



3 Rs Declaration

1. – Preamble

The Protocol on Protection and Welfare of Animals annexed to the EC-Treaty aims at ensuring improved protection and respect for the welfare of animals as sentient beings. In formulating and implementing the Community's policies, the Community and the Member States shall pay full regard to the welfare requirements of animals.

All industry sectors, including pharmaceuticals, chemicals, cosmetics, agrochemicals and foods manufacturers, are already obliged to apply available methods to replace, reduce and refine animal use (Three Rs) in safety and efficacy evaluations under the existing animal protection legislation (*Directive 86/609/EEC*).

The 7th Amendment to the Cosmetics Directive 76/768/EEC, established specific requirements for the cosmetic industry relating to the use of replacement methods for animal-based safety studies by introducing testing and marketing bans¹.

According to the “Fourth Report on the Statistics on the Number of Animals Used for Experimental and other Scientific Purposes in the Member States of the European Union” the total number of animals used in 2002 was 10.7 million. The European Commission's recent Proposal on the Registration, Evaluation and Authorisation of Chemicals (REACH) has served to highlight stakeholder and general public concerns regarding the continued need for animal testing as a means to protect human and animal health and the environment. At the same time it should be recognised that there is considerable pressure from the public and the regulators to better understand risks to humans and the environment from chemicals and to increase assurance in product safety. In the absence of validated alternative methods, the current legislative paradigm requires animal use.

Likewise, the pharmaceutical industry is largely dependent upon animal studies for predicting human toxicity and efficacy of pharmaceuticals. The need for animal studies prior to any human exposure is explicit in the World Medical Association's [Ethical Principles for Medical Research Involving Human Subjects](#) (“The Helsinki Declaration”).

¹ Cut-off dates 2009/2013 even in the absence of alternative methods

In fact, most sectors are currently under specific regulatory obligations that today can only be fulfilled with the results of animal studies.

Coupled with a genuine desire of stakeholders to see faster progress towards ultimately replacing animal testing, Community legislation and financing tools represent both challenges and opportunities in the development of alternative approaches. However, further efforts should be made to speed up work toward the replacement of animal testing where possible and reduction and refinement where replacement cannot yet be achieved. In order to achieve this necessary change, the Commission is taking leadership in initiating and organising a partnership with Industry on alternative approaches to animal testing based on the 3 Rs principle.

A number of activities are under way to promote the development and validation of Three Rs methods under the EU Research Framework Programmes. Industry has been implementing replacement, reduction, and refinement methods for some time. Some human health effects can already today be assessed using replacement methods, i.e. skin corrosion, skin absorption and acute phototoxicity. Other health effects, such as systemic toxicity, can now be tested using fewer animals and with less severe effects on them.

But despite success achieved to date, it is also recognized that there are still more opportunities to exploit the advantages of increased synergies between the activities carried out at national, European and international level (i.e., through OECD, ICH, VICH and other mechanisms) by all relevant stakeholders.

Advanced technologies (e.g., genomics, proteomics, bioinformatics) and increased knowledge are helping to develop a diverse range of approaches that are less reliant on animals. There is undoubtedly potential to harness such technologies within novel approaches to safety assessment that reduce the reliance on animal use, whilst providing appropriate reassurance of human and animal health and environmental protection. Such potential may also prove to be a market incentive to certain industry sectors. The approach is entirely in keeping with the Lisbon agenda, which calls for the development of new technologies and approaches in order to maintain European competitiveness.

The conference on “Alternative Approaches to Animal Testing – Europe Goes Alternative” on November 7, 2005, in Brussels demonstrates that the European Commission and all other stakeholders keep laboratory animal welfare high on the political agenda. They collectively recognise the need for a new, more coordinated and strengthened approach to laboratory animal welfare and 3 R-approaches to animal testing. Such an approach needs to balance the substantial technical and scientific challenges with the requirements of consumer, patient, occupational, animal and environmental safety.

2. Partnership

A voluntary “European Partnership to Promote Alternative Approaches to Animal Testing” is therefore established to support the development, validation and acceptance of alternative approaches to replace, reduce and refine animal use and apply advanced methodology from biosciences and medicine to develop novel approaches.

The Partnership will allow the European Commission and Industry to collaborate effectively on the basis of an action programme identifying concrete activities and priorities for the promotion of alternative approaches to animal testing. The partnership will facilitate wider dialogue with key

stakeholders thereby promoting use of available knowledge, greater transparency and understanding. It will be jointly undertaken by the Commission and industry, and would also seek to establish appropriate links with relevant bodies at national and international levels.

The partnership will be based on pragmatic mechanisms aimed at achieving impact that can be supported by both partners. Participants will contribute to the establishment of the procedures for the management of the partnership, including identification of respective responsibilities and development of performance criteria.

3. Principles

The Partnership should:

- Aim at stimulating the development, validation and implementation of alternative approaches via appropriate resources and financing tools and their regulatory acceptance.
- Identify European and international opportunities to address barriers to progress, foster acceptance and harmonisation of tests by regulators, ensure mutual acceptance and avoid redundancy wherever possible (through OECD, ICH, VICH and other mechanisms).
- Build on past achievements from the different partners in applying the Three Rs to animal use. This will require effective mapping of existing efforts in order to provide a point of departure.
- Support development and use of other modern approaches to gradually change the way safety assessment is carried out.
- Ensure a mechanism for dialogue and communication with other relevant stakeholders on developments that effectively contribute to animal welfare.
- Be mindful of the need to consider innovation, the protection of intellectual property arising from innovation and the implications for the overall competitiveness of European industry.

4. Participation

The participants of the Partnership;

- Commit themselves to contribute to an Action Programme to be reviewed and updated every year that identifies short, medium and long term activities and appropriate responsibilities;
- Understand that progress in life sciences provides potential opportunities to further replace, reduce, refine the use of animals;
- Recognise the importance of the need to maintain a high level of consumer, patient, occupational, animal and environmental safety;
- Acknowledge there is further potential for cooperation and sharing of knowledge between

industry sectors;

- Recognise that the regulatory requirements of each industry sector are unique and that this will be reflected in the implementation of any deliverables
- Call on all stakeholders to intensify jointly efforts to make available validated alternatives based on the 3Rs principles: Replacement, Reduction and Refinement;
- Invite interested parties sharing these goals to engage and contribute to the Partnership.

Addendum to the 3 Rs Declaration

Next Steps for the Implementation of the Declaration

- The participants of the Partnership on alternative approaches to animal testing based on the 3 Rs principle commit themselves to contribute to an Action Programme that identifies short, medium and long term activities. The Action Programme will be designed from the perspective of identifying barriers to progress and propose appropriate solutions in order to promote the development, validation, regulatory acceptance and practical implementation of alternative approaches. A range of issues will be tackled, including the establishment of priorities, in areas such as:
 - Mapping of research activities and current strategies,
 - Cooperation in research to strengthen and enlarge current activities between the partners and other relevant stakeholders,
 - Development of alternative approaches, including intelligent testing strategies,
 - Practical mechanisms to improve the validation process using available knowledge,
 - Practical mechanisms to facilitate the regulatory acceptance process of alternative approaches,
 - Widening stakeholder dialogue and education,
 - Practical mechanisms to foster innovation in the area of alternative approaches.
- The action programme will identify and establish appropriate mechanisms and timetables for the implementation of the programme, such as the setting-up of technical working-groups for the different priority areas.
- All the necessary steps will be taken to ensure that the action programme will be available during first quarter 2006.
- An annual report from the Partnership on the implementation of the action programme will be published for the attention of the Council, European Parliament and other relevant stakeholders. The first report on implementation should be published by December 2006.