Minutes of Coordination Group Meeting
on the SAM HLG topic for Scientific Opinion:

Authorisation Process for Plant Protection Products (PPPs) in Europe from a Scientific Point of View
– A 'Forward Look'

Brussels, 30-31 August 2017

Participants:

SG Members:

Sir Paul Nurse, SAM High Level Group (PN)
Prof Rolf Heuer, SAM HLG, SG Chair (RH)
Prof Janusz Bujnicki, SAM High Level Group (JB)

Others:

Johannes Klumpers, SAM Unit (JK)
James Gavigan, SAM Unit (JG)
Jeremy Bray, SAM Unit (JBr)
Stuart Kirk, SAM Unit (SK)
Gerjon Ikink, SAM Unit (GI)
Annabelle Ascher, SAM Unit (AA)
Nina Hobbhahn, SAPEA (NH)
Cosmas Lambini, SAPEA (CL)
Jean Golding, SAPEA expert (JGo)
Susanne Hougaard , SAPEA expert (SH)
Colin Ockleford, SAPEA expert (CO)
Evangelia Ntzani, SAPEA expert (EN)
Guilhelm de Seze, EFSA (GdS)
Benedicte Vagenende, EFSA (BV)
Hubert Deluyker, EFSA (HDL)
Marta Hugas, EFSA (MH)
Guy Van den Eede, DG JRC (GVDE)
Barbara Raffael, DG JRC (BR)
Raffaella Corvi, DG JRC (RC)
[1]Wolfgang Reinert, DG SANTE (WR)
Karin Nienstedt, DG SANTE (KN)
Marina Marini, DG SANTE (MM)
Jürgen Helbig, DG ENV (JH)
Hilke Riemer, DG ENV (HR)
Alberto D'Avino, DG AGRI (ADA)

[1] DGs SANTE,ENV, AGRI only present on Day 1

Unable to attend:
Alan Boobis, SAPEA expert
David Coggon, SAPEA expert
Paul Miller, SAPEA expert

DAY 1

2. Introductions

Following the round table, PN recalled the main questions of the scoping paper in which the College asked SAM two questions. First, how the current EU dual system for the approval and authorisation of PPP could be made more effective, efficient and transparent including comparing the situation in the EU with non-EU OECD countries and discussing the advantages and disadvantages of different systems. Second, what influences risk acceptance and whether scientific conflict resolution can be used to solve issues arising from diverging risk assessments.

He briefly presented the context raising the REFIT exercise carried out in parallel by DG SANTE and the possible overlaps with the PPP opinion. He then added that, while REFIT looks at the past, the PPP opinion should focus on forward looking science rather than policy and not only on scientific issues but also on 'scientific procedure' which defines how decisions are reached that reflect realistically societal and political issues.

Following a brief presentation of the SAM mechanism by JK, DG SANTE presented the present system for the authorisation of PPPs in Europe, which DG SANTE was requested to prepare by PN via the SAM secretariat on the day prior to the meeting.

3. Progress against plan – a brief summary

EN, the SAPEA working group chair, recalled that many working group 'meetings' took the form of teleconferences and that the first physical working group meeting with all experts took place in Brussels in June. This working group meeting resulted in a clearer understanding of the sub questions guiding the draft outline of the ERR. She explained that since then and over two months (with the hindering factor of the summer break) the experts have been preparing the draft Evidence Review Report (ERR) for discussion at this SG meeting. EN reaffirmed the original question which the experts considered in the drafting of the ERR, namely 'What is the scientific state-of-the-art and promising novel methods and procedures for assessing potential harmful effects on human health from the use of PPPs'? She then briefly summarised the current status of report and the literature review methodology.
EN explained that, at this stage, experts focused on scientific shortcomings of the current EU system and possible future scientific approaches. She added that the ERR's preliminary analysis of shortcomings of current systems has been empirical and proposed by panel experts based on their knowledge. She then explained the methodology of evidence review mentioning that an unbiased literature search was performed by her based on key words and key references provided by the experts in PubMed (focussing on English, empirical literature). The question was raised whether the PubMed database was not too limited due to its focus on medical literature. It was mentioned that the JRC was asked to perform a similar literature search in SCOPUS to complement the PubMed search.

4. Draft structure of the evidence review / How to bridge the evidence review report to the 'Opinion' document

After EN introduced the sections of the ERR, SK reiterated how SAPEA's ERR would feed into the SAM HLG Scientific Opinion and provided a schematic overview of the different elements. The ERR will ideally take along all lines of evidence, including a literature review, grey literature and expert elicitation. The upcoming expert workshop would therefore be an

integral part of the ERR, while the expert workshop will simultaneously provide significant insights for the HLG Opinion. The HLG Opinion will primarily be informed by SAPEA's ERR.

