European Commission

Scientific Advice Mechanism

Authorisation Processes of Plant Protection Products in Europe from a scientific point of view

Stakeholder Meeting Report

Stakeholder Meeting hosted by the High Level Group (HLG) of Scientific Advisors of the European Commission's Scientific Advice Mechanism (SAM)

(*23 February 2018, Brussels*)

Research and Innovation

Authorisation Processes of Plant Protection Products in Europe from a scientific point of view

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23 February 2018, Centre Borschette, Brussels

MEETING REPORT[1]

The primary purpose of this meeting was for the High Level Group of Scientific Advisors to gather views from stakeholders on the areas it is considering making recommendations to the European Commission in its Scientific Opinion on the EU's authorisation system for Plant Protection Products (hereafter the EU PPP system).

To set the scene, the participants were presented with overviews of: the Scientific Advice Mechanism (SAM); the scoping paper setting out the mandate for the SAM-HLG's work on the EU PPP system; and the findings in the draft SAPEA Evidence Review Report on the subject.

Twenty-five stakeholder representatives took part (see list at the end of this document).

The following is an unattributed synthesis of the main points raised in the discussion.

General background

- Consideration of increased centralisation in the EU PPP system should bear in mind that the efficiency potential of the current system is not being realised due to non- or under-utilization of mutual recognition provisions.
- Improvements in Risk Assessment (RM) methods such as mechanistic Adverse Outcome Pathway approaches which reduce animal testing are welcome. In addition, new paradigm RM approaches are needed given the rising number of pesticides based on microbial agents, botanicals, nanotechnology and semiochemicals. In all cases, test validation is crucial.
- In moving from classical tests to new methods, flexibility in what is mandatory would help but should not come at the expense of comparability and consistency. Furthermore, in the interest of cross-border business operations, international harmonization of all such developments should be pursued. Advantage should also be taken where relevant of what applies under other related pieces of legislation such as REACH, biocides, etc. whether to emulate good practices or to avoid repeating mistakes. Some participants cautioned that flexibility may lead to difficulties in the comparability of PPP risk assessments.

Long-term EU vision for food production & use of PPPs

- Overall, the idea for a recommendation relating to this seemed to be welcome though with a number of caveats and suggestions.
- It should take into account on-going and completed work such as last year's European Parliament discussions and a resolution on accelerating the development

[1] See meeting agenda and list of participants at the end this document

of low risk pesticides or on-going EFSA work comparing EU agricultural practices to those in other regions of the world.

- From a farmer/ farming perspective which responds to very diverse market and consumer needs, the idea of a single EU vision might be very difficult and unrealistic.
- The development of such a vision should involve all stakeholders (industry, NGOs, consumer groups, etc.) but also link up with FAO and OECD discussions as well as giving adequate attention to how developing countries follow practices in Europe and other developed regions of the world.

Protection goals

- Comments made ranged from stating that the protection goals (zero risk to human health) are clear to others stating that the clarity is only apparent as the goals not as simple as they sound.
- Ambiguities and inconsistencies pointed out included: the differences between human health at the level of the population and that of individuals or sub-populations; the meaning of minor adverse effects to operators, or even of nocebo effects – literal application of the legislation would lead to all substances being banned; or the conflict between competiveness and other protection goals. The overall picture – with reference also to the previous discussion – is exacerbated by poor or inexistent links and coordination with other relevant legislation and policy areas including agricultural policy and environmental protection.
- The clarity of human health and environment protection goals would require better definition and grading of the confidence levels with which a stated protection goal can be achieved.
- Lack of clarity according to some also comes from the role played in the system by hazard criteria for whom goals based on risk coupled with risk-benefit analysis would work much better. Others however took the view that the current hazard cut-off criteria should be maintained, implemented and not be put in question before being applied in practice and fully tested.
- Some called for improved communication to the general public and to make information more accessible to all interested parties regarding the monitoring of how goals are being met when they are clear and measurable. Some participants noted the importance of involving e.g. retailers more effectively in the communication of issues related to PPP usage.

Organisation and operation of the EU PPP system

- Overall, it was acknowledged that the current system as far as the split between approval of active substances at EU level and authorisation of PPPs at MS level, does not work as well as it might as there is too much lee-way for divergence between the practices and interpretation of guidelines that differ between Member States. Furthermore, competence and capacity is lacking in many Member States, especially on emerging new classes of pesticides.
- On this basis, the idea of centralising RA would be welcome especially if quality and adequate expertise could be guaranteed. One participant remarked that much improvement in AS/PPP assessment should result from a more complete application of current rules including in regard to issues such as synergists, safeners, mixtures, black list of coformulants, etc.

