useful, than to elaborate on uncertainties. The goal is to influence human behavior with action-oriented, illustrative risk communication methods, not lengthy comprehensive reports. One idea is to communicate risk in simple categories of threat, used by multiple actors.

5.2 Risk and hazard: Implications for perception and communication

Hazard and risk assessments are not mutually exclusive. They offer different possibilities for communication and are perceived very differently by the society. Comparing both approaches, risk assessments seem to be superior to hazard classification in pesticide regulation, because risk measuring is based on more expansive data and allow risk-benefit comparisons.

Hazard classification examines the potential for a substance, activity or process to cause harm. This kind of assessment is appropriate when exposure conditions cannot be estimated or predicted with any confidence, or no threshold for adverse effect can be identified. Hazard assessments are also appropriate when the exposure to the threat is avoidable. Decision-making on the basis of hazard classification, however, usually ignores exposure and dose-effects functions, and in doing so can lead to poor regulatory policy making. Hazard assessments are needed in order to complete a risk assessment that combines the likelihood and the severity of a substance, activity or process to cause harm.

Some NGOs are opposed to risk assessments and prefer hazard classifications. The International Chemical Secretariat stated in 2011: "The basis for risk assessment is the unscientific belief that risk can be foreseen and controlled. In an infinitely complex system, such as chemicals,

the risk is simply impossible to anticipate." Government organisations often take a different view. The House of Lords Select Committee on Economic Affairs argued, that ill-defined and ambiguous terms in risk management and regulatory documents were generally unhelpful. There would be a danger that they could induce an excessively cautious attitude to risk.

The advantages of hazard classifications are that they are relatively cheap to undertake and they need less data. For that, they are quick to produce and easy to understand for the public. However, hazard classifications can lead to the stigmatisation of certain products, because they cannot say anything about the likelihood that these hazards manifest themselves in risks or actual damage. They also ignore risk-risk trade-offs from possible substitute substances and alternatives.

Risk assessments rely more on scientific in-depth investigations than hazard classifications. They are based on expansive data and require considerable scientific expertise to model exposure, as well as developed technical capacity. Because of that, risk assessments can include considerable uncertainty in making extrapolations from animal data to derive points of departure for risk assessment.

The advantage of risk assessment is that it allows risk-benefit comparisons. Therefore, unnecessary stigmatisation of certain products and risk-risk trade-offs can be avoided. Risk assessment can have substantial socio-economic benefits over hazard based approaches.

In Europe certain NGOs, campaigning academics, politicians and regulators have been pushing to ban pesticides based on hazard classifications, because they can produce contradictory messages. For example, the results produced by the International Agency for Research on Cancer (IARC) in 2015 concluded that Glyphosate is carcinogenic. On the other hand, in 2016, the Joint FAO[1] /WHO Meeting on Pesticide Residues (JMPR) concluded through risk assessment that Glyphosate is unlikely to pose carcinogenic risk to humans for exposure through the diet.

Hazard classifications are often considered more trustworthy than risk assessments. Anti-chemical researchers are often seen as intrinsically motivated heroes, while many academics working in the risk space are seen by NGOs and others to have conflicts of interest. Risk assessment is often seen as bought by the industry and industries themselves are commonly distrusted.

1 Food and Agriculture Organization of the United Nations (FAO)

Conclusively, pesticides need to be regulated on the best available evidence, which means adopting risk-based approaches. To improve the trust in risk assessment, regulators and policy makers should be trained with regard to conduct and interpret risk assessments. Also, the funding for neutral evidence-based regulators should be increased to establish risk communication advisory boards at the major EU regulatory agencies, such as the European Chemicals Agency (ECHA), EFSA and the European Medicines Agency (EMA). Finally, risk analysis should be introduced to school children and be represented more frequently in quality media.

5.3 Addressing uncertainty in pesticide risk assessment

The current regulative objective of *EU Regulation N° 1107/2009* is to "ensure that [...] substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment". However, "ensure" and "not... any harmful effects" are not further defined, nor assessed directly. Instead, regulators conduct risk assessments according to standard procedures using surrogate measures of risk, such as the estimated exposure for "high" (commonly, 95th percentile) consumer compared to a reference dose based on toxicity studies in animals. The procedures include standard factors for extrapolation from animals to humans and other provisions that are intended to account for uncertainty. However, the standard procedures have not been explicitly calibrated, so it is unclear whether they achieve the level of protection required by the regulation. Specifically, it is unclear what level of certainty they provide that "not...any harmful effects" will occur.