5a. Main findings to date and emerging messages – draft text and powerpoint presentations

The SAPEA experts explained in detail the progress of the ERR so far. PN thanked the experts for the draft ERR which was a good starting point containing most of the information. During the presentations, questions from the HLG on the presentations often sparked a lively discussion. The ensuing discussion took the form of on open brainstorming and knowledge exchange between the HLG members, academics (SAPEA experts), expert practitioners (EFSA), DGs (risk managers, legislators and science & knowledge services) and the SAM Secretariat. A variety of topics emerged and was captured in a more structured way during the following day (see agenda item 2 of Day 2). The main topics included: Choice of Rapporteur Member States (RMS) for Active Substance (AS) approval; inconsistencies due to scientific interpretation and its communication to decision makers (Glyphosate as example); biological relevance of AS versus statistical significance; regulation of co-formulants; need to look at formulation/product; positive vs negative list of AS; usefulness of PPP authorisation at MS or rather at EU level; coverage of burden of the disease with available tests; inconsistent reporting, management and use of historical control experiments; division into hazard/uncertainty/risk; risk-benefit analysis; literature review to see if there have been scientific analyses on the use of common principles; microorganisms; and the environmental impact (as secondary to the primary focus which is human health) which should be addressed in the in the ERR and possibly dealt with more in detail at a later stage. PN suggested everybody to consider the overarching question 'How would you design the system from scratch today' to initiate a pragmatic approach and out-of-the-box thinking towards possible improvements to the PPP authorisation process?

[Considering the time, point 5b on the agenda was moved to day 2]

6. Design and preparation of the autumn expert workshops (PPP and risk perception) and stakeholder meeting

- 26 October Expert Workshop (to discuss final draft ERR and bridge to Opinion)
- 7 December (tbd) 1-day Workshop on Question B (to discuss the societal aspects, factors and mechanisms that influence risk perception and acceptance)
- 12 Feb (tbc) Stakeholder meeting - ½ day (to discuss positions by relevant interest parties such as NGOs, industrial organisations, user groups and civil society)

Following this meeting, it may become necessary for SAPEA to identify further experts for the expert workshop in October.
Following the HLG meeting planned for 5 September, PN, RH and JB will forward the HLG's views on the current version of the SAPEA ERR to SAPEA. These HLG indications will provide the experts with guidance on how to further develop a more balanced and complete

ERR. NH added that the ERR which will include the proceedings of the expert workshop (possibly as an Annex) will be a separate document to the scientific opinion.
The workshop on question B, under SAPEA's lead will be yet another separate document feeding into the scientific opinion.

DAY 2

1. Recap of Day 1

PN summarised the main points that were discussed and suggested to address open point of the agenda of day 1 and to continue the discussion by looking at the full cycle of the authorisation of PPPs in Europe step-by-step.

[Point 5b on the agenda of day 1 was moved to day 2 and addressed now]

5b. Preliminary findings on the EU policy framework and regulatory context for PPPs in EU and elsewhere including an overview of non EU OECD country schemes

GI briefly presented the progress on the information gathering for a comparison between PPP authorisation schemes between the EU and non-EU OECD countries. The focus for the SAM Secretariat was a high level description, although more detailed and technical information surfaced as well. The information is based primarily on expert input (among others from the SAPEA experts), but also on some reports and websites of relevant (inter)national authorities.
A single overarching system was mentioned as one of the useful aspects in non-EU OECD countries. New Zealand's approach of group approval of hazardous substances may provide inspiration for increased speed and simplicity. The US EPA's approach for cumulative risk assessment of pesticides was considered pragmatic. Each of these aspects would, however, require changes to EU legislation.

2. Next steps: changes to report structure, format and style; actions necessary to develop draft findings and to fill gaps

The discussion followed from the previous day (agenda item 5a). PN launched the debate by asking the experts to examine the current system step-by-step offering their appreciation of possible shortcomings and improvements. PN suggested focussing on forward looking science rather than policy as well as on 'scientific procedures' which defines how decisions are reached that reflect realistically societal and political issues. Various elements that emerged from the brainstorming of the previous day were further elaborated in this structured discussion on the stepwise evaluation of the PPP authorisation system.

