EUROPEAN COMMISSION
JOINT RESEARCH CENTRE

Institute for Health and Consumer Protection
European Union Reference Laboratory for Alternatives to animal testing (EURL ECVAM)

Summary Record

Meeting of the Preliminary Assessment of Regulatory Relevance (PARERE) Advisory Network held at EURL ECVAM, JRC on 4th June 2013

The PARERE network, established under the EU Directive for the Protection of Animals used for Scientific Purposes (DIR 2010/63/EU), provides EURL ECVAM with advice on the relevance of proposed alternative test methods for use in regulatory safety assessment. The meeting agenda is included in Annex I. More specifically, the role of PARERE is to;

- Provide upstream input on potential regulatory relevance and suitability of proposed test methods and testing strategies.
- Comment on draft EURL ECVAM Recommendations following ESAC peer review of validation studies.
- Provide feedback on EURL ECVAM "strategy" documents.
- Highlight areas within the 3Rs domain that need specific attention.
- Identify regulatory experts that could participate in ECVAM project groups (e.g. workshops, ITS design, VMGs, etc.).
- Support and facilitate EU NETVAL within Member States (MS).

Discussions during the PARERE meeting of June 2013 centred on the current state-of-play regarding the establishment of the PARERE network in MS and its important role in helping to shape EURL ECVAM strategies and prioritise actions towards method validation, promotion and acceptance. The meeting agenda addressed in particular the following questions:

- How is information currently shared within MS between the PARERE representative, the representative to the DG ENV network of National Contact Points (NCP) for the implementation of DIR 2010/63/EU, and the National Coordinator of the OECD Test Guidelines programme (WNT)?
- What ministries and agencies are involved in the administration of the networks in MS?
- How do PARERE representatives interact with the various regulatory authorities within MS to gather their input *e.g.* regarding the relevance of specific test methods or providing feedback on EURL ECVAM strategy documents that PARERE has been requested to review?

It was evident from the discussions that MS had implemented PARERE and its functions in many different ways and formats. Several MS demonstrated established communication structures involving all three networks (PARERE, NCP and WNT) and the relevant regulatory authorities while other MS have not yet fully established their PARERE network. Some MS have selected the same entity, and in some cases the same expert, as the representative for PARERE, NCP and WNT while others have nominated several different

representatives for the networks. In implementing the PARERE in accordance with DIR 2010/63/EU, some MS have a strong focus on animal welfare ethical issues, training and education while other MS have strong emphasis on development of alternative test methods for regulatory safety assessment. Some cover both fields. It seemed that these differences to a large degree were dependent on the ministry or agency responsible for the implementation of DIR 2010/63/EU in addition to individual MS priority setting and resources available.

Currently it is foreseen that PARERE provides feedback to EURL ECVAM on three specific items/documents namely, i) draft EURL ECVAM Recommendations, ii) selected test method submissions and iii) draft EURL ECVAM strategy papers. Particularly in the cases of Recommendations and test method submissions, it was agreed that ECVAM should endeavour to be proactive and transparent in the handling of the comments received to reassure PARERE that the feedback had indeed been taken on-board and to make it clear what impact it actually had on decision making and/or document revision. In addition, it was also considered desirable that EURL ECVAM's opinion on the potential regulatory relevance is clearly communicated to PARERE regarding test method submissions. There were also some concerns raised regarding possible duplication of work between the PARERE network and the EU National Coordinators of the WNT if the mutual interaction, communication and workflows are not managed properly. It was agreed therefore that PARERE representatives should make every effort to coordinate with NCs within MS after receiving a request from EURL ECVAM. In addition, the European Commission's own NC will assist where possible to efficient and effective cooperation.

In discussing and comparing the individual setups in MS for the PARERE networks, no ideal composition of a network could be identified since the optimum composition depended on the MS and different compositions could fulfil the role of PARERE. However, it was considered of high relevance that the different ministries/agencies in MS responsible for the three networks should be better harmonised in terms of information sharing and gathering of feedback, especially concerning the inclusion of the WNT National Coordinators in any PARERE commenting rounds. This issue is of special importance to MS where the representatives to the PARERE and the WNT are not the same person/agency and also in situations where the main focus of the PARERE representative is on ethical animal welfare topics and not primarily alternative test method development.

PARERE representatives expressed their commitment to the role of PARERE and to establishing a functional network within MS. In order to provide the type of feedback that EURL ECVAM expects, some representatives felt that ECVAM needs to be more explicit in its requests to ensure that the experts who are being consulted by the PARERE representatives have the clearest possible idea what aspects they should focus on in formulating their opinions and comments. It was noted however that whatever the nature of the consultation (e.g. draft Recommendation, test method submission, strategy document), in general the PARERE network should focus on regulatory needs, relevance and context rather than on more technical aspects. It was recognised that opinions related to regulatory aspects were also received on occasion from ESTAF (ECVAM Stakeholder Forum), ESAC (ECVAM Scientific Advisory Committee) and ICATM (International Cooperation on Alternative Testing Methods) during a consultation process and thus there might be some overlap in opinions. However, EURL ECVAM believes that since these other bodies focus on other aspects such as, for example, scientific relevance, industrial use and validation, then for the most part the feedback received from these bodies is very much complementary to that received from PARERE.