When a pesticide does not fully pass the procedure, regulators have several options to proceed. They can either decide that the deviation is negligible, request more detailed data from applicants, apply an additional uncertainty factor to the assessment, or conclude that the risk is not acceptable. Choosing between these options involves judgements about uncertainty that are often implicitly quantitative but rarely explicit. Consequently, the assessed levels of risk are ambiguous, often resulting in diverging assessment results by different authorities.

To improve the assessment and authorisation of pesticides, the regulatory objectives should be defined more explicitly, in terms of relevant metrics for adverse effects, and the standard procedures should be calibrated against the objectives to confirm that they achieve the desired level of protection. This requires quantification of the relationship between the procedure output and the regulatory objective, as illustrated in the figure below. The solid curve represents the estimated relationship between the output of the standard procedure (horizontal axis) and the measure of effects it is desired to regulate (vertical axis). If the relationship were known with certainty, then the curve could be used to read off the procedure output that would

correspond to an acceptable level of risk (horizontal dashed line). However, the estimated relationship will be subject to uncertainty, as indicated by the dashed curves. Quantifying that uncertainty allows a threshold for regulation to be determined that will achieve an appropriate level of certainty of acceptable risk, as illustrated in the figure. Applying the calibrated procedure with the resulting threshold takes account of the uncertainties that are normally present, so it can be used in regulation in the normal manner. Further analysis of uncertainty is necessary only when non-standard uncertainties are present, e.g. when the available data do not fully meet the required standards, or when there are special considerations regarding the pesticide under assessment.

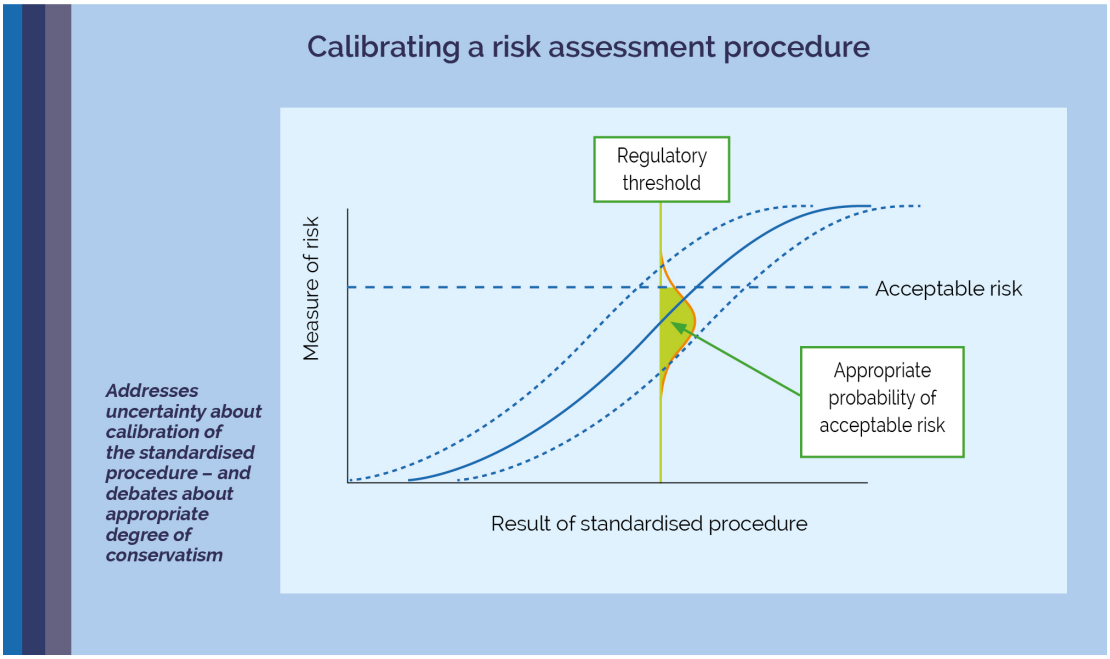


Figure 4: Calibrating a risk assessment procedure

Detailed methods for calibrating standard procedures and for taking account of non-standard uncertainties are described in the Guidance Document on uncertainty recently published by the European Food Safety Authority.[2] EFSA has also published guidance on defining protection goals for environmental risk, the principles of which could be applied also to human health risks. Methods for quantifying uncertainty in chemical hazard characterisation have been developed by the International Program on Chemical Safety (IPCS)[3]. Concerns have been expressed that quantifying uncertainty would render the assessment outcome "unclear", but this can be avoided by defining what level of certainty is required to qualify as "safe". Taken together, these methods make it possible to retain clear conclusions but improve the rigor and transparency of the underlying assessment, and to ensure that it properly addresses the regulatory objectives.

