Consultation on options for the transposition of european directive 2010/63/eu on the protection of animals used for scientific purposes

RESPONSE FROM ONEKIND

OneKind welcomes the opportunity to respond 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 into UK legislation.

OneKind was founded in Edinburgh in 1912 as the Scottish Society for the Prevention of Vivisection and re-named as Advocates for Animals in 1990. Former Director Les Ward contributed to the formation of the Animals (Scientific Procedures) Act 1986 and served on the Animal Procedures Committee, as well as forming and taking part in the Boyd Group.

OneKind now works on a UK basis to promote the recognition of animals as sentient beings and to build on the connections between people, animals and the natural world in a positive, inspiring and practical way. OneKind effects positive change for animals through high-profile campaigns, political lobbying, investigations, public education, promoting compassionate living and by leading the OneKind movement.

SUBJECT MATTER AND SCOPE

Article 1: subject matter and scope

Limit on protection of foetal forms of mammals to the last third of the gestation period

Question 1: Is our analysis of the impact of this provision correct? Is there scientific evidence that suggests that the UK should continue to protect mammals from half way through gestation using Article 2 to the Directive?

The UK currently protects foetal mammals from half way through their gestation period, whereas the new Directive 2010/63/EU protects only from the last third of gestation or 'normal development'.

As stated in the consultation (section 39) there is a large degree of variation in the gestational development of mammals. It should also be noted that the evidence quoted in reference to the appearance of first consciousness (Mellor et al. 2007) relates only to lambs and chicks. The different degrees of sentience and cognition in different species – and the limited knowledge of this in some cases – mean that it is difficult to set one particular cut-off point which will offer equivalent protection for all species. In the absence of clear scientific evidence to the contrary, OneKind believes that all animals should be given the benefit of the doubt.

This could best be done by continuing to protect foetal mammals from halfway through their gestation period and retaining the stricter measures in the Animals (Scientific Procedures) Act 1986.

Exclusion of foetal forms of birds and reptiles from protection

Question 2: Is there scientific evidence to support the continued protection of foetal forms of birds and egg laying reptiles using Article 2 to the Directive?

OneKind believes it is essential that protection for foetal forms of birds and egg laying reptiles is retained using Article 2 of the Directive. Whether there is scientific evidence of the exact level of consciousness and ability to suffer of the wide range of animals covered by this category is probably less important than the fact that an animal is born fully-formed and able to exist independently from the egg. Chicks are fully formed at birth and have to peck their way out of the shell. Mother hens are heard chirping to their chicks, which cheep back from inside the shell. We feel that this is sufficient evidence that these young animals are sensate and should not be subjected to scientific procedures without the protection of the law.

Inclusion of cephalopods

Question 3: Are our assumptions correct? Do you have any further information of the current use of cephalopods?

Unfortunately we do not have further information on the use of cephalopods other than *Octopus vulgaris* in the UK. However we strongly support transposition of Article 1(3)(b), so that all live cephalopods are covered. If cephalopods are being used, it is only sensible to gather information about the extent and manner of this use. In view of our growing understanding that cephalopods (and decapod crustaceans) possess substantial perceptual ability, pain and adrenal systems, emotional responses, long- and short-term memory, complex cognition, individual differences, deception, tool use, and social learning[1], OneKind believes that the level of protection for all cephalopods (and decapod crustaceans) should be increased and it would be regrettable if this opportunity were not to be taken.

Inclusion of animals specifically bred for organs and tissues

Question 4: Are our assumptions correct? Do you have any further relevant information of the current breeding and use of animals bred for organs and tissues?

Unfortunately we do not have first-hand information about animals bred specifically so that their organs or tissues may be used for scientific purposes. However we agree with the assumption in the consultation that their inclusion, under Article 1(2), is unlikely to have any significant regulatory or animal welfare impact in the UK, given that they are already bred and used at designated establishments.

Conversely, it is in the nature of the purpose for which these animals are bred that they will be subjected to procedures at some point or killed: it is therefore essential to ensure that they continue to receive equivalent protection to other animals used directly in

[1] Broom,DM *Cognitive ability and sentience: Which aquatic animals should be protected?* UK DISEASES OF AQUATIC ORGANISMS Dis Aquat Org Vol. 75: 99–108, 2007

experiments. This would be particularly relevant if animals were to be brought from other member states where the condition about breeding in designated establishments did not obtain.

Absence of special protection for cats, dogs and equidae

Question 5: Is loss of special protection likely to lead to increased use of cats, dogs and equids? Should the UK retain its current special protection for dogs, cats and equids using Article 2 to the Directive?

OneKind is not in a position to judge whether loss of special protection for cats, dogs and equids would lead to increased use of these species in the UK. The numbers of cats and equids used are currently relatively low although, at over 3,700 in 2010, the number of dogs is not. However we are not aware of representations from the scientific industry to the effect that there is any great necessity to use more of these species, and clearly in our view, that would be a retrograde step.

