Expert Elicitation Workshop Report: Authorisation Processes of Plant Protection Products in Europe from a Scientific Point of View

Brussels, 26 October 2017

SAPEA

Science Advice for Policy by European Academies

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Workshop Report 2

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.

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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.

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

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Background

The first essential step towards the production of a Scientific Opinion by the Group of Chief Scientific Advisors of the Commission's Scientific Advice Mechanism (SAM) was the drafting of an evidence review report. This report is prepared by an international working group of the Science Advice for Policy by European Academies (SAPEA) consortium in response to a request from the European Commission for a rapid evidence review to inform the deliberations of itsGroup of Chief Scientific Advisors.

Among other things, the Group has been asked to consider whether the current dual system for approval and authorisation of plant protection products (PPPs) in the EU could be rendered more effective, efficient and transparent, and if so, how this could be achieved. The SAPEA working group was asked to focus on methods and procedures for assessing potential harmful effects on human health from the use of plant protection products, and to report both on the current scientific state-of-the-art, and on the potential for future developments. 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? To which extent would full alignment of risk assessment procedures solve the problem of different risk acceptance by different authorities? Seven independent working group experts reviewed the scientific evidence on the questions asked in the scoping paper.

Workshop focus

The purpose of the external expert elicitation workshop held on 26 October 2017 was to obtain expert assessment of the preliminary findings of the working group's evidence review report. In total, there were 41 participants at the workshop with twelve external experts invited and selected based on their applied knowledge and experience in regulatory risk assessment for PPPs and/or the underpinning science.

The experts were provided with some guiding questions and the draft report in advance of the workshop to familiarise themselves with the content. They were asked to address questions that are raised in the draft report and areas of disagreement, relevant points that may have been omitted, and any inaccuracies that require correction and provide evidence which may have been missed in the literature presented. The meeting was held under Chatham House Rule and the report prepared in an anonymous and non-attributed style.

Session 1: Toxicology

It was expressed that the report in its draft stage captured key points well and had no major gaps. It becomes evident that regulatory bodies (e.g. the European Food Safety Authority, EFSA) are taking up the new science and adapting their guidelines. However, it was argued that the level of progress that has been made in the last years could be better reflected in the evidence review report.

Adverse Outcome Pathways (AOP) are well addressed and have become a key component of decision-making. Indeed, scientists often don't know what is most useful for regulators. There is a need to become better in documenting the already available data, to allow for future comparisons. However, harnessing the process of AOP based on transparent peer review becomes important to increase scientific credibility, trustworthiness and acceptance of scientific information. Methods based on **animal testing** were discussed at length and although it was felt that in vivo methods cannot be fully replaced, there is a need to try to supplement these tests, especially through in silico methods. It was suggested that the industry could help in providing insight into modern testing methods. It was mentioned that the aspect of **validation** was rightfully brought up in the report, but that more in-depth explanation of the three "P's" (Principles, Purposes and Process) might be required. Formal validation is a heavy process whose rigidity refrains it from adapting to new approaches but is needed to strengthen its credibility. This **tension between innovation and communication** is critical especially when the usage of imperfect methods is more easily communicated than more complicated methods which may yield more accurate results. The aim is not 100% predictability but **a system that can be well-communicated**, where trust can be increased, but without compromising the level of accuracy which state-of-the-art science permits.

As a conclusion, it was suggested to make it clearer in the report that a clear-cut suggestion for a new system does not exist, but that there is willingness to have a better system.. The objective of having a "zero risk" is not feasible.

Session 2: Epidemiology

This session related to the application of epidemiological evidence to risk assessment.

It was emphasised that current epidemiological studies can be useful for hazard identification, as these studies are increasingly informative on the association between low-dose pesticide exposures and human diseases. Epidemiology can be very helpful to monitor and understand acute effects. Epidemiological methods using biomarkers help to establish what are the major determinants of exposure in different set situations.

However, it was underlined that the major challenge in including epidemiology for risk assessment lies in appropriateness and availability of data. Data produced in these areas of investigation are not currently used in a systematic and consistent manner, particularly because of the limitations of observational studies on pesticides. It is also currently difficult to identify chronic effects with existing epidemiological data.