The following more general comments/questions can be summarised: Why not equally (to AS) regulate co-formulants; use of positive vs negative list of AS; can we look for inspiration from other, similar European approvals processes (e.g. pharmaceuticals); need for new AS to demonstrate significant additional benefit or reduced risks as part of their approvals process, by comparison with the incumbent; general data management issues (too much data requested, use of historical controls, etc.), in particular: better use of IT tools for the distribution of work

or the collection and sharing of data, better sharing of confidential data for greater transparency while not compromising legitimate protection of commercial data; opportunities for improved communication on how these processes operate to increase public trust; can the system for follow up and monitoring of pesticides be improved; how well do we cover the burden of disease with tests we have (animal and epidemiology, data issues); need for risk/benefit analysis on pesticide use; scientific concern about inconsistent reporting; is there sufficient expertise to cater for the increasing number of applications based on the use of microorganisms; how do we deal with environmental impacts of PPPs in addition to the priority of human health; opportunities for engagement with different stakeholders/buy-in for social science workshop.
Further, some specific comments relating to the approval of active substances included: can the adverse outcome pathway be made better use of; need for independence of rapporteur/co-rapporteur (choice of both should be done at EU level to spread the workload among MS); need for guidance/common principles in relation to employment of statistical techniques.
Others related to the approval of products at member state level: Is regional classification always sensible (example France's different zones); how can uniform principles' implementation be made more effective and does that protect against MS' difference in implementation; contribution to resolution of divergences in scientific opinion / increase of transparency and how to deal with mixtures.

3. Next meetings

See agenda item 6 of Day 1.

Actions (and responsibilities):

- Circulate DG SANTE's 'Overview report on the authorisation of PPPs' – (SAM sec)
- As per request of PN, analysis of this report – (SAPEA, with support from JRC)
- As per request of PN to SAPEA, delivery of comments on most effective way of doing the authorisation process for AS and PPP step-by-step – (SAPEA)
- Circulation of comments/recommendations to SAPEA on how to improve the ERR (following the HLG meeting on 5 Sept) – (HLG)
- Following HLG's recommendations on improving ERR, allocation of tasks to experts – (SAPEA)
- Identification of additional experts needed for the expert workshop – (SAPEA, with support of DG JRC (via unbiased clustering of topics and analysis of key authors) and SAM Secretariat
- Carry out literature review whether there have been scientific analyses on use of uniform principles, e.g. in relation to conflict resolution – (SAPEA)
- Clarify how the literature and data is processed (e.g.: the ERR literature review methods mentions the identification of 14 publications out of which only 9 were further used for review: specify why 5 were not used) – (SAPEA)
- Relating to Workshop on Question B (risk acceptance/risk perception, resolution of divergences of scientific opinions) (SAPEA to lead)
    - Consider risk-benefit analysis. (SAPEA)
    - Consider opportunities for engagement with different stakeholders/buy in (SAPEA)

AGENDA

Coordination Group Meeting
on the SAM HLG topic for Scientific Opinion:

Authorisation Process for Plant Protection Products (PPPs) in Europe from a Scientific Point of View
– A 'Forward Look'

Day One 30 Aug 2017, 13:00-17:30

VENUE: Palais des Académies, rue Ducale 1, 1000 Bruxelles

Participants: *(HLG Representative/s, SAM Unit PPP team, SAPEA Staff, the SAPEA Experts, EFSA and ECHA experts and concerned DGs as observers)*

Chairperson: Paul Nurse

***Today's Objective**: Presentation and review of: a) progress in producing the planned evidence review; b) draft structure of the Evidence Review Report (ERR) (and its relationship with the 'Opinion'); c) main findings to date (draft text) d) Plans to complete the review*

1. Tea/coffee on arrival

2. Welcome, House-keeping, Introductions, Agenda and Today's Objective [P. Nurse/SAM sec]

3. Progress against plan – a brief summary [SAPEA]

4. Draft structure of the evidence review [SAPEA + support from SAM sec]
   - Sections – main themes
   - Format and Style
   - How to bridge the evidence review report to the 'Opinion' document

Break

5a. Main findings to date and emerging messages – draft text and powerpoint presentations [SAPEA experts]

b. Preliminary findings on the EU policy framework and regulatory context for PPPs in EU and elsewhere including an overview of non EU OECD country schemes [SAM sec]

6. Design and preparation of the autumn expert workshops (PPP and risk perception) and stakeholder meeting [SAM sec and SAPEA]

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Coordination Group Meeting
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Day Two 31 Aug 2017, 09:00-13:00

VENUE: Palais des Académies, rue Ducale 1, 1000 Bruxelles

Participants: *(HLG Representative/s, SAM Unit PPP team, SAPEA Staff, the SAPEA Experts, EFSA ECHA experts, DG JRC)*

Chairperson: Paul Nurse

***Today's Objective**: Way forward for the completion of the evidence review and for the Expert and stakeholder workshops*

1. Recap of Day One + items to be addressed today [Paul Nurse]
2. Next steps – agree on:
    - Changes to report structure, format and style [SAPEA]
    - Actions necessary to develop draft findings and to fill gaps [SAPEA]
    - Implications for the Expert Workshop [Paul Nurse]
3. Recap all agreed actions and set date of next meeting [Paul Nurse/HLG]