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NAVS and ADI comments regarding the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012

NAVS and ADI have numerous concerns regarding important omissions in the draft regulations. Certain topics, included in the EU directive, are missing from the draft regulations. We believe this imperfectly achieves the policy objectives of the Directive and inappropriately implements the European Union Legislation.

Thematic Review

NAVS and ADI proposed the system of 'thematic reviews' to the European Commission during the work on the new Directive; these were incorporated into 2010/63/EU. Article 58 of the Directive provides: "The Commission shall, where appropriate, and in consultation with the Member States and stakeholders, conduct periodic thematic reviews of the replacement, reduction and refinement of the use of animals in procedures, paying specific attention to non-human primates, technological developments, and new scientific and animal-welfare knowledge" [1]

Throughout the process in the European Parliament, the aim of thematic review was to provide a regular process to enable all stakeholders to work to identify and agree specific animal experiments and specific uses of animals that can be replaced – with binding targets. The concept of thematic review discussed and envisaged by the European Parliament, the Commission and the Council of Ministers provided a clear mechanism to move forward, primarily, on the replacement of the use of animals in specific experiments, as well as establishing the scope for refinement and reduction of animal used in specific protocols.

Consultation with Member States is one of the conditions in the article on thematic review, so it is a matter of the gravest concern that thematic review does not appear in the draft SI laid before Parliament. This raises the question of why this critical mechanism is omitted. It also raises further questions regarding the commitment to bring this mechanism to bear on scientific procedures with animals. The omission of thematic review makes it impossible to determine how the Government plan to implement this important mechanism in reality.

The subject of thematic review was originally omitted from the public consultation on the transposition of directive 2010/63/EU. This was drawn to the attention of the Home Office, and an additional question was added to the consultation.

The mechanism of thematic review has been sustained throughout all the revision stages - its omission at this stage is unacceptable and must be addressed.

Public accountability and freedom of information

The process of creating a new European law animal on experiments was based on a call for "a proposal for a revision of that Directive with more stringent and transparent measures in the area of animal experimentation", as stated in Recital (4).

Article 38 of the directive states "The project evaluation process shall be transparent" and "the project evaluation shall be performed in an impartial manner and may integrate the opinion of independent parties". In this regard it is essential that those parties assessing work with animals should be comprised of people with differing expertise, such as non-animal methods and alternatives. Lay members should sit on committees to provide impartial input.

In order for the process to be transparent, as required by the EU Directive, there should be true public accountability. One way to ensure this would be for project applications to be available to stakeholders for a specific period prior to granting the licence, to provide independent and scientific scrutiny before project licences are granted, all applications should be placed online, possibly on a password protected database, with

[1] 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes.

a time limit for response. Personal information is not needed, so could be redacted. This would enable stakeholders to identify trends in animal testing, avoid unnecessary duplication and monitor the replacement, reduction and refinement of the use of animals in research. Applications must also include more detail with a critical and meaningful assessment of the proposed work. Without such provisions it is unclear how the opinion of independent parties can be integrated into the project evaluation process.

The importance of public accountability is acknowledged by many parties. The House of Lords select Committee on animals in scientific procedures stated that "We consider the current levels of secrecy surrounding animal experiments to be excessive" and that "There should be a presumption in favour of complete openness, and consideration should then be given as to what information should remain confidential." [2]

A section on the commitment to public accountability and freedom of information which brings together the different elements covering these topics would ensure that transparency is at the centre of this Act, as intended with the EU Directive. This would elaborate what reporting there will be, the ability for stakeholders to have input regarding the licence applications prior to them being granted and we would also want to see details concerning the composition of the National Committees. This would properly address the Directives requirements for transparency and accountability by outlining how these will be achieved.

The composition of the national committees

Under Article 49 of the Directive, the purpose of the National Committee is "for the protection of animals used for scientific purposes." The intention of this Article is supported by Recital which states that the national committees "give advice to the competent authorities and animal- welfare bodies in order to promote the principles of replacement, reduction and refinement."

NAVS feel that the draft regulations for amending ASPA inappropriately implement EU Legislation by including, in the functions of the committee, to have regard for "the legitimate requirements of science and industry" and by omitting any mention of the national committee's responsibility to consider replacement, reduction and refinement. The intention of the Directive, regarding the national committees, is clear – to their role is to protect animals which may endure pain, suffering or distress during any stage, from acquisition onwards. The committee would be cognisant of science and industry, it should not be a required function; the Directive does not require it.

It is also questionable whether the proposed Committee for the Protection of Animals Used for Scientific Purposes will be able to adequately report on animal welfare, when the expertise of the members of the committee are not described. The Animal Procedures Committee required a membership composition such that the committee had "regard to the desirability of ensuring that the interests of animal welfare are adequately represented". This sentiment should remain. Alternatives and animal welfare experts must participate so that these specific issues are addressed by individuals qualified to give an informed opinion; the Directive requires that advice is given in this area so these measures would ensure appropriate implementation of the EU legislation.

Section 24

Section 24 of the Animals (Scientific Procedures) Act 1986 (ASPA) [3] places a blanket ban on the release of any information from animal experimentation laboratories. This has prevented open public debate and wider scientific scrutiny of the use of animals in research, a matter of intense public concern. However since the passage of the ASPA, the Freedom of Information Act 2000 (FOIA) has established a right to freedom of information and improved the accountability of public bodies. The FOIA does allow for certain information to be withheld, where there are concerns about health and safety (S.38), or personal information (S.40, S.41) and for the protection of intellectual property (S.22).

Public accountability and access to information is a fundamental tenet of Directive 2010/63/EU. The transposition of the Directive into UK law should profoundly affect public access to information, accountability

[2] http://www.publications.parliament.uk/pa/ld200102/ldselect/ldanimal/150/150.pdf - accessed 1st October 2012.

[3] Animals (Scientific Procedures) Act 1986, Section 24: protection of confidential information, http://www.legislation.gov.uk/ukpga/1986/14/section/24

and wider scientific scrutiny of animal research. Section 24, which is currently used to pursue a policy of blanket confidentiality, should be repealed. Recital 41 of the Directive provides "To ensure that the public is informed, it is important that objective information concerning projects using live animals is made publicly available" [4]

At a 2002 conference held for the House of Lords Select Committee on Animals in Scientific Procedures which addressed freedom of information, it was reported that "Section 24 should be repealed because, in practice, little information is considered by the Home Office to be non-confidential and little is therefore released to the public on request. Repealing section 24 would help to change the culture of secrecy" [5] If Section 24 remains, it would contradict and seriously compromise the "transparency" that the new Directive attempts to establish. It would likely be subject to legal challenge. The APC stated they believed "that Section 24 of the ASPA should be abolished."

The APC have also stated that "In the experience of some members, over-interpretation of Section 24 has also hampered the dissemination of good practice, which is another reason to abolish it in the new legislation." [6] To allow section 24 to remain part of the Act would cause an obstruction to the appropriate implementation of the European Union legislation, by prohibiting transparency and public accountability.

[4] (Directive 2010/63/EU on the protection of animals used for scientific purposes http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:276:0033:0079:En:PDF)
[5] Select Committee on animals in Scientific Procedures. Proceedings of the Conference held in the House of Lords on 21 May 2002.
[6] Consultation on options for the transposition of European Directive 2010/63/EU on the protection of animals used for scientific purposes. Response from the Animal Procedures Committee.