It was considered important by the meeting participants that EURL ECVAM communicates its planned validation studies (after a successful pre-validation phase) to the PARERE and EU NCs (WNT) at an early stage so that there could be general discussion and agreement on whether an OECD Test Guideline should be pursued and if so, when and how a Standard Project Submission Forms (SPSF) should be submitted to the OECD/WNT. It was also considered important that PARERE members inform ECVAM about test method needs, to better address the various regulatory requirements, and in preparation for forthcoming Regulations.

It was concluded that information on upcoming PARERE consultations should be communicated to the PARERE in the format of a 1-year work plan (Annex 2); updated regularly as new information becomes available. This would help PARERE representatives to alert the relevant experts in their networks of when their input is needed and to better organise the workflow within their MS. Regarding the time allocated to consultation/commenting rounds, it was proposed that when possible, EURL ECVAM should allow for longer commenting times to ensure that PARERE representatives can gather as much feedback as possible within their MS. This applied in particular to more substantial items such as draft EURL ECVAM strategy documents.

The network concluded that the meeting had been valuable in providing the opportunity for information sharing between MS. It was agreed that PARERE representatives should continue to discuss the different approaches that have been followed in MS to implement the PARERE network, and therefore this should be included as an agenda item for the next PARERE meeting.

PARERE

Meeting of the Preliminary Assessment of Regulatory Relevance (PARERE) Network
Tuesday, 4 June 2013
EC JRC, Ispra, Italy, Building 36/02

Agenda PARERE Meeting 4 June 2013

(Version 17 May 2013)

Time	Tuesday, 4 June PARERE Meeting	
12:30 – 14:00	Sandwich lunch	
14:00 – 14:10	Opening of Meeting, tour de table	
14:10 – 14:30	**Presentation** - Role of PARERE (M. Whelan)	Presentation | Discussion
14:30 – 17:00	**Discussion session** (including a coffee break) Short informal contributions are expected from PARERE members in relation to the following discussion points: I. Information sharing within Member States (MS) between the PARERE representative and the representatives to the DG ENV network of National Contact Points for the Implementation of DIR 2010/63 and the National Coordinator to the OECD Test Guidelines programme (WNT). II. Ministries/agencies involved in the administration of the networks in each MS. III. Interactions with regulatory authorities within MS in relation to gathering e.g. feedback on test methods or strategy documents that ECVAM asks the PARERE to comment on. IV. Upcoming PARERE work plan; practical aspects of providing feedback	Presentation | Discussion
17:00 – 17:30	**Conclusions and Follow-up Actions** (M. Whelan)	Discussion
17:30	Wrap up and closure of the meeting	
N.B. The meeting on the first day ends with a social dinner on Tuesday, 4 June 2013, 20:00 at the Hotel Lido.		

Annex II

Preliminary rolling work plan for PARERE consultations

Consultation	Timelines
Recommendation on the BHAS Cell Transformation Assay (CTA) to support carcinogenicity assessment of chemicals.	Commenting round until 25 June 2013
Recommendation on the Direct Peptide Reactivity (DPRA) Assay to support the assessment of skin sensitisation potential of chemicals.	Commenting round until 25 June 2013
Strategy document on Genetic toxicity testing	1st draft available for commenting until 31 July 2013
Recommendation on the KeratinoSens™ assay to support the assessment of skin sensitisation potential of chemicals.	Commenting round until 20 September 2013.
Recommendation on the Zebrafish embryo toxicity test (ZFET) to support the assessment of acute aquatic toxicity of chemicals.	1st draft for commenting expected in late 2013
Strategy document for Ecotoxicity toxicity testing	1st draft for commenting expected in 4th quarter 2013
Recommendation on the hCLAT assay to support the assessment of skin sensitisation potential of chemicals.	ESAC peer review expected autumn 2013 and 1st draft for commenting expected 1-2nd quarter 2014
Strategy for Acute systemic toxicity testing	1st draft for commenting expected for 2nd quarter 2014
Recommendation on the EpiOcular assay to support the assessment eye irritation testing of chemicals.	ESAC peer review planned for 1st-2nd quarter 2014 and 1st draft for commenting expected latter part of 2014
Recommendation on 2 CYP-induction assays to support assessment of toxicokinetics/biotransformation of chemicals.	ESAC peer review planned for 1st-2nd quarter 2014 and 1st draft for commenting expected latter part of 2014
Recommendation on the MELN estrogen receptor transactivation assay to support the assessment of chemicals with endocrine disruption potency.	ESAC peer review planned for 1st-2nd quarter 2014 and 1st draft for commenting expected latter part of 2014

Note: Consultations on test method submissions will be performed on an *ad hoc* basis.