Comment

Comments on UK *Options for Transposition of European Directive 2010/63/EU*

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Summary — The British Government's proposals for the transposition of *European Directive 2010/63/EU* are discussed under five main headings: direct transposition without major effects on the UK legislation, introduction of stricter requirements in the Directive, retention of stricter controls in the *Animals [Scientific Procedures] Act 1986*, questions requiring further consideration, and matters of concern. The Home Office had published a consultation on the options in 2011, which resulted in 98 responses from organisations and 13,458 responses from individuals. Our main concerns relate to the use of non-human primates, the annual publication of the UK statistics on laboratory animal use, and the provision of greater transparency on how animals are used, and why. Finally, we conclude that the new Directive and its transposition into the national laws of the Member states provide a renewed opportunity for genuine commitment to the Three Rs, leading to progressive and significant *Reduction*, *Refinement* and *Replacement*.

Key words: *animal experimentation, Animals [Scientific Procedures] Act, European Directive 2010/63/EU, great apes, Three Rs.*

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Introduction

European Directive 2010/63/EU on the protection of animals used for scientific purposes (1) came into force on 9 November 2010, when it replaced *Directive 86/609/EEC*, with the requirement that the Member States must transpose its provisions into their own legislation by 10 November 2012 and implement them by 1 January 2013.

The UK Home Office held a formal consultation between 13 June and 5 September 2011. The consultation document (2) posed 76 questions and explained that three options for transposition were being considered, namely, *no change* (retain the provisions of the current *Animals [Scientific Procedures] Act 1986* [ASPA]), *copy out* (transpose the minimum requirements of the Directive into UK legislation), and *retain some current higher UK standards* (as permitted by Article 2 of the Directive).

On 17 May 2012, the Home Office published a summary report and Government response, *Consultation on options for the transposition of European Directive 2010/63/EU on the protection of animals used for scientific purposes* (3). Responses were received from 98 organisations and 13,458 individuals. The responses from organisations were from 15 animal protection organisations, 15 organisations concerned with animal welfare and alternatives (including FRAME [4]), 61 organisations in the biosciences sector, and 7 organisations concerned with laboratory animal care and welfare, and training.

The summary report is in tabular form, dealing in turn with the 64 articles of the Directive and its five annexes, with five columns, on the *Article*, the *Issue*, the *Consultation response*, the *Government response* and the *Estimated impact*. It is a remarkable document by any standards, and those who produced it deserve to be congratulated and thanked for summarising the vast amount of information and comment before them so clearly and so succinctly.

There are, however, points that should still be made, especially as there is still a little time before the Government's proposals are put before Parliament and the Home Office publishes the promised guidance on the application of the new UK legislation.

In an attempt to match the efficiency of the summary report, our comments on the Government's response to the consultation will be put forward under five main headings, namely, direct transposition without major effects on the UK legislation, introduction of stricter requirements in the

Directive, retention of stricter controls in the ASPA, questions requiring further consideration, and matters of concern.

Direct Transposition

Many of the articles of the Directive can be transposed, more or less as they stand, albeit sometimes with guidance, because they are consistent with the current requirements of the ASPA. They include Article 1, protection of fetal mammals, but from the last third of gestation, rather than the second half of gestation, as in the ASPA. A degree of compromise is necessary here, as not all mammals develop to the same stage *in utero*, as shown by the greater independence of calves and lambs at birth, as compared with kittens and puppies. However, birds and reptiles will continue to be protected during the last third of their development *in ovo*, and cephalopods will be protected from when they are capable of independent feeding, as is the case for fish.

Articles 4 (principle of the Three Rs), 5 (purposes of procedures), 9 (animals taken from the wild), 10 (animals bred for use in procedures), 12 (where procedures are carried out), 14 (anaesthesia), and 15 (severity classification) present no major problems. However, listing one class of "severity" as "severe" is not ideal — "substantial" would have been a much better term.

Articles 20 (authorisation of breeders), 21 (suspension or withdrawal of authorisation) and 22 (requirements for installations and equipment) are outside our experience, but the provisions of the Directive and the Government's response are sensible. The same could be said of articles 28 (primate breeding), 29 (re-homing), 30 (animal records), 31 and 32 (information on, and marking and identification of, dogs, cats and non-human primates), and 33 (care and accommodation).