The main reason for invoking Article 2 would not be to "favour" these species over others used in experiments, but simply to continue to discourage the use of animals and resist any reduction in protection, as a point of principle. Nonetheless we also believe that public concern for these animals and the special place that they have in UK society offers justification for invoking Article 2 of the Directive and retaining the particular protection which is afforded to dogs, cats and equids, and to primates.

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?

OneKind agrees with the interpretation in the consultation that removal of the reference to 'pain, suffering, distress and lasting harm' could allow more painful methods to be used, and this should not be permitted. We believe that the current conditions in s. 2(5) of the Animals (Scientific Procedures) Act 1986 should be retained.

4. PROVISIONS ON THE USE OF CERTAIN ANIMALS IN PROCEDURES

<u>Article 7: Endangered species</u>

Question 7: Should the UK retain its current restrictions on the use of endangered species using Article 2? What implications would adoption of the provisions of Article 7 of the Directive have for the use of endangered species in the UK?

OneKind believes that the current restrictions on the use of endangered species should be retained, using Article 2. The Directive allows the use of endangered animals for a number of reasons, including the avoidance of disease in humans, animals or plants and the development of foodstuffs and "other substances or products". The Animals (Scientific

Procedures) Act 1986 allows endangered species to be used only for research into the preservation of the species in question or "essential biomedical purposes," where that species "exceptionally proves to be the only one" suitable. The trade in endangered species is recognised as a serious animal welfare and conservation problem and it could increase if protection is reduced.

Article 8: Non-human primates

Permissible uses and the definition of 'debilitating condition'

Question 8: Do you agree with our analysis of the likely impact of Article 8 on work involving non-human primates? Are there any further issues we should consider when transposing these provisions relating to the use of non-human primates?

OneKind agrees that the restrictions set out in Article 8 must be transposed into UK legislation to minimise use of non-human primates. Use of non-human primates should only be based on robust scientific assessment, having already accounted for retrospective assessment of previous experiments on non-human primates and existing experimental data, whether published or not.

The use of non-human primates should not be accepted simply because no other species is practically available.

The likelihood that Article 8 of the Directive will affect research which is currently being conducted using non-human primates would depend very heavily upon the exact definition of "debilitating condition". If the word is interpreted strictly, the number of primates and the permissible research would be minimised, which is in the spirit of the Directive. If almost any condition can be considered to be "debilitating", then the number of permissible procedures and protocols will increase. For this reason, an exhaustive list of "debilitating" medical conditions for which the use of primates could be permitted should be established; and the use of non-endangered NHPs in basic research should not be allowed, since basic research does not aim at finding cures.

Question 9: Are there any further issues we should consider when transposing these provisions relating to the use of endangered species of non-human primate?

OneKind believes that there should be a prohibition on the use of all species of non-human primates, whether endangered or not, in scientific procedures.

There is now overwhelming scientific evidence that non-human primates suffer during transportation, captivity and during experiments. All primate species are intelligent, some use tools, others show self-awareness and they are good at problem-solving. Most live in family groups with complex social structures. They have proved themselves capable of learning rudimentary arithmetic, have demonstrated reasoning, and some have even learnt to speak in human sign language; they also display similar emotions to humans. It is acknowledged that these animals suffer in the limited, often very restrictive, facilities

available in laboratories. Confining primates in the laboratory has a significant adverse effect on their welfare. Lab primates are kept in small, barren metal cages often isolated from other primates. Their level of awareness means that they are capable of suffering greatly from isolation and during even basic experimental procedures – for example the stress of being restrained has been known to cause monkeys to suffer rectal prolapse.

Primate research is always said to be justified on the grounds that it is essential, indeed unavoidable, in the interests of medical progress. However, the review panel led by Professor Sir Patrick Bateson, and funded by the Biotechnology and Biological Sciences Research Council (BBSRC), Medical Research Council (MRC) and the Wellcome Trust concluded recently that 9% of primate experiments between 1997 and 2006 produced "no clear scientific, medical or social benefit". In addition:

- Much primate research had a high welfare impact on the animals
- Alternatives to using primates were not always sufficiently explored
- Benefits of primate research were not always commensurate with welfare costs
- Evidence was not always available of actual medical benefit stemming from primate research, such as changes in clinical practice or new treatments
- In some cases, previous work was repeated, or confirmed earlier results from human studies
- Some primate research was never written up for dissemination

When considering the use of an endangered species of NHP, it must be mandatory to review and assess all related procedures (whether published or not) and perform a rigorous cost benefit analysis. The UK must retain, as an absolute minimum, the restrictions on endangered NHP under the Animals (Scientific Procedures) Act 1986 s.10(3)(c).
Specific examples of situations should be provided to demonstrate 'essential biomedical purposes' when only a particular species of NHP could be used. The term 'essential biomedical purposes' is very vague and must be clarified. Measures of this nature in the transposition would help to reduce and finally eradicate primate use.

