EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection
Systems Toxicology Unit
EU Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM)

Summary Record

PARERE Meeting

5th June 2014, Somma Lombardo, Italy

The PARERE meeting was held on the morning of 5th June 2014 (agenda included in Annex I) and was followed by a joint PARERE-ESTAF meeting (summary record available).

1. Tour de table on follow-up activities within Member States since the last PARERE meeting

- PARERE members gave an overview of the establishment of the PARERE network in their respective countries i.e., national bodies/agencies/experts involved, as well as a brief description of its functioning and difficulties encountered e.g., one Member Country experienced a lack of available experts; another Member Country mentioned that no National Coordinator to the OECD Test Guideline Programme with whom to interact had yet been nominated.
- They presented how PARERE contacts managed to link up with other networks such as OECD National Coordinators (NCs) of the WNT[1] or EU National Contact Points (NCPs[2]).
- They emphasised that interaction and communication between PARERE representatives and OECD NCs should be encouraged and re-enforced. Mutual exchanges between those networks can avoid duplication of work.
- Some Members had the impression that PARERE activities were overlapping to some degree with those of the OECD Test Guideline Programme, while others considered PARERE activities being upstream to the OECD work. Moreover, the range of activities addressed by PARERE network is broader than that of OECD as methods applicable for safety assessment related to pharmaceuticals, biologicals and food are additionally examined, whereas the OECD WNT focuses primarily on chemicals. PARERE work also contributes to the identification of priorities and the development of strategies in a variety of areas relevant to the 3Rs.
- DG ENV presented feedback from the meeting of NCPs and described how the PARERE network was established in the context of Directive 2010/63/EU in order to support the development and validation of alternative approaches relevant to regulatory applications.

Actions:

(i) *PARERE members will continue working with EURL ECVAM in the mapping exercise of the network by sending further updates on the PARERE situation within their MS*

[1] Working Group of National Coordinators of the OECD Test Guideline Programme
[2] National Contact Points for the implementation of Directive 2010/63/EU

(ii) *EURL ECVAM will make available to PARERE members details of EU National Contact Points and OECD National Coordinators*

2. Roles and responsibilities of PARERE

- EURL ECVAM highlighted Article 47 of Chapter V within Directive 2010/63 that relates to alternative approaches and the need to establish their regulatory relevance.
  Roles and responsibilities of PARERE have been already discussed in previous meetings where an initial set of tasks was proposed and agreed. At this latest meeting PARERE members and EURL ECVAM reviewed and further refined these tasks. It was agreed that PARERE should carry out six main tasks (below) wherein tasks 1 to 3 are core tasks directly related to the provisions of Directive 2010/63, while tasks 4 to 6 can be considered as important supporting tasks:

  1. Provide upstream input on potential regulatory relevance and suitability of proposed alternative approaches and identify approaches that deserve attention;
  2. Highlight 3Rs priority areas within the regulatory domain and provide feedback on draft EURL ECVAM strategy documents;
  3. Comment on draft EURL ECVAM Recommendations;
  4. Identify regulatory experts that could participate in specific EURL ECVAM project groups (e.g. supporting validation studies, peer-review working groups);
  5. Support and facilitate the work of the EU Network of laboratories for the validation of alternative methods (EU-NETVAL) within Member States;
  6. Contribute to the promotion, dissemination and communication of alternative approaches within Member States, including surveillance of utility and uptake, in cooperation with other stakeholders.

- It was agreed that regular exchanges with EURL ECVAM should be developed further to best address these tasks, in addition to the annual meeting.

3. PARERE Consultation

- EURL ECVAM presented its validation workflow and the key points when the PARERE network may be consulted. This is typically at the stage of test method submission and concerns the assessment of potential relevance and added value of the method, but also includes upstream consultation on EURL ECVAM strategies in particular areas, and downstream consultation on EURL ECVAM Recommendations.

