Briefing – Development of Alternative Methods

Proposal for a Directive on the protection of animals used for scientific purposes (revising Directive 86/609/EEC): Articles 45 and 46.

Eurogroup For Animals and Animal Defenders International (ADI) are calling for increased activity at both EU and Member State level to accelerate the development and implementation of alternatives to replace animal procedures, including those carried out for the purpose of applied and basic research as well as regulatory testing.

We consider that the draft position of the Council indicates considerable progress in this area, but we would like to see the Parliament position reflected more fully in the final text to ensure that the promise of replacing animal methods becomes a reality. This is especially important with regard to strategy setting at EU level, the creation of national centres for alternative methods, and increasing access and availability of alternative methods.

Background

Directive 86/609 EEC states that 'The Commission and Member States should encourage research into the development and validation of alternative techniques which could provide the same level of information as that obtained in experiments using animals'. It is this wording that led to creation of ECVAM (the European Centre for the Validation of Alternative Methods) at the Commission's Joint Research Centre in 1991. Since then both Member States and the Commission have focused their efforts on the replacement (as well as reduction and refinement) of animal tests used for regulatory purposes, and indeed the EU can be said to lead the world in this field.

However, it is important to stress that regulatory testing accounts for only around 10% of animal use, and that there are both scientific and ethical reasons for prioritising the development of alternatives to all animal procedures, including those carried out for the purpose of applied and basic research.

Indeed, a revolution in the development of non-animal techniques and enormous expansion in this area, including huge advances in human diagnostic techniques, has not been reflected by a significant decline in fundamental research on animals. There remains a disconnect between the development of new research techniques and the implementation of these in place of animal experiments. Only a Europe wide strategy will effectively address this.

Whilst the replacement of regulatory tests with a clear end point may be a simpler task in terms of validation and implementation, the new Directive needs to ensure a replacement strategy that has an impact on animal experimentation across the EU as a whole.

Eurogroup for Animals and Animal Defenders International believe that the revision of Directive 86/609 provides a unique opportunity to do this. We would like relevant and well-funded research to be underpinned by coordinated efforts to identify those areas of research where there is the greatest scientific need for the replacement of animal research techniques, where alternative techniques are shown to be emerging, and those that cause the greatest harm to animals.

Our views on the present positions of the different institutions are outlined below:

Commission

Article 45 of the Commission's proposal would require the Commission and Member States to 'contribute' to the development and validation of alternative approaches. While the national contribution envisaged is described in some detail, there is no elaboration of the EU level of commitment. The emphasis at both national and EU level appears limited in scope to the validation of alternatives to animal testing (omitting reference to applied and basic research).

National level: The proposal would require designation of a 'national reference laboratory for the validation of alternative methods' in each Member State and sets out rules relating to training of personnel and access to equipment and administrative infrastructure. The laboratories would be required to cooperate with the Commission in their area of competence, participate in the pre-validation and validation of alternative methods under the coordination of the Commission, communicate information on the availability of alternative methods and provide scientific and technical assistance to the relevant authorities of the MSs.

EU level: There is no further mention beyond requiring a 'contribution' from the Commission and coordination/priority setting regarding pre-validation and validation studies.

European Parliament

The European Parliament position would require the European Commission and the Member States to contribute, **financially and otherwise**, to the development and promotion of alternatives to all animal procedures.

National level: The Parliament has called for nomination in each Member State of '*a centre responsible for supporting the development, validation and promotion of alternatives to animal tests used for regulatory purposes, and facilities to develop and promote the use of alternatives to animal procedures undertaken for other purposes such as basic and applied biomedical and veterinary research*'. The national centres for alternative methods would be required to '*perform tasks to advance strategies for replacing animal procedures*' and '*work with all relevant stakeholders to further the aim of replacing all animal procedures*'.

EU level: The Parliament has called for extension of the remit of ECVAM so that it *'includes the coordination and promotion of the development and use of alternatives to animal procedures including applied and basic biomedical research and veterinary research'*, and for the expanded ECVAM to conduct and coordinate research, commission research, consult with stakeholders to create strategies to replace, reduce and refine animal procedures, disseminate information including publicly, provide databases to allow exchange of information including unpublished studies, coordinate the work of the national centres for alternative methods, conduct pre-validation and validation studies, facilitate the scientific endorsement and regulatory acceptance of alternative test methods and make information on these processes publicly available.

Council

The Council position has improved upon the requirements at EU level through creation of Annex VIII (Duties and Tasks of the Community Reference Laboratory) which lists EU functions and specifically mentions replacement of animal procedures conducted for the purpose of applied and basic research. However, there is no mention of the strategy-setting roles called for by the Parliament, and provisions relating to national laboratories are, in our view, too focused on regulatory test methods.

National level: The draft Council position requires Member States to '*assist the Commission in identifying and nominating suitable specialised and qualified laboratories to carry out [those] validation studies*', and for the Member States to '*ensure the promotion of alternative approaches and the dissemination of information on these at national level'*. The Council draft also calls on the MSs to nominate a single point of contact to provide advice on regulatory relevance and suitability of alternative approaches, which is most welcome.

EU level: The draft Council position requires creation of a Community Reference Laboratory (a designation of the Joint Research Centre) to carry out functions outlined in the new Annex VIII including coordinating and promoting the development and use of alternatives to procedures in the areas of basic and applied research and regulatory testing, coordinating the validation of alternative approaches at EU level, acting as a focal point for the exchange of information, setting up and

maintaining public databases, promoting dialogue between legislators, regulators and all relevant stakeholders, and conducting validation studies and research to facilitate the development of alternatives to animal procedures. Rules would also exist for subsequently introducing detailed measures for implementing the new provisions.

The position of Eurogroup and ADI during the trialogue discussions

Eurogroup for Animals and Animal Defenders International are calling for all the functions supported by the European Parliament to be allocated appropriately, so that EU level activities and those undertaken by the Member States are carefully coordinated, and are informed by high-level scientific discussion and strategy setting.

At Member State level we would like to see creation of National Centres for Alternative Methods, which would ideally be affiliated with national research funding bodies, in order to be able to effectively support the development and promotion of alternatives to animal procedures as envisioned by the Parliament. These National Centres could be very simple in structure and would range from providing basic administrative functions and information through a designated website to more elaborate bodies such as already exist in some MSs. In addition, we would like to see specific mention of the need for MSs to assist the Commission in creating and implementing strategies to replace the use of animals in applied and basic research.

At EU level we would like to see the addition of points to Annex VIII requiring the Commission to consult with stakeholders in order to identify priorities for replacement of animal research techniques and set strategies for their replacement, and to provide a mechanism for this input to be reflected in future EU Framework Programme calls for proposals.

Thematic Review - Articles 8 and 53
Eurogroup for Animals and Animal Defenders International strongly support the European Parliament amendments under Articles 8 and 53 that call for thematic review of non-human primate experiments (specifically) and for broad areas of procedures with a view to setting targets for replacement. These will be important measures for a co-ordinated EU strategy on replacements. However, to be truly effective will require the structures and support outlined above.

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