

Public Consultation on 'working mandate' and call for the submission of information or data on the need for non-human primates in biomedical research, production and testing of products and devices.

Response by: Eurogroup for Animals, 6 rue des Patriotes, B - 1000 Brussels

Eurogroup for Animals is grateful for the opportunity to respond to the *Public Consultation on 'working mandate' and call for the submission of information or data on the need for non-human primates in biomedical research, production and testing of products and devices.*

Below are Eurogroup's comments specifically on the Working Mandate.

1. General comments

1.1 The request for an opinion is headed:

“Request for a scientific opinion on the need for non-human primates in biomedical research, production and testing of products and devices”

This implies that the Committee is being asked only whether primates are needed for these purposes at present, and not how their use can be phased out. Establishing that primates are needed in various fields of research would of course involve an assessment of whether the objectives could be achieved by the use of another approach, technique, or species (genetically modified or not). However, there is no indication that the Committee is being asked to do more than express an opinion on the *status quo*. It is therefore vitally important that the terms of reference make it clear that what is needed is a forward-looking view of the prospects for replacing the use of primates, and the scientific actions necessary to bring this about.

1.2 On page 2, the Commission response to the 2007 Parliament Declaration on primates is referred to. This response states that a timetable with a fixed deadline to phase out all use of primates is not possible. In addition, the penultimate paragraph of section 1 states that:

‘Already today, non-human primates are only used in exceptional circumstances where no alternative methods are available and no other species may suffice for the purposes of the research.’

The section concludes with:

‘..It is understood that, with the current scientific knowledge, not enough alternative methods are yet available’.

These statements appear to pre-judge the issue on which the Committee is being asked for an opinion and to pre-empt any conclusion the Committee might reach. The request for an opinion thus has the appearance of a leading question. This is totally unacceptable.

1.3 In our opinion, the Committee should be invited to take a more forward-looking and creative approach to identifying ways in which a phase-out might be achieved, and how this could be facilitated. Any Terms of Reference should guide the Committee towards:

- a) a more critical assessment of the objectives of research and testing involving primate use,
- b) the reasons why it may be considered that these objectives cannot currently be achieved by any other means,
- c) what would be needed (in terms of more detailed consideration of the problem, laboratory research, technical development, and strategic thinking) to make a phase-out of primate use possible.

2 Specific comments on Terms of Reference as currently defined

2.1 Terms of Reference, Point 1

The first item of the Terms of Reference should refer to current and foreseeable uses of primates, and an opinion on the need for primate use in each case (as implied in the title of the request for an opinion).

Surveys of current primate use, and assessments of the need to use primates, have been published quite recently, e.g. by the SSC in 2002, and the UK Weatherall Committee in December 2006, as quoted in the Mandate. It is doubtful whether another survey and opinion would be of any great value unless it (a) places more emphasis on likely future uses of primates, (b) examines in more depth the precise purpose of the current and possible future uses of primates, and (c) critically assesses the scientific reasons put forward in each case to support the contention that no other species or method can be used. None of these points is made in the current Terms of Reference.

2.2 Terms of Reference, Points 2 and 3

It is not clear what is meant by 'currently available possibilities' for replacement in Point 2. This might refer to available methods which could be used now (although according to the 'Background' information alternatives are always used where possible), or it might include the possible future use of new technologies. However, Point 3 concerns 'Scientific outlook', and so we conclude that Points 2 and 3 are intended to make a distinction between methods which are currently available and those which might be developed in future.

In our opinion, this distinction is not helpful. It would be more useful to combine these two points by asking the Committee to consider how the scientific objectives of the research and testing applications identified in Point 1 might be achieved without the use of primates, i.e. what alternative approaches or methods can be envisaged, and what are the scientific barriers to developing these approaches.

The preconception that each type of primate experiment must necessarily be replaced by an alternative method should be avoided. Scientific strategies are not necessarily tied to individual and specific test methods, test subjects or steps in a scientific enquiry. Objectives might be reached by a complete change of approach.

What is needed is more creative and imaginative thinking about research strategies, not just an attempt to continue in the same way, with individual procedures replaced one at a time.

To establish a timetable for phasing out specific uses of primates, it will be necessary to identify possible approaches, the scientific barriers to their implementation, and the current status of knowledge or technical capabilities necessary to support them. Only then can an assessment be made of the time required to bring them into operation. To expect this assessment to be made in a few months is inviting a very general and pessimistic view of the prospects for replacement, exactly as adopted by the Commission in its response to the Parliament Declaration. One option available to the Committee should be to suggest a process or strategy for the thorough investigation of these issues.

2.3 Terms of Reference, Point 4

We support the 3Rs principle and normally welcome discussion of all three Rs in relation to the use of animals. However, the discussion of some aspects of reduction (such as statistical design of studies), and certainly the inclusion of refinement, seems to have little relevance to an opinion on the need for primate use, or on the prospects for phasing out their use. Given that the Committee has been asked specifically to focus on the need, our concern is that inclusion of this point is at best a distraction from the main remit of the Committee, and at worst a means of expressing commitment to animal welfare without tackling the central issue of scientific need. We suggest that this point is deleted.

2.4 Terms of Reference, Point 5

Identification of research areas requiring investment should follow logically from the assessment in the second/ third point above (para 2.2). We have no difficulty with this point, subject to the reservation about including refinement as noted under Point 4.

2.5 Terms of Reference, Point 6

By obliging the Committee to consider the consequences of a hypothetical ban, this point in the Terms of Reference appears to invite bias in favour of the continued use of primates.

A 'ban' on the use of primates is not mentioned previously in the document, or in the Parliament Declaration. Phasing-out does not necessarily imply a ban, and certainly not an immediate or blanket ban. Even if the words 'with a fixed deadline' are added, and this is taken to mean a ban, it gives no indication of when the deadline would be. There seems to be no scientific purpose, although there may be a political one, in considering the consequences of a scenario that has not been suggested.

We have criticised the report of the Weatherall Committee for confusing scientific need with societal need. In making a judgement on whether the use of primates is necessary and indispensable for achieving a particular scientific objective, the importance of the objective in terms of human health and safety is not relevant.

Neither should the scientific judgement be influenced by commercial or other interests.

If this point remains in the terms of reference, it should be made clear when this hypothetical ban is envisaged as coming into effect. Secondly, it should be stressed that the implications referred to are the scientific implications for biomedical research. Neither commercial implications, nor implications for the 'status' of EU research, nor the transfer of research outside Europe, should form part of the remit for this Opinion.

There is no mention of the use of primates in safety and efficacy testing in this point. This is surprising given that it is in the title of the request for an opinion. It is not clear whether testing has been deliberately excluded (in spite of being the greatest user of primates) and if so, why. It may be that testing has been excluded because there would be a strong temptation to include commercial implications rather than scientific ones. In our view, the position should be clarified. In addition, the inclusion of examples of biomedical research in the Terms of Reference pre-empting the results of the survey in the first point above, is unnecessarily prescriptive, and should be removed.

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