Several methods were put forward to strengthen the role of epidemiology in risk assessment. It was suggested that the use of **evidence synthesis techniques**, such as systematic reviews and meta-analyses, could provide information that strengthens the understanding of the potential hazards of pesticides. The **AOP** framework could also be very helpful to support both a mechanistic-driven hazard identification and biological plausibility of epidemiological associations, in order to incorporate adverse human health outcomes as part of the hazard identification process. It was also suggested to use studies through **pooling analysis**, in consortia or meta consortia and in different domains. In the report, the proposal to use **Mendelian randomisation** was deemed good, as it has shown strong results. However, Mendelian randomisation and meta-analyses must be seen within their limitations: they are methods of summarising published scientific evidence, but the strength of evidence in the individual studies must be verified.

The opinion was expressed that epidemiology's contribution had not yet been ascertained. However, its potential is significant, as it offers information on associations between real exposure and health outputs. However, efforts should be put into: 1. harmonising the existing data which would require consortium-based efforts. And 2. incorporating epidemiological design into legislation. For regulated chemicals requiring pre-marketing authorisations, epidemiological studies should be considered as the third evaluation line for confirmation, to assess if the two first lines, pre-marketing authorisation and post-marketing control and

monitoring, were adequate or not. Some epidemiology can already now be used, and be integrated, but it can only likely be used in the post-marketing scenario.

Finally, regarding toxicity and risk assessment, it was suggested that **epigenetic transgenerational inheritance** should be considered, also to take into account the health of future generations. Epigenetics can be an interesting area for future investigation but not one that in the short term can influence advice to be given on the topic. A similar conclusion was reached in an EFSA workshop on the topic last year.

Session 3: Mixtures and Co-formulants

Co-formulants comprise a large group of substances included in PPPs that have a widely varying toxicity. They increase direct or indirect exposure by increasing dermal absorption and decreasing the efficacy of protective clothing, and by increasing environmental mobility and persistence. Currently, exposure assessment to multiple compounds is only conducted to a very limited extent. When a PPP containing more than one active ingredient is being risk-assessed, the combined effect is taken into account in a simple tiered approach. Constraints for addressing mixture effects include **lack of data** (in particular for co-formulants) and **lack of tools** (i.e. models) to address more complex spatial and temporal scenarios (e.g. tank mixes, or crop scenarios over different seasons and scales).

It was mentioned that it is good the report touches upon this complex issue, and the report's proposal to switch from negative lists to positive lists was deemed sufficient. One participant underlined the issue that people sometimes are exposed to the same chemicals from very different sources and not only pesticides (e.g. veterinary drugs or human drugs), which should be an incentive to **collaborate with other regulatory sectors.** It was suggested to use **AEP** (aggregate exposure pathway) to try and better understand which exposure pathways are more relevant, to systematise data and to draw realistic conclusions.

One of the main challenges regarding mixtures is the fact that practices (of mixing and applying) vary so much from one EU country to the other, even though guidance documents have been published at EU level or are being developed. It is thus particularly difficult to

assess risks. The current regulatory framework is poorly equipped to engage with this complexity. It was thus suggested to **collect data from existing European and international databases**, including REACH, European Food Safety Authority (EFSA), European Chemicals Agency (ECHA), German Federal Institute for risk assessment (BfR). The question of **data availability and quality** concerning co-formulants was raised as a main challenge. While databases do exist (e.g. in REACH), many seem incomplete and data should be treated with great care. Another limitation brought up in the session was the fact that **chronic toxicity data** is more difficult to obtain than acute toxicity data through laboratory analysis. Regarding **dietary exposure**, combined exposures to several active ingredients are already taken into consideration in evaluations. However, specific approaches on how this should be handled in a prospective setting (i.e. during the authorisation process) are still under development.

Our current knowledge about co-formulants' toxicity or exposure is very limited. There are already substantial lacks in the understanding of single substance toxicity, this becomes even more complex concerning mixture that contains them.

Session 4: Exposure Assessment

Exposure to PPPs can be defined as follows:

- Dietary exposure from consumption of treated plants and their derivatives;
- Direct exposures of production workers mainly from contact with concentrated formulations;
- Direct exposures of agricultural workers mainly from contact with concentrated formulations and treated crops;
- Direct exposure of residents and by-standers in close proximity of an application of PPPs;
- Exposure of a population due to dispersed products and deposition on non-target surfaces;

Several **population groups** are identified as potentially exposed to PPPs: operators (those who use the products), workers (exposed once the product has been used), bystanders, residents and consumers. There also exists three different orders of **magnitude of exposure**: dermal, inhalation and oral. Currently, dermal exposure is considered more harmful than inhalation and oral exposure.