2 EFSA. (2018). Guidance on Uncertainty Analysis in Scientific Assessments. *EFSA Journal 2018*, in press

3 IPCS. (2014). Guidance Document on Evaluating and Expressing Uncertainty in Hazard Assessment. *IPCS Harmonization Project Document No.11*. http://www.inchem.org/documents/harmproj/harmproj/harmproj11.pdf

The European Commission request to the Scientific Advice Mechanism asked, among other questions, "Which methodology of arbitration could be used to solve issues arising from diverging assessments by different competent authorities based on the same science, or on a different assessment of uncertainties?" Diverging assessments arise from various causes, including, differences in the regulatory questions, different interpretations of the same but ambiguously-defined regulatory question, using different subsets of evidence, using different assessment methods, and normal variation in scientific opinion. The improved approaches described above would reduce these problems by establishing well-defined questions and regulatory objectives, and through explicit expression and accounting for uncertainty. They would also allow a clearer understanding of the reasons for any remaining divergence, which could then be addressed by a formal scientific 'arbitration' process. Key steps in such a process would be to review and clarify the regulatory questions, work with a common pool of shared evidence, bring relevant experts together, and follow a structured process for weighing the evidence, making expert judgements and expressing uncertainty, while leaving risk management considerations to the relevant authorities. Such a process could be constructed using methods described in EFSA's Guidance Documents on uncertainty, weight of evidence and expert judgement[4,5,6]. Ideally the process would be organised jointly by the parties involved, assisted by an independent facilitator; alternatively it could be organised by an independent body such as a national or international scientific institution.

4 EFSA. (2018). Guidance on Uncertainty Analysis in Scientific Assessments. *EFSA Journal 2018*, in press

5 EFSA. (2017). Guidance on the use of the weight of evidence approach in scientific assessments. *EFSA Journal 2017*, 15(8):4971.

6 EFSA. (2014). Guidance on Expert Knowledge Elicitation in Food and Feed Safety Risk Assessment. *EFSA Journal 2014*, 12(6):3734

6. Conclusion

Toxicological risks from pesticides in food are assessed and perceived very differently by scientific researchers, stakeholders and the publics. Risk assessment is a complex process that has to cope with high levels of uncertainty and produces ambiguous statements on risk-benefit trade-offs. Especially in the EU, the formal risk assessment process is very detailed and formalised, including large-scale and long-term studies and periodical reviews, and involving multiple stakeholders from academia, industry and the different member states. This kind of risk assessment is constantly competing with diverging results from less scientific hazard classifications.

Stakeholders and members of the public are often unable to react appropriately to scientific risk assessments and tend to over- or underestimate risks. Individuals are determined by perception heuristics and biases, and they react according to risk perception clusters when confronted with different types of risks. Chemicals and pollutants are often perceived as creeping risks, which constantly threaten human health although they are not perceptible by the human senses. Harm from pesticides can also be interpreted to be a pending danger that is unpredictable and can affect everybody at any time.

The level of trust in the risk assessing authority is one of the crucial variables that determine whether a person is willing to accept a certain risk to obtain the corresponding benefit, or whether that person weights the risk higher than the benefit. The level of trust in risk managers and regulators often determines whether information is accepted and how risk exposure is evaluated by individuals. Unfortunately, it is easier to destroy trust than to build it, and the perception of scientific dissent about the severity of a risk destroys trust. Sociological research has shown that people in industrialised countries are becoming less loyal to reference groups that were traditionally considered trustworthy. At the same time, new forms of media and other auxiliary sources of evidence are gaining importance and tend to amplify people's distrust.

Successful risk communication has to acknowledge that risk perception is an essential part of handling risk in society and has a strong influence on how a society copes with uncertainty and ambiguity. While there are no obvious solutions for handling uncertainty and ambiguity in risk assessment and for dealing with society's lack of trust, risk communication can only be effective if risk communicators put risks in context, include different perspectives on how to interpret risk assessment results, and focus on benefit-oriented, empowering messages. People must become better prepared to deal with scientific dissent and to understand stochastic information. Most importantly, risk communication has to show the boundaries

between what is possible, likely, certain or definitely wrong or absurd. The worst that could happen would be that people believe that risk assessments are arbitrary and their results depend on who pays for them. Scientific assessments are able to place risk in a proper perspective, characterise remaining uncertainties and provide reliable anchors for prudent judgements of how to manage and regulate risks.