Articles 36 (project authorisation), 37 (application for project authorisation), and 40 (granting of project authorisation) raise no major issues. However, precisely what is meant by "multiple generic projects" (Article 40[4]) and by "complex and multidisciplinary projects" (Article 41) needs to be clarified in the future Guidance, as the Government proposes.

Article 45 (documentation) requires that all relevant documentation must be kept for at least three years from the expiry of the project, but a longer period of retention might be advisable, if the (unnecessary) duplication of procedures is to be avoided (Article 46).

Introduction of Stricter Requirements in the Directive

Only in a few cases do the provisions of the Directive require the introduction of totally novel considerations into the UK legislation.

Article 1(2) provides protection for animals that are bred specifically so that their organs or tissues can be used for scientific purposes. This will be transposed, but it also raises the question of the appropriate methods for killing such animals (Articles 3 and 6), which will presumably be dealt with in the Home Office Guidance on the application of the new legislation.

Article 39, on retrospective assessment, is particularly important, since it could be said that, up to now, insufficient attention has been paid to whether the benefits promised when authorisation for a project was sought, were, in fact, delivered, or whether the suffering of the animals concerned was at the level predicted. Not surprisingly, the bioscience sector groups were less enthusiastic about this than were the other respondents to the consultation. The Government's attitude should be welcomed, since it is proposed that retrospective assessment should be applied to all projects involving cats, dogs or non-human primates, and that the blanket exemption of all "mild" or "non-recovery" projects, as permitted by the Directive should not be applied in the UK.

It will be interesting to see what is included in the forthcoming Home Office Guidance, but it is clear that retrospective assessment will deserve further consideration in its own right, as experience in its application becomes available.

Retention of Stricter Controls in the ASPA

We were greatly encouraged to see many indications of the Government's intention to use Article 2 or other strategies to retain the stricter controls of the ASPA. For example: special protection will be retained for dogs, cats and horses (Article 1); current UK methods for killing will be retained, where they are more humane (Article 6 and Annex IV); the requirement for the purpose breeding of ferrets will be retained (Annex I); the current restrictions on the use of members of endangered species will not be weakened (Article 7), nor will those on the re-use of animals (Article 15) and the requirements related to the welfare of animals at the end of regulated procedures (Article 17), including their setting free or re-homing (Article 19).

Of particular importance is the retention of the current requirements for personal licences (Article 20[3]), and for maintaining a strong and properly-resourced inspectorate (Article 34), whilst not accepting the introduction of simplified administrative procedures for certain kinds of projects (Article 42). We also agree with the Government's cautious approach to requirements for education and training (Article 23[2]), but urge further consultation with those in the UK who have useful expertise and experience, including FRAME.

We welcome the decision to retain the UK standards for care and accommodation that are stricter than those laid down by the Directive (Annex III).

One question of particular concern to us was the question of whether the derogation clause in the Directive (Article 8[3] in conjunction with Article 55) could ever be used as a means of permitting the use of great apes as laboratory animals in the UK. The All Party Parliamentary Group on the Replacement of Animals in Medical Experimentation (APPRG) and BUAV/ FRAME (5) had separately written to the Home Office Minister, Lynne Featherstone MP, to point out that such use would be ethically unacceptable, scientifically unnecessary and logistically impossible. Having at first said that Article 8(3) would be transposed as it stands, although it was not envisaged that derogation would ever be sought, the Minister assured the APPRG that the ban on the use of great apes would be on the face of the new bill. We were therefore surprised to see that the proposal for direct transposition had been included in the summary report. As it happened, members of the APPRG met the Minister on 17 May 2012, the day on which the summary report was published, and were given the assurance that the ban would be on the face of the bill, and that any attempt to apply the Directive's derogation clause in the future, would require new UK legislation (6, 7).

Questions Requiring Further Consideration

We understand that the summary report was aimed at providing an insight into the responses to the consultation and an indication of the Government's intentions, but we have identified a number of issues on which further consideration, and possibly, further consultation, is necessary, either before the bill for the new legislation is published or following the publication of the promised Home Office Guidance.

In Article 1(5)(e), the Directive excludes practices undertaken for the primary purpose of identifying an animal, but the Government proposes to retain the additional requirement that the procedure causes only momentary pain or distress and no lasting harm, but what this means in practice needs to be clearly spelled out in the Guidance. The same could be said of requirements relating to capture and trapping (Article 9[3]).