- The PARERE network was presented with the GreenScreen™HC (GSHC) test method submission for the detection of genotoxic potential *in vitro.* For this consultation, EURL ECVAM presented four possible scenarios (elaborated by EURL ECVAM) where the GSHC assay could possibly be used to satisfy regulatory information requirements. To support the consultation, EURL ECVAM provided

submission documents drafted by the submitter, the EURL ECVAM evaluation report (inc. descriptions of the use-case scenarios), and a series of charge questions.

- Emanating from a general discussion on the validation and acceptance of alternative approaches, PARERE members expressed an interest in pursuing more in-depth dialogue with EURL ECVAM on the topics of i) sources of uncertainty of *in vivo* reference data and ii) priority setting concerning specific regulatory endpoints.

Actions:

(i) PARERE members should provide comments on the draft EURL ECVAM strategy on fish toxicity bioconcentration/bioaccumulation (already circulated and presented in the joint PARERE-ESTAF meeting that followed) by 31 July 2014.

(ii) PARERE members should provide comments on the draft EURL ECVAM strategy on acute systemic toxicity (already circulated and presented in the joint PARERE-ESTAF meeting that followed) by 31 July 2014.

(iii) PARERE members should provide their opinion on the regulatory relevance of the GreenScreen®HC test method (inc. responding to the charge questions and considering the four regulatory-use scenarios proposed by EURL ECVAM) by 15 July 2014 (later extended to 31July 2014).

(iv) EURL ECVAM will make available on CIRCABC all documents and presentations related to the items discussed at the meeting.

(v) EURL ECVAM will update the list of PARERE members and their details so that they are all included in mailing lists and have access to documents via CIRCABC.

ANNEX I

PARERE MEETING

5th June 2014

Agenda

Item	Time	Description	Format
	9:00-9:15	Opening of the meeting and welcome *M. Whelan*	
1	**9:15-10:30**	<u>Tour de table on follow-up activities within Member States since the last PARERE meeting</u> • Update since the last PARERE meeting (4 June 2013) on progress within Member States (MS) on the establishment of the PARERE network and sharing of information between PARERE members, MS regulators, the National Contact Points (NCPs) for the implementation of DIR 2010/63/EU, and the National Coordinator of the OECD Test Guidelines programme (WNT). • In this context, the mapping exercise initiated in 2013 through a survey of PARERE members should be completed and will serve as a living internal reference document on PARERE. • Feedback from the meeting of the ENV network of National Contact Points (NCP) for the implementation of DIR 2010/63/EU	Presentations by MS (slide or oral) Discussion
	10:30-11:00	*Coffee break*	
2	**11.00-12.00**	<u>Review of roles and responsibilities of PARERE</u> • Presentation of Directive 2010/63, Article 47. Especially para. 5 and its interpretation. • Tour de table on how PARERE members see their roles and responsibilities. The aim is to achieve a common understanding between all parties. Should we consider drafting Terms of Reference? • How to ensure that MS regulators continue to support a test method selected to undergo validation if it then	Presentation Discussion Agreement

		enters the OECD process to form the basis of a Test Guideline.	
3	**12:00-12:45**	<u>Consultation of PARERE</u> • EURL ECVAM consults PARERE at different stages of its validation workflow. Beside the consultation of PARERE on EURL ECVAM Strategy documents and EURL ECVAM Recommendations, discussions will focus on how to best engage PARERE at the early stage in the validation workflow, for example at the level of test submission assessment and priority setting. • For the consultation of PARERE on the merit of individual test methods, specific and focused questions will be defined so that regulatory experts have a clear idea of the aspects they should focus on in formulating their opinions. Discussion will be support by a case study.	Presentation Discussion Agreement
4	**12:45-13:00**	• Conclusions. • Follow-up actions.	
	13:00	Meeting close	

13:00-14:00 Lunch

<u>Joint PARERE-ESTAF meeting starts at 14:00.</u>