List of Participants

Name	Affiliation
Annabelle Ascher	SAM Unit
Janusz Bujnicki	European Commission Group of Chief Scientific Advisors
Petar Bulat	University of Belgrade School of Medicine, Serbia
Magdalena Cara	Biochemistry of Pesticide and Phytotoxins Analytical Laboratory, Agricultural University of Tirana, Albania
Orges Cara	University of Giessen, Germany
Ozana Cucu-Oancea	Romanian Academy
Lynn Frewer	Newcastle University, United Kingdom
Viola Gerlach	Institute for Advanced Sustainability Studies (IASS), Germany
Andy Hart	Visiting Professor at Newcastle University, United Kingdom
Susanne Hougaard	SAPEA Working Group Expert
Marta Hugas	EFSA
Joschka Jahn	Institute for Advanced Sustainability Studies (IASS), Germany
Matthias Kaiser	University of Bergen, Norway
Stuart Kirk	SAM Unit
Johannes Klumpers	SAM Unit
Piotr Kwiecinski	SAM Unit
Cosmas Lambini	SAPEA
Ragnar Löfstedt	King's College London, United Kingdom
Mark Lohmann	German Federal Institute for Risk Assessment (BfR)
Evelin Loit	Estonian University of Life Sciences
Inese Martinsone	Laboratory of Hygiene and Occupational Diseases, Latvia
Katherine McComas	Cornell University, USA
Sir Paul Nurse	European Commission Group of Chief Scientific Advisors
Mihnea Preotesi	Romanian Academy
Ortwin Renn	Institute for Advanced Sustainability Studies (IASS), Germany
Marc Saner	University of Ottawa -Institute for Science, Society and Policy, Canada
Shpend Shahini	Agricultural University of Tiran, Albania
Tony Smith	EFSA
Günter Stock	SAPEA Board
Rainer Waldhardt	University of Giessen, Germany
Peter Wiedemann	Australian Centre for Electromagnetic Bioeffects Research

Programme

Timings	Activity	Topic	Speakers
09.30-09.40	Welcome and Opening Remarks	Objects and tasks of the day	Günter Stock Sir Paul Nurse
09:40-09:50	Introduction		Ortwin Renn
09:50 – 10:35	EU Current Authorisation System	Current EU authorization system and introducing glyphosate and neonicotinoids as a case study (plus short discussion)	Marta Hugas
10:35 – 11:05	Toxicological risk assessment	Current and future approaches to toxicological risk assessment for pesticides (plus short discussion)	Susanne Bennekou
11:05 – 11:30	Coffee break		
11:30 – 12:00	Risk and uncertainty	Setting the scene: Risk and uncertainty perception and acceptability	Ortwin Renn
12:00 - 12:40	Misperception and biases	Misperception and biases	Katherine McComas
12:40 – 13:30	Lunch		
13:30 – 14:15	Breakout sessions	Breakout sessions: Experiences, Observations and Questions about the relationship between science and the public with emphasis on pesticides	Peter Wiedemann, Lynn Frewer Viola Gerlach
14:15 – 14:45	Report on breakout sessions and panel discussion	Short report by the facilitators about the parallel sessions: Addressing the collected questions to the panel	Ortwin Renn, Peter Wiedemann, Lynn Frewer Viola Gerlach Ragnar Löfstedt Katherine McComas
14:45 - 15:15	Addressing Uncertainty	Addressing uncertainty in pesticide risk assessment	Andy Hart
15:15 - 15:45	Risk and Hazard	Risk and Hazard: Implication for Perception and Communication	Ragnar Löfstedt
15:45 - 16:15	Coffee Break		
16 :15 – 17 :00	Summary	Discussion on recommendations	All Moderator: Ortwin Renn

Spanning the disciplines of engineering, humanities, medicine, natural sciences and social sciences, SAPEA brings together the outstanding knowledge and expertise from over 100 academies, young academies and learned societies in over 40 countries across Europe. SAPEA comprises the European Academy Networks: Academia Europaea, ALLEA, EASAC, Euro-CASE and FEAM.

SAPEA is part of the European Scientific Advice Mechanism (SAM) which provides independent, interdisciplinary and evidence-based scientific advice on policy issues to the European Commission. SAPEA works closely with the European Commission Group of Chief Scientific Advisors.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 737432

www.sapea.info
@SAPEAnews