Article 13 prohibits the use of an animal in a procedure, if a scientifically satisfactory, non-animal method, or testing strategy, is recognised by EU legislation. Applied with diligence and force, this could contribute dramatically to the replacement of animal procedures which should now be obsolete and encourage greater investment in developing new alternatives. It could also prohibit some testing done by contract research organisations in the UK at the request of third parties in non-EU countries. But why should it apply only to alternative methods recognised by EU legislation? It takes time for progress to be made at the multination EU level, so methods might be approved in, for example, the UK or the USA, years before the EU process had been completed. Therefore, as we proposed in our consultation response, we suggest that the wording "as recognised by EU legislation" is not transposed.

The severity of the effects on the animals is a very important aspect of laboratory animal experimentation, and the most humane methods should be used. However, that does not necessarily mean that death as an endpoint should be avoided (Article 13[3]), for complex reasons which we will discuss elsewhere. The severity classification as a whole (Article 15) raises many questions, and the guidance on this will need to be of the highest quality.

There is a need for further consultation on project evaluation (Article 38), and, in particular, on project evaluation transparency (Article 38[4]). We support the transposition of Article 43, on the publication of non-technical summaries of projects, but further consultation and guidance will be needed here, if the summaries are to be a truly worthwhile source of information on what is done, and why. There should also be further guidance on the criteria to be used when the amendment or renewal of project authorisation is sought. This also applies to the renewal of authorisation (Article 20[3]).

The Government would be wise to embark on consultations in other areas where considerable experience is available in the UK, such as alternative approaches in general (Article 47), especially with regard to replacement alternatives, the sharing of tissues (Article 18), and the introduction of thematic reviews (Article 58), which open up new possibilities for sensible progress on the basis of the Three Rs. We also await, with interest, the Government's proposals for the membership and role of the National Committee (Article 14), and how the establishment of an Animal Welfare Body in each breeder, supplier and user organisation (Articles 26 and 27) will strengthen the already-successful Ethical Review Process. No less important are the specific requirements for personnel (Article 24) and the role of the designated veterinarian (Article 25), which need to be reviewed in detail in the Guidance.

There are a number of instances in the summary report, where the Government proposes to transpose the wording of the Directive, rather than using Article 2 to make the retention of the UK's higher standards legally binding. For example, many respondents to the Consultation advised that the ASPA ban on the use of stray and feral

animals (Article 11) should be retained. This also applies to the use of neuromuscular blocking agents (Article 14), for which there was almost unanimous support across all sectors for retention of the current UK provisions. Therefore, we would ask the Government to reconsider transposing these Articles as they stand, given the consensus and support there is for retaining the current UK wording and position.

Matters of Concern

Although we were pleased to receive clarification of the Government's position on the use of great apes, we are disappointed that there will not be stricter controls on the use of other non-human primates. As with the use of great apes, we are not convinced that a sound or acceptable ethical, scientific and logistical case can be made for using other non-human primate species in relation to "the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings" (Article 8[1]). We hope that the UK will at least insist on a satisfactory definition of such conditions, without necessarily adopting what is considered acceptable by the other EU Member States.

We consider that Article 2 should be used to have stronger limits on the use of endangered species of non-human primates (Article 8[2]), as in ASPA 10(3), in accordance with the unanimous view of those who took part in the consultation. We are encouraged by the Government's proposals regarding the use of animals captured from the wild (Article 10, Annex II), but there are uncertainties about what is meant by bred in captivity, where breeders/suppliers outside the EU are involved.

We are particularly concerned that the direct transposition of Article 54 (Report) may result in the "streamlining" of the UK statistics to meet the minimum requirements of the Directive. This has long been the ambition of the bioscience sector groups, but would be viewed with great concern by those genuinely interested in animal protection and welfare. The Government has indicated that discussions are on-going with the Commission and other Member States, and has promised further consultation when these discussions are complete.

We expressed our concern as follows, in our response to the Consultation (4):

"In our view, it is imperative that the UK should continue to publish comprehensive annual statistics. While what is published should be continually reviewed, there should be no streamlining merely for the sake of streamlining. It is important to ensure consistency and transparency.

"There is a strong case for extending the statistics to cover other topics and to provide greater depth, since what is currently published only gives an overall impression. For example, in the testing of pharmaceuticals, it would be helpful to know whether dogs and non-human primates were used because preliminary work had shown that they could provide data of specific relevance to the compound under consideration, or whether they were used for routine purpose, e.g. to comply with a regulatory requirement for testing in a non-rodent species."

