European Partnership for Alternative Approaches to Animal Testing (EPAA)

Action Programme (2011-2015)

1. Introductory remarks

The EPAA was launched in 2005, with the aim to support the development, validation and acceptance of alternative approaches in meeting regulatory requirements.

It adopted its first Five Years Action Plan in 2006, which it reviewed in 2008.

As the EPAA enters into the last year of its initial 5-year term, all partners recognised its value added and recommended continuation for another 5-year term. This required a revision of the initial action plan.

This process was based on a critical assessment of the first activities conducted from 2006 to 2010 on the one hand and on mapping of forthcoming scientific, policy and legislative challenges on the other hand to secure continuity, adequate scope and prioritisation.

The revised action plan also reflects the structural changes which EPAA partners implemented in 2009 to increase its efficiency and make the best use of resources.

Throughout this process, the EPAA benefitted from the strong support and recommendation by the EPAA Mirror Group, in which participate highly qualified experts coming from academia, NGOs, legal risk assessors and other interest.

While certain activities are implemented jointly by all partners, EPAA also acts as a sounding board whose recommendations are implemented by individual partners outside the partnership in their respective area of competence or referred to third parties (feasibility studies, EU or international regulatory dialogue, etc.).

Finally, the model of public private partnership established by EPAA is carefully looked at by regulatory authorities in other regions of the world, opening up possibilities for further collaboration and for achieving one of the EPAA key objectives for the next 5-year term, i.e. enhancing international coordination on scientific and regulatory matters.

The EPAA partners have decided to adopt a staged approach, with a revision of the action plan mid-term to assess progress on actions before adding/removing actions or revisiting their scope.

This approach does not exclude that a follow-up can be given and means to be made available to further proposals and recommendations developed in the framework of the implementation of actions mentioned here, or suggested by the Mirror Group.

2. Criteria for selecting and prioritising actions

This second action plan is designed in continuity of the first action plan and builds on its achievements: some actions would be moved to the next stage of the cycle research-(validation)-acceptance-dissemination. Some new activities emerged as a follow up to scientific and regulatory debates conducted during first term.

One lesson from the first EPAA plan is the need for flexibility in planning activities and the need to conduct regular review to adapt them to evolving environment and outputs from third parties' projects. Some actions may also be discontinued or not initiated to avoid duplication. This led us to adopting a step–by-step approach to allow more flexibility in addressing challenges and avoiding duplication where activities have been taken on board by other bodies

1) identification of fewer additional activities or "a selected number of actions in the global portfolio"
2) a mid-term review of the action plan in 2013 to add new actions if appropriate

Prioritisation of activities was based on the following criteria:

- Relevance to EU policy objectives/legislation (sectoral legislation, animal welfare legislation and policies)
- Unmet scientific challenges
- Tangible impact on numbers and welfare of laboratory animals
- EPAA partners competence and resources
- Recognition of third parties activities to avoid any duplication

Through this action plan the EPAA partners also aim to achieve three main objectives as means to effectively promote alternative approaches:

- Closer international coordination on scientific and regulatory matters
- Closer links with national regulators in the EU
- Higher profile for EPAA for the merits of all 3Rs methods

3. Work streams and actions

3.1. Platform on Science

Actions

1) Identify knowledge/scientific gaps in the fields of computational chemistry and systems biology and recommend areas for further research in these fields
2) Identify and address research needs for developing or optimising alternative methods through relevant plans and calls for proposals of the European Commission and other research funding institutions.
3) Seek involvement of young scientists and scientists from areas not directly related to biosciences to increase knowledge and leverage understanding of 3Rs within scientific community (science award)

4) Assess the feasibility of technology transfer across sectors (e.g. optimization of study design in toxicological testing).

The first activity builds up on the outcomes of the work stream on New Perspectives for Safety Testing. The first workshop in 2008 highlighted several areas of new and emerging science that may, in the future, be harnessed to develop completely new approaches to the assessment of systemic toxicity caused by chemicals and drugs without the use of experimental animals. The objective of EPAA is to move from scientific debate to deliverables through EPAA sponsored and other collaborative projects.

This platform also encourages scientific dialogue to increase coordination with international research and dissemination initiatives, extending the fields of cooperation portfolio (i.e. sharing the work on scientific studies, etc…).

3.2. Platform on 3Rs in Regulation

Actions

5) Identify areas where implementation of regulatory requirements could be optimized/rationalized in line with the 3Rs principles.
6) Foster regulatory acceptance of rationalised acute toxicology testing methodologies (waiver of one of the administration routes)
7) Support further development of the scientific data to promote the vaccines consistency approach
8) Promote acceptance of extended one generation study by regulatory authorities.
9) Understand regulators' requirements for levels of confidence in integrated testing strategies.

Case studies, such as acute toxicology or consistency approach in vaccines are pilots to test the most efficient way of achieving this objective. The second series of actions aims at helping reflection and addressing concerns about how to consider new approaches such as integrated testing strategies in the regulatory context, including in the global regulatory context. Finally, the 3Rs in Regulation platform seeks to promote identify the scope for international harmonization mechanisms and bring it to the attention of interesting parties.

3.3. Platform on Dissemination & Communication (EPAA market place)

Actions

10) Review key 3Rs topics, so as to present the options available today to regulators and users in a form of thematic reviews (launch reprotox review in 2010, others to follow).
11) Development and improvement of communication existing tools (including an annual EPAA communication prize) to improve understanding of what results 3Rs approaches can deliver in different sectors;
12) Define mechanisms to provide greater access to information and opportunities to connect those who have and those who need information (examine Web 2.0 possibilities).

13) Promote the potential of alternative approaches with young scientists, for instance through an EPAA Science Award.

Dissemination is understood as variety of tools and mechanisms to improve acceptance and uptake of 3Rs methods – information, education, sharing good practice. For doing so effectively, the EPAA created its market place. Under this "umbrella" concept, information needs of target audiences are identified and addressed and adequate tools used to connecting regulators, academia and industries and their ideas to progress the development and implement of 3Rs approaches and good practice sharing. The EPAA science award is part of this endeavour.

EPAA Communication activities aim at improving understanding amongst policy, decision makers and stakeholders about the scientific and policy framework, opportunities and limitations of 3Rs methods in the regulatory framework and impact of EPAA activities.

Communication and dissemination come in support to the two first work streams of EPAA work.

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