Exposure is very variable between these different groups, but also within these different groups, which makes the exposure assessment extremely complex. Indeed, the way pesticides are applied can vary, different pesticides are used depending on the crop, practices to manipulate PPPs or to mitigate exposure can vary considerably, not to mention the temporal variations due to seasonal uses. There exists significant uncertainties and data limitations regarding **human behaviour** when applying substances. It was mentioned that this complexity was not conveyed well enough in the draft report. Current assessment methods also seem to be based on gross oversimplifications and more solid, probabilistic exposures assessments could be reached with more advanced methods.

There currently exist limitations regarding assessment of **dietary exposure.** The opinion was made that analytical methods for the **post-authorisation monitoring of residues** should be part of the authorisation process. The determination of acceptable quantities of an active substance in food items follows the ALARA principle (As Low As Reasonably Achievable), which is achievable and used to assess good agricultural practice. New measurements are currently being developed but they should be validated, endorsed by all Member States then implemented by all EU agencies to help reach comparable conclusions.

Models for risk assessment are continuously being improved. However, one of the central challenges to exposure assessments is the quality of the data available for the different groups, especially for **workers**: studies among pesticides manufacturing workers are lacking. There is also a need to gather information on the international level, and to harmonise it.

Session 5: Making better use of available scientific data

It was stated that the current system of risk assessment was not using scientific data to its full potential. Indeed, while scientific data could present **nuances** in risk, the system conveys the idea that a product is either safe (on the market) or unsafe (not on the market). Such a simplistic approach to risk assessment was regarded as problematic, as passing on information was mentioned as critical. It was thus suggested that comparative risk assessments could be used to make **risk profiles** available to farmers and consumers.

There is available scientific data from the local to the international scales, but this data should be more systematically integrated and sampled for use at the political level.

It was underlined that aspects of public acceptance are crucial for consideration in the whole system. Increasing **transparency** was mentioned as a key endpoint, also to increase trust between Academia, Applicants and Agriculturists (AAAs). The following three "Ts" were proposed: Transparency of all processes; Transparency of scientific methodology; Transparency of all data.

The **registration of all planned animal research and studies** involving pesticide exposures should be legally required and organised by a relevant independent body (e.g. «German Centre for the Protection of Laboratory Animals»). Additionally, the **publication of all studies** with specific products would make the information readily accessible to applicants, national agencies and other stakeholders, such as academia and the interested public.

In order to develop the best epidemiological research, the option of a new **international centre for pesticide research**, presented in the draft report, was supported as long as it remained transparent, free from interest, and made its data publicly available in order to gain confidence from the public. Such centres were considered valuable if they don't constrain "curiosity-driven" research. An international organisation would facilitate the use of data being collected internationally.

Several Member States have implemented occupational surveillance programmes, following European regulations or fulfiling national necessities. However, this data is difficult to harmonise and often not made publicly available, which makes the **surveillance of acute and (especially) chronic health effects** very difficult. One of the objectives of the EU Strategic Framework on Health and Safety at Work 2014-2020 is the improvement of statistical data collection to yield better evidence and also for developing monitoring tools. It is hoped that this will contribute to making better use of scientific data.

Session 6: Risk and uncertainty communication

There was broad agreement that uncertainty assessment, and the communication of it, should be included in the report. If the report mentions that "*scientific uncertainty is usually the greatest challenge in regulatory risk assessment and addressing the uncertainty of data is as important as the data themselves*", it doesn't include anything further on the assessment of this uncertainty. To do so, a speaker suggested that **protection goals** (or management objectives) should be defined by answering the following questions: 1) What is the appropriate measure of risk? 2) What is the acceptable level of risk required? 3) At what level of certainty

is safety 'ensured'? In essence: what is it that we are willing to protect and what level of risk are we willing to accept?

Practical tools for routine assessments ('**standardised procedures**') should then be developed so that the protection goals are reached with the desired level of certainty. To know whether they are appropriate and whether they have achieved the objective, the next step would be to **calibrate** the relationship between the standardised procedures and the measure that we are concerned about. The relationship between the assessment procedures that are being used and the levels of risk accepted in the goals enable a risk manager to assess whether the risk is acceptable, or appropriate. Non-standard issues can be dealt with by extending and adapting the standardised procedure, and if necessary by case-specific assessment. However, concerning mixtures risk assessment, the uncertainties are severe. In these cases, a speaker expressed a belief that a viable deterministic standardised procedure is unlikely.