Finally, careful consideration needs to be given to the balance between the focus of the Directive on the need for greater transparency in relation to the use of animals in scientific research and the prohibition of the disclosure of confidential information according to section 24 of the ASPA. We accept that personal details, intellectual property and commercial information will continue to need protection. However, as we have said above, even with the extensive annual statistics currently published by the Home Office, which go far beyond the requirements of the Commission under *Directive 86/609/EEC*, it is not possible to discover how or why animals such as dogs and non-human primates are used by industry and contract research organisations, since the results obtained are not published in the open literature. We look forward to the Government's further proposals, and hope that there will be an opportunity for consultation.

Concluding Remarks

While there has been considerable progress in improving the husbandry, care and treatment of laboratory animals (*Refinement*, e.g. 8), since the introduction of *Directive 86/609/EEC* and the ASPA in 1986, relatively little has been achieved in terms of the other two Rs, *Reduction* (e.g. 9, 10) and *Replacement* (e.g. 11, 12).

Directive 2010/63/EU and its transposition into UK law provide a new opportunity for genuine commitment to the Three Rs, not merely as a diversionary tactic, but as an effective way of improving the quality of the science and its output, whilst avoiding the causation of unnecessary suffering in animals. This is not a matter only for governments and animal welfarists, but places a special responsibility on scientists such as those in the 12 member organisations of the UK Bioscience Sector Coalition and in the 17 organisations which endorsed the Coalition's response to the Home Office Consultation on the transposition of the Directive (13), which listed "the application of the 3Rs" as a major priority.

References

1. European Union (2010). *Directive 2010/63/EU* of the European Parliament and of the Council of 22

September 2010 on the protection of animals used for scientific purposes. *Official Journal of the European Union* **276**, 20.10.2012, 33–79.
2. Home Office (2011). *Consultation on Options for the Transposition of* European Directive 2010/63/EU *on the Protection of Animals Used for Scientific Purposes*, 45pp. London, UK: Home Office. Available at: http://www.homeoffice.gov.uk/publications/about-us/consultations/transposition-protection-animals/consult-transp-scientific?view=Binary (Accessed 18.05.12).
3. Home Office (2012). *Consultation on Options for Transposition of* European Directive 2010/63/EU *on the Protection of Animals Used for Scientific Purposes. Summary Report and Government Response*, 73pp. London, UK: Home Office. Available at: http://www.homeoffice.gov.uk/publications/aboutus/consultations/transposition-protection-animals/summary-response-transposition?view=Binary (Accessed 18.05.12).
4. Hudson, M. & Balls, M. (2011). *FRAME Submission to the Home Office Consultation on Options for the Transposition of* European Directive 2010/63/EU *on the Protection of Animals Used for Scientific Purposes,* 29pp. Nottingham, UK: FRAME.
5. Thew, M., Bailey, J., Balls, M. & Hudson, M. (2012). The ban on the use of chimpanzees in biomedical research and testing in the UK should be made permanent and legally binding. *ATLA* **40**, 3–8.
6. Balls, M. (2012). Ban on the use of great apes as laboratory animals in the UK. *ATLA* **40**, 69–71.
7. Anon. (2012). *FRAME Welcomes U-turn on Great Ape Experiments*. Press release, 21 May 2012, 2pp. Nottingham, UK: FRAME.
8. Jennings, M. (2009). Refinement: A sense of progress. *ATLA* **37**, 149–153.
9. Festing, M. (2009). Fifty years after Russell and Burch, toxicologists continue to ignore genetic variation in their test animals. *ATLA* **37**, 1–5.
10. Hudson, M. (2011). The latest *Statistics on Scientific Procedures on Living Animals* reveal little Three Rs progress in Great Britain in 2010. *ATLA* **39**, 403–411.
11. Bhogal, N. (2009). 21st century drug development: Advances, opportunities and challenges. *ATLA* **37**, 335–339.
12. Balls, M. (2009). Animal experimentation and the Three Rs: Time for honest answers to some leading questions. *ATLA* **37**, 229–232.
13. Anon. (2011). *UK Biosector Response to the Home Office Consultation on the Transposition of* European Directive 2010/63/EU. Published on 02.09.11, 40pp. Available at: http://www.societyofbiology.org/documents/view/797 (Accessed 06.06.12).