- It was remarked that it would be more realistic if RAs concentrated more on final formulations (i.e. the actual products used) - the fact that active substance RA includes testing on a number of representative uses was deemed insufficient and of questionable value.
- The rigidity of the system was lamented by some commentators – e.g.: the difficulty to take on board new pertinent knowledge and to incorporate new/ revised elements into an application file in real time and in a flexible and pragmatic manner, given the long timescales involved in the authorisation process. Likewise, the impact of changes in PPP authorisations for businesses dealing in food commodities with long shelf lives (e.g. nuts, grains and cereals) or those transitioning to precision agriculture, requires continued dialogue.
- The separation between the risk management (RM) decision-making at political level and RA was considered important to preserve.

Post-market monitoring

- The comments on this issue ranged from concern about the cost and difficulty to undertake dedicated collection of new data, to the opportunity to gain from accessing, aggregating and analysing relevant existing data collected in a wide range of other areas. Examples mentioned include Water Framework Directive monitoring of chemical residues, a DG Environment commissioned soil survey running for many years, data collected under the CAP, and *ad hoc* initiatives in individual Member States such as a twelve-year monitoring and mapping programme in the Netherlands plus a mention of guidelines by European Poison Centres on centralising documents and data.
- One participant pointed out that as monitoring obligations are built into dozens of approval decisions, there should be no lack of data. Another pointed to a recent guidance document on monitoring published by the Commission in the context of the sustainable use of pesticides directive.
- One view expressed was that, even for new data collection, if done intelligently in conjunction with existing / heretofore underused data sets, this could be of relatively low cost and could fill some glaring gaps such as data on the actual use of PPPs by farmers and the actual practices of operators.
- Any new data collection should be undertaken with a clear purpose and be hypothesis driven. It should also have a clear regulatory link as well as factor in considerations and implications that extend beyond Europe to other regions of the world for which Europe is an important reference and trading partner.

Scientific knowledge and capacity in RA

- The idea to suggest setting up a RA centre of excellence to better avail of the current scattered expertise and to cope with the rate of progress in the field was cautiously welcomed.
- International cooperation (including via OECD, the UN Codex, etc.) was seen as a must in order for Europe and other regions of the world to stay aligned.
- The inability to avail of top level industrial RA expertise in an independent and transparent manner and which does not interfere with or compromise RM decisions (in the way industrial experts participate in science advisory panels to the US's EPA) was lamented by some participants as a missed opportunity. Another suggested to

add 'independent' as a qualifier of 'scientific knowledge and capacity'. This, however, raises the question of what actually constitutes 'independence'. In this context mention was made of comments submitted by stakeholders as input to the revision of EFSA's independence policy as well as a recent discussion organised by the European Risk Forum which identified the conflation of conflict of interest and bias as the real problem.

- The biocide legislation was put forward by one participant as an example of a model where industry expertise was involved all along the process and where provisions exist for comments to be made as input to decision making.
- Independence should also be seen in the context of transparency such that all input pertaining to a given matter be made available along with the grounds for comments made by all contributing parties.
- One participant suggested that RA might benefit from exploiting relevant audits carried out by the Food and Veterinary Office as well as conducting more public controls and feeding the results back into the system.
- It was also pointed out that in the current system, even though effort is made to stay up-to-date on validated RA methodologies and techniques, the decision on whether or not to use data/guidelines lies in the hands of the risk manager rather than the risk assessor. This means that the best available techniques are sometimes not employed.

Divergent scientific assessments

- Some sympathy was expressed for the idea of a mechanism of last resort outside the normal way of working in the event of an impasse. The idea would be to unblock the impasse at the level of experts before handing the issue over to the political arena in which science-based reasoned views can get swamped by other considerations and arguments - as happened in the glyphosate case.
- Any mechanism of this sort would need to be thought through in relation to potential divergences in two different settings – the EU and the international scene (e.g. OECD) – both of which would be receptive to the output or findings of such a mechanism.
- One participant suggested that a mechanism for arbitration in the area of PPPs could be modelled on what exists within the biocides framework.

The application process

- Given that the bulk of activity concerns re-registration of existing active substances, participants suggested that something equivalent to what in the US is termed a "data call-in" and used in many regulatory agencies worldwide combined with pre-meetings to explain what exactly would be required, would result in a big efficiency increase.
- Additional relevant information should be possible to submit when it becomes available – currently not admitted.
- One participant pointed out an inconsistency in the legislation whereby data requirements upon application have to comply with the current guidelines, but that the decision to authorise (perhaps four or five years after application) is made on the basis of current science, which of course can be decidedly different from what was the state of the art at the time of application.

- As capacity is limited, effort should focus on where the risk is highest and the framework set at the outset such that active substances and products be assessed within the same frame. As for renewal, attention should only focus on what is new and not involve an integral reassessment.
- Views were expressed that all data used in the application process should be published and none kept confidential.