Most importantly the speaker argued that one should not aim at "total certainty", which is unattainable, but rather "**appropriate certainty**". Difficulties that exist in communication of risk and uncertainty arise in part from the lack of operational definitions for 'safe' and 'ensure'. The non-expression, or qualitative expression, of uncertainty may exaggerate divergence or competing assessments. **Uncertainty analysis would clarify degrees of difference, identify the key sources of disagreement, and help move towards consensus**. There needs to be a transparent and rigorous assessment of uncertainty in both pre-market approvals and the reviews of PPPs, especially when dealing with complex cases such as mixtures. This would also apply to the endpoints one is concerned about, and that none of them will exceed an acceptable level of risk.

The proposal of strengthening systematic consideration of uncertainty was supported by many experts present. Although some limitations were brought up (time-consuming, spurious objectivity, precision), it was argued that these could be mitigated and controlled, and that expert judgement could always be called upon to resolve doubts. **Uncertainty assessment should never be excluded all together**.

It was mentioned that the management goals and how the assessment of safety will be achieved should be communicated. It was pointed out that possible inspiration could come from other fields of science, e.g. medicine, where one speaks about safety in terms of avoiding harm. Multiple experts expressed again that the challenges of communication should not stand in the way of including something as important as uncertainty characterisation and assessment.

Session 7: The ideal regulatory system

A proposal for an ideal approval system for PPP's in the EU is presented in the report. It is understood that this ideal system should be effective, efficient, transparent and dynamic scientifically, by including aspects of safety for humans and the environment, by using the relevant data available, and by including an evaluation process. This proposal incorporates some suggestions already elaborated by EFSA (in the Draft "Scientific risk assessment of pesticides in the European Union (EU), Summary of EFSA experience and identified issues requiring consideration", 2017). The steps presented include the following:

- Data collection
- Data evaluation
- Database of validated endpoints
- Integration into a single EU pesticide risk assessment IT-frame
- Risk characterisation of the outputs

In summary, this proposal should allow a scientifically effective, efficient, transparent and dynamic pesticide risk assessment system in Europe. It was argued that this was rather an "assessment system" than an "approval system". Furthermore, a participant mentioned that the calibration of risk assessment was missing in the system. The uncertainty associated with a proposition could be analysed if the proposition is well defined.

Summary and close

The Working Group mentioned that all comments and thoughts raised will be considered for inclusion in the final draft of the report. They will describe options based on the evidence gathered. Specifically, post marketing approval and surveillance will be further elaborated in the report. Uncertainty, transparency, protection goals, as well as additional evidence on Benchmark Dose (BMD) and No Observed Adverse Effect Level (NOAEL) will also be developed. Discussion on risk-assessment vs. risk acceptance are further discussed in a workshop organised by SAPEA: "Risk Perception and Acceptability of Human Exposure to Pesticides" on 20 December 2017 in Berlin.

List of expert contributors and other attendees

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External experts	
Professor Thomas Backhaus	University of Gothenburg (Sweden)
Dr Hubert Deluyker	Retired from the European Food Safety Authority (Italy)
Professor Damjana Drobne	University of Ljubljana (Slovenia)
Paul Hamey	Chemicals Regulation Division, Health & Safety Executive (HSE) (United Kingdom)
Professor Antonio Hernandez Jerez	University of Granada (Spain)
Dr Malyka Galay Burgos	Independent scientist at Galay Biosciences (Spain)
Professor Andy Hart	Visiting Professor at Newcastle University (United Kingdom)
Dr Marie-Odile Rambourg	French Agency for Food, Environmental and Occupational Health and Safety (ANSES) (France)
Dr Wolfgang Reinert	DG Santé (European Commission)
Professor Michael K. Skinner	Washington State University (USA)
Dr Roland Solecki	German Federal Institute for Risk Assessment (BfR) (Germany)
Dr Kurt Straif	International Agency for Research on Cancer (IARC) (France)
Dr Jose Tarazona	European Food Safety Authority (Italy)
Dr Guy Van Den Eede	Joint Research Centre (European Commission)
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SAPEA experts	
Professor David Coggon	University of Southampton (United Kingdom)
Professor Jean Golding	University of Bristol (United Kingdom)
Dr Susanne Hougaard Bennekou	Danish Environmental Protection Agency (Denmark)

Dr Paul Miller	Silsoe Spray Applications Unit Ltd. (United Kingdom)
Professor Evangelia Ntzani	University of Ioannina School of Medicine (Greece); Center for Evidence Synthesis in Health, Brown University School of Public Health (USA)
Professor Colin Ockleford	Lancaster Medical School (United Kingdom)
Other attendees	
Professor Janusz Bujnicki	Member of the Group of Chief Scientific Advisors
Professor Rolf-Dieter Heuer	Member of the Group of Chief Scientific Advisors
Sir Paul Nurse	Member of the Group of Chief Scientific Advisors
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Programme

