CONSULTATION ON OPTIONS FOR THE TRANSPOSITION OF EUROPEAN DIRECTIVE 2010/63/EU ON THE PROTECTION OF ANIMALS USED FOR SCIENTIFIC PURPOSES

The following response has been prepared by the MRC and BBSRC to reflect the views of our researchers, Biological Services managers, technicians and policy staff. MRC and BBSRC staff/users together make up a significant proportion of academic researchers using animals in the UK. Approximately one fifth of the grants that BBSRC funds involve the use of animals. MRC employees hold more than 100 project licences and MRC establishments currently account for around 12% of the procedures using animals in the UK. Views were assembled via a focus group made up of representatives from the different interests and through email correspondence.

The MRC and BBSRC support, and have signed up to, the UK Bioscience Sector Coalition response to this consultation; the areas we have commented on below are those where the MRC/BBSRC community have additional expertise and experience, which may be of help to the Home Office.

[Articles on which the MRC and BBSRC have nothing to add to the UK Bioscience Sector Coalition response have been deleted].

Options for transposition

We believe that Option 2 is a good starting point for transposition of the Directive given the benefits of harmonisation across Europe. However, we note that it will not be appropriate to 'copy out' the text on every occasion and there will need to be careful deliberation when deciding whether or not to retain current UK standards that are more stringent than the requirements of the Directive. In these cases, we would like to emphasise that we believe priority should be given to consideration of the effects on animal welfare. We would support a welfare assessment forming part of the evidence for those decisions, where this is feasible. Where it is not possible to make a decision based on scientific evidence it will be important to consider the impact that those decisions might have on public confidence in research using animals and the implications if that confidence were to be lost or damaged.

CONSULTATION QUESTIONS

3: SUBJECT MATTER AND SCOPE

Practices to which the Directive does not apply

Question 6: Is our assessment of the impact of this omission correct? Should we retain our current requirements exempting only those methods of marking (used for scientific purposes) which cause no more than momentary pain or distress, and no lasting harm?

We support ensuring ear biopsy is recognised as a routine husbandry procedure, which is below the threshold and would welcome clear, unambiguous and robust guidance on this matter.

4. PROVISIONS ON THE USE OF CERTAIN ANIMALS IN PROCEDURES

Article 9: Animals taken from the wild

Question 11: Are there any issues we should consider relating to the prohibition on the use of animals taken from the wild? What impact will the more limited derogation provided in Article 9 have on the conduct of research in the UK?

We are aware of a number of examples where wild caught animals are currently used in research. It would not be possible to undertake this research should a blanket prohibition on the use of animals taken from the wild be introduced. Therefore the more limited derogation would have an impact on this work, although we believe that the scientific justification (that the purpose of the procedure cannot be achieved by the use of an animal which has been specifically bred for use in procedures), would mean that exemptions by the competent authority could be applied.

Examples include the use of wild caught corvids in comparative cognition research and studies of scent communication in wild mice. One MRC institution uses electric eels caught from the wild, where the specialised tissue which generates the electric shock provides a model for essential processes in nerve transmission. These are caught by commercial fishermen to order in South America and are euthanased using a Schedule 1 method on, or shortly after, arrival to obtain the tissue of interest. This institution also uses torpedo marmorata fish, caught in the Atlantic Ocean by commercial fishermen, for similar purposes. The requirement for capture by "competent persons" could also be a barrier to this work, as there are obvious practical difficulties in ensuring the "competence" of fishermen operating outside the EU.

Article 10: Animals bred for use in procedures

Question 13: Are our assumptions regarding the impact of Article 10 correct? Is there a case for retaining the current UK requirement that common quail and ferrets should be purpose bred, as permitted by Article 2?

We agree with the Bioscience Sector Coalition response and believe that there is a strong case for retaining the current UK requirement that ferrets should be purpose-bred. Their use in flu research means that a source of purpose-bred animals is essential to ensure their health status and lack of prior exposure to human flu viruses.