Hazards, risks and benefits

- One participant observed that it is too soon to question the hazard based cut-off criteria approach given that it has not been long enough in operation. Another said that it is already predictable which compounds will lose approval in the near-future and that this will be problematic for farmers (e.g. due to resistance).
- Some observed that very high dose toxicological effects could result in hazard-based exclusion which may not be representative of actual usage and exposure; others still observed that existing methods are insufficient to allow the adequate assessment of low dose non-monotonic effects.
- Some argued for consistency in the use of hazard criteria across different regulations (PPPs, industrial chemicals) while others pointed out that in spite of criteria similarity, regulatory consequences are not the same.
- Some would welcome the use of hazard criteria as a trigger to look at the risk as with general chemicals rather than automatic rejection which is seen to be a very blunt instrument. A plea was made to better inform EU legal services regarding the full implications of the use of hazard criteria as presently provided for.
- The question of whether the application of hazard cut-off criteria involves intrinsically an assessment of risk – however crude – as opposed to it being a determination of whether or not a substance unambiguously has or does not have harm-causing properties was raised but was not commented on.
- It was also stated that the application of hazard cut-off criteria does not speed up the decision-making process because of the provision for derogations and because hazard-classification by a rapporteur Member State may be altered during peer-review.
- One participant however said that they were unaware of arguments that a hazard-based approach could result in less protection for citizens and the environment which, ultimately, is the aim of the legislation – i.e. to maximise protection.
- Regarding risk-benefit, mention was made of PPRA Canada which looks at the positive attributes of biological pesticides for agriculture and the environment.

The meeting ended with the chair thanking all for their views and for giving of their time as well as acknowledging that the points made would help the High Level Group in its final deliberations on what to include in its Scientific Opinion for the European Commission.

Agenda

Authorisation processes of plant protection products in Europe

Stakeholder Meeting

23 February 2018

Venue: Centre Borschette, Meeting Room 3D,
Rue Froissart 36, 1000 Brussels

23 February 2018, 11:00 – 17:00

Chair: Sir Paul Nurse FMedSci FRS, SAM High Level Group Member & Director of the Francis Crick Institute, UK

Welcome coffee
(10:00-11:00)

1. **Chair's opening remarks**
   - Sir Paul Nurse
   (11:00-11:05)
2. **Introduction to the High Level Group (HLG) and the Scientific Advice Mechanism**
   - Johannes Klumpers, Head of the SAM Unit, DG RTD.01, European Commission
   (11:05-11:15)

Part I – General background

Overview of the HLG's mandate (scoping paper)
- Sir Paul Nurse
(11:15-11:20)

3. **SAPEA Evidence Review Report**
   - Prof David Coggon, SAPEA Working Group Co-Chair & Professor of Occupational and Environmental Medicine within Medicine at the University of Southampton, UK
   - Dr Susanne Hougaard Bennekou, SAPEA Working Group Member & Senior Advisor - Toxicologist, The Danish EPA
   (11:20-12:15)
4. **Q&A**
   (12:15-12:30)

(12:30-13:30 Lunch)

Part II – Chair-led Discussion of topics in draft Opinion

5. **Stakeholder comments and reactions on possible recommendations**
   (13:30-15:00)

(15:00-15:30 Coffee break)

6. **Stakeholder comments and reactions on possible recommendations (ctd.)**
   (15:30-16:45)
7. **Wrap-up of the meeting**
   (16:45-17:00)

LIST OF PARTICIPANTS AND OTHER ATTENDEES

Stakeholders	
CAAT-Europe	Francois Busquet
BEE-LIFE	Noa Simon
BVL-DE	Mathias Uteß
CIBE	Alexander Krick
COCERAL	Kevin Bosc
COLEACP	Morag Webb
COPA-COGECA	César González
CTGB-NL	Janine Van Gelder
DEPA-DK	Louise Stab Bryndum
ECCA	Johannes Mattaar
ECPA	Phil Botham
EFSA	José V. Tarazona & Stephen Pagani
ELO	Robert de Graeff
EPPA	Pavel Glukhov
EUROGROUP FOR ANIMALS	Alessia Virone
EUROPATAT	Raquel Izquierdo
FOODDRINK EUROPE	Beate Kettlitz
FRUCOM	Anna Boulova
GREENPEACE	Franziska Achterberg
IBMA	David Cary
INIA-ES	José Luis Alonso Prados
PAN-EUROPE	Martin Dermine
PROFEL	Jean-Bernard Bonduelle
TP Organics	Pia Pedross
WIP	Peter Koof
Scientific Advice Mechanism (SAM)	
High Level Group of Scientific Advisors	Sir Paul Nurse
SAPEA	David Coggon & Susanne Hougaard
DG RTD.01 (SAM Unit)	Johannes Klumpers, Jeremy Bray, Annabelle Ascher, Stuart Kirk, Gerjon Ikink & James Gavigan
EC Observers	
DG SANTE.E4	Wolfgang Reinert & Karin Nienstedt
DG GROW.D2	Eric Liegeois
DG AGRI.B2	Patrizia Eleonora Ganci
DG AGRI.D4	Angelo Innamorati
DG JRC.F7	Guy Van den Eede
DG RTD.E5	Tuomo Karjalainen
DG RTD.F1	Massimo Burioni