Workshop Chairs

Sir Paul Nurse, Member of the European Commission Group of Chief Scientific Advisors

Prof. Evangelia Ntzani, University of Ioannina, Greece

Prof. David Coggon, University of Southampton, United Kingdom

Workshop programme

08:30-09:00	Coffee on arrival
09:00	Welcome and introduction Prof. David Coggon, University of Southampton
09:10	Introduction by Group of Chief Scientific Advisors Prof. Rolf-Dieter Heuer, Chair of the Group of Chief Scientific Advisors
09:15	SAM overview Dr Johannes Klumpers, Head of the SAM Unit, European Commission
09:20	SAPEA overview Prof. Ole Petersen, Vice-President of Academia Europaea, Member of SAPEA Board
09:25	Introduction to the Evidence Review Report Prof. Evangelia Ntzani, University of Ioannina
Session 1: Toxicology	
9:30	Keynote: Dr Maurice Whelan, Head, Chemical Safety and Alternative Methods Unit incorporating the EU Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM), European Commission, Joint Research Centre

09:55	Overview of relevant areas in the report, highlighting questions for discussion: Prof. Colin Ockleford, Lancaster University and chair of the EFSA Panel on Plant Protection Products and their Residues
10:00	Discussion with responses led by: Professor Antonio Hernández Jerez, University of Granada Dr Malyka Galay-Burgos, Galay Biosciences Prof. Damjana Drobne, University of Ljubljana
10:50-11:05	Coffee break
Session 2: Epidemiology	
11:05	Keynote: Professor Antonio Hernández Jerez, University of Granada, member of the EFSA Panel on Plant Protection Products and their Residues
11:30	Overview of relevant areas in the report, highlighting questions for discussion: Prof. Jean Golding, University of Bristol
11:35	Discussion with responses led by: • Dr Kurt Straif, Section of Evidence Synthesis and Classification, Head of the IARC monograph programme, IARC • Professor Michael K. Skinner, Washington State University
Session 3: Mixtures & Co-formulants	
12:15	Overview of relevant areas in the report highlighting questions for discussion: Dr Susanne Hougaard Bennekou, Danish EPA, Vice-chair of the EFSA Scientific Panel on Plant Protection Products and their Residues
12:20	Discussion with responses led by: • Dr Roland Solecki, The German Federal Institute for Risk Assessment (BfR) • Prof. Thomas Backhaus, University of Gothenburg
13:00-13:25	Lunch
Session 4: Exposure Assessment	
13:25	Overview of relevant areas in the report, highlighting questions for discussion: Dr Paul Miller, Silsoe Spray Application Unit Ltd, UK

13:30	Discussion with responses led by: • Paul Hamey, Head, Exposure Team, UK Chemicals Regulation Division • Dr Roland Solecki, The German Federal Institute for Risk Assessment (BfR)
Session 5: Making better use of available scientific data	
14:05	Overview of relevant areas in the report, highlighting questions for discussion: Prof. David Coggon
14:10	Discussion with responses led by: Dr Marie-Odile Rambourg, Chargée de mission Toxicovigilance ANSES
Session 6: Risk & Uncertainty Communication	
14:35	Overview of relevant areas in the report, highlighting questions for discussion: Prof. Evangelia Ntzani
14:40	Discussion with responses led by: Prof. Andy Hart, The Food and Environment Research Agency, UK
15:00-15:15	Coffee Break
Session 7: The Ideal Regulatory System	
15:15	Keynote: Dr Hubert Deluyker, EFSA's Scientific Adviser
15:40	Introduction, highlighting questions for discussion: Dr Susanne Hougaard Bennekou, Danish EPA, Vice-chair of the EFSA Scientific Panel on Plant Protection Products and their Residues
15:45	Discussion with responses led by: Dr Jose Tarazona, Head, Pesticides Unit, EFSA • Wolfgang Reinert, Head of Sector, DG Sante • Dr Guy Van Den Eede, Head, Knowledge Management Health and Consumer Protection, Joint Research Centre of the European Commission
Summary and close	
16:35	Summary of discussions and next steps: • Sir Paul Nurse • Prof. Rolf-Dieter Heuer • Prof. David Coggon • Prof. Ole Petersen

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