Great apes

Question 10: Do you agree that the UK should continue to operate a policy ban on the use of great apes? Are there any further issues we should consider relating to the use of great apes?

The consultation document states that the government cannot envisage any circumstances under which it would wish to alter the current policy ban on the use of great apes, and OneKind welcomes that stance.

The "safeguard clause" at Article 55(1) of the Directive broadens the potential uses of great apes beyond the already ill-defined circumstances set out in Article 8(1)(a). (We have already expressed our concern in the response to Question 8 at the potential for words such as "debilitating" to be very broadly defined.) The safeguard clause would extend these uses to circumstances which appear to require no clear scientific or ethical basis. In view of the current policy ban on the use of great apes in the UK, OneKind believes that the safeguard clause should not, and need not, be transposed.

All primates suffer in laboratories, but great apes are likely to suffer even more due to their high intelligence, complex social lives, large size and long lives. The UK ban on use of great apes must be retained. In addition, the new Directive aims at ending the use of wild-caught primates, but a 12-year phase-out is too long. The UK should lead the way and set a much earlier deadline.

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?

OneKind believes that only those few experiments which actually focus on wild animals *per se*, and are for the benefit of those animals themselves, or their species, could offer any justification for using animals taken, ideally very briefly, from the wild. Studying wild animals in their own environment is clearly more humane and often more scientifically robust with regard to the achievement of research objectives.

The impact on these animals would also be significantly different from the impact on – for example – non-human primates captured and taken permanently from their family groups, transported and confined in laboratories for use in procedures which are of no benefit to them or their species. This creates a vast ethical gulf between the different types of capture and procedure. The only feasible approach would appear to be to provide for a robust case-by-case cost benefit analysis, comparing predicted outcomes to previous related procedures using both wild-caught and laboratory bred animals.

The restrictions in Article 9 on use of wild-caught animals are based on the purpose of the procedure and should be transposed. The Animals (Scientific Procedures) Act 1986 currently permits wild-caught primate use when suitable animals from are not available from designated breeders or suppliers which is not an adequate justification. However, permitting supply only from designated breeders or suppliers does afford some control and must be retained as a sub-condition.

Additionally, issues related to uncontrolled worldwide supply of wild-caught animals into the UK must be rigorously controlled and the UK must seek opportunities to implement its own strict bans where areas of the Directive are vague. This is critical to prevent even further suffering of animals caught in very poor conditions by people of low or no competence, with little or no consideration for animal welfare.

New requirements relating to trapping and capture

Question 12: What criteria should be applied to ensure the competence of persons capturing animals in the wild?

Recital 19 of the Directive regarding non-human primates proposes moving towards an end to the capture of non-human primates from the wild, after a transition period; and Recital 20 proposes that, for reasons of animal welfare and conservation, the use of animals taken from the wild should be limited to cases where the purpose of the procedures cannot be achieved using animals bred specifically for use in procedures. Article 9(1) prohibits the use of animals taken from the wild in procedures. It appears to us that that is the only aspect of the Article which is mandatory, and there would be no obligation on the UK government to allow the exemptions referred to in 9(2).

In general it is totally undesirable to allow the use of wild-caught animals. There are welfare, scientific and environmental concerns associated with the capture of wild animals for experiments, or for laboratory animal suppliers to replenish their stocks. The level of suffering and mortality associated with capture, handling and housing of wild animals includes violence, stress and fear during capture; sudden confinement, indiscriminate tearing apart of family groups and broken populations left behind (young animals can be left without parents or siblings).

Article 9 (3) offers no definition for the competence of persons capturing animals from the wild: it is perhaps more constructive to focus on the methods which may be used, and how to ensure that these do not cause the animals avoidable pain, suffering, distress or lasting harm. Clearly the best way to avoid these negative effects would be not to carry out wild capture in the first place. That failing, it would be desirable to list permitted methods and their manner of use (for example, stringent provisions on regular inspection of live traps) and prohibit all others.

Given the potential for wild-caught animals to enter the UK via another member state, classing the capture of wild animals as a procedure under the Act would allow some regulation of personnel, including a requirement for formal training in capture, animal welfare and care procedures. Since the Animals (Scientific Procedures) Act 1986 does not currently class the capture of animals from the wild as a scientific procedure, there would be value in amending the Act to include this.

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 that the provisions of Article 10 and Annex 1 should be transposed, insofar as extending the requirement for purpose-breeding to the xenopus and rana frogs, and to zebra fish is concerned. Given that these species are largely bred in designated establishments or by specialist breeders in the UK, this would appear to create little or no

additional regulatory burden. While relatively few frogs appear to be used currently in scientific procedures, the use of zebra fish is growing rapidly and it is important to ensure that these are only sourced from regulated establishments.

Regarding common