5. PROCEDURES

Article 17: End of the procedure

Question 22: Should we retain current stricter UK requirements relating to the welfare of animals at the end of a regulated procedure? What issues may arise if animals suffering mild effects are released?

In addition to the Coalition response we ask that the transposition takes into account the outcomes from the meeting organised by the Home Office on 5th October 2010 at which the removal of GA animals without harmful phenotypes from project licence authority or the Act was discussed. This meeting included a large number of stakeholders including several MRC representatives.

6. METHODS OF KILLING

Article 6 and Annex IV: Methods of killing

Question 24: Do you agree with our analysis of Article 6 and Annex IV? Should the UK retain some methods listed in ASPA Schedule 1 using Article 2? Which methods should be retained?

We have concerns about the omission and provision of certain specific methods of killing permitted in annex IV. Some examples are included below and we endorse waiting for advice from LAVA and others.

Rodents

Carbon Dioxide – a definition of 'neonatal' is required for rodents; resistance to the effects of the gas is a problem.

Cervical dislocation – the sedation prior to cervical dislocation (CD) should be optional; CD without sedation is fast and humane and having to sedate the animals will increase stress.

Decapitation – clarity on the meaning of 'not possible' is needed; this could be a useful method for unwanted neonates, but evidence is required.

Inert gases – there is insufficient evidence to support the use of this method and is therefore unsupportable.

Fish and amphibians

Anaesthetic overdose – 'prior sedation' should be optional.

8. AVOIDANCE OF DUPLICATION OF PROCEDURES AND ALTERNATIVE APPROACHES

Article 46: Avoidance of duplication of procedures

Question 28: We propose to transpose the provisions of Article 46 as they stand. Are there any further issues we should consider relating to avoidance of duplication of procedures?

In agreement with the Bioscience Sector Coalition's response, we support a proposal to transpose the provisions of Article 46 as they stand. However, it is essential to good science to be able to validate the findings of scientific research, and so there needs to be a provision to allow experiments to be repeated with good scientific justification.

Article 47: Alternative approaches

Question 29: Are there any further issues we should consider in relation to the provisions for alternative approaches set out in Article 47?

We agree with the Bioscience Sector Coalition's response and believe that alternative approaches must be science-led and science-based. In the UK, the

science underpinning alternatives should continue to be driven by organisations such as the NC3Rs and enforced by the Home Office.

10. BREEDERS, SUPPLIERS AND USERS

Article 20: Authorisation of breeders, suppliers and users

Question 32: Are the changes to the requirements for authorisation of breeders, suppliers and users and the need to notify changes likely to raise any problems? Are there any further issues we should consider in relation to the requirements set out in Article 20?

We agree with the Bioscience Sector Coalition's response, and believe that the local Animal Welfare Body would be best placed to take the decisions on what changes are likely to have a negative impact on welfare and thus need to be notified.

11. CARE AND ACCOMMODATION

Annex III: Care and accommodation standards referred to in Article 33

Question 40: Are there any specific issues we should consider when preparing guidance and codes of practice on accommodation and care?

Please see Appendix II for detailed questions on Annex III.

We support the view put forward by the Bioscience Sector Coalition; however, the joint funders guidelines on 'Responsibility in the use of animals in bioscience research' encourage researchers to exceed the minimum care and accommodation requirements where practical. The MRC and BBSRC will continue to stand by those expectations.

We also wish to highlight the need for sound evidence to underpin the requirements, which we assume will be in a Code of Practice, for environmental conditions. The Coalition's response draws attention to the need for evidence in the case of humidity levels. In addition, with the introduction of IVCs, it is possible to lower the room temperature and humidity, whilst maintaining the conditions at the prescribed level inside the cages. Both these considerations would allow the research community to make a substantial contribution to the Government's efforts to reduce energy usage, without detriment to animal welfare.

12. COMPETENCE AND AUTHORISATION OF PERSONNEL

Article 23 and Annex V: Competence of personnel

Impact on the UK personal licensing system

Question 41: Should the UK: (a) retain its current system of personal licensing using Article 2, as necessary; or (b) adopt a simplified version of that system with greater local accountability? What might be the features of a system involving greater local accountability? What risks might be associated with such a system and how might

these be mitigated? What will be the cost to individual breeders, suppliers and users of implementing such a system?

We support the Bioscience Sector Coalition's response and we would also like to highlight that the current system has been a barrier to getting people with skills in from Europe to train people in the UK. The current regulations do not allow UK centres to invite internationally renowned experts in *in vivo* physiology either to train our investigators or to conduct experiments in the UK. This has the added disadvantage of not allowing specific collaborative work between institutions in the UK and elsewhere. It also denies a valuable opportunity to invite world experts to train several of our junior investigators simultaneously.

Examples are provided below:

i) A researcher had been invited by a European medical society to run a 4-day training course in the UK in summer 2012 for 20-25 of the most promising post-doctoral researchers in Europe. However, the current legislation would severely limit the type of course provided, because international experts could not be invited to train the students using live animals for hands-on training.

ii) An institution purchased a new piece of equipment from overseas. However, the company rep could not demonstrate how it worked on live animals as he was not licensed to work in that institution. Therefore, he had to talk and supervise someone unfamiliar in the use of the equipment (in the presence of a Vet) through a regulated procedure.

iii) An ECHO cardiogram and ECG was installed at an institution; however, as the collaborators were Dutch, they would have to sit all the HO modules to actually be able to demonstrate a technique in which they were extremely proficient. Instead, they had to sit by the side of an inexperienced PIL holder and guide them through the technique without being able to demonstrate properly or perform part of the procedure.

iv) A post-doc was recruited for a new project but could not immediately undergo training by a world-renowned scientist at another institution until the PIL was amended for secondary availability. This resulted in a 2-3 month delay in starting the project.

Education and training

Article 24: Specific requirements for personnel

Question 43: Are there any further issues we need to consider regarding the requirements for personnel?

We agree with the Bioscience Sector Coalition's response and would like to note that flexibility will be important at multi-component Campuses where the change in the locus of overall responsibility from the Holder of the Certificate for the 'place' to the corporate body of the 'user' will have particular implications. We would support the retention of individual responsibility in the new system so that there are clear lines of delegation and accountability. We suggest that the personnel responsible for animal care and welfare should continue to be known as the NACWO and NVS in the UK.

13. PROJECTS

Article 38: Project evaluation

Question 45: We propose to transpose the provisions of Article 36, 37 and 38 as they stand. What type of information should be placed in the public domain about the the project evaluation process to ensure transparency of the process? Under what circumstances would you expect project applications to be referred to external experts and/or the new national committee required under Article 49? Are there any further issues we should consider relating to project authorisation and evaluation?

Further to the Bioscience Coalition's response, the MRC and BBSRC communities welcome the direction of the evolution of project licence forms and see the current form as an improvement; and this direction should be continued to result in as clear a form as possible. We also support iterations with Inspectors which can add value and often result in useful refinements.

19. PENALTIES

Article 60: Penalties

Question 57: Should the UK incorporate the penalties from Part 3 of RESA into transposing legislation? Should they include provision for monetary penalties?

We agree with the Bioscience Sector Coalition's response and would like to add that we do not believe that monetary penalties would be useful in the academic sector, as these would inevitably be taken from research budgets from government or charitable sources, thus preventing other research from being undertaken.

APPENDIX I: COMPARISON OF ANNEX IV AND ASPA SCHEDULE 1

Birds, rodents and rabbits: Cervical Dislocation

Question 62: Should sedation be used where it is in the welfare interests of the animal?

The requirement for mandatory sedation prior to cervical dislocation (CD) should be optional; CD without sedation is fast and humane and having to sedate will increase stress for the animals by introducing an unnecessary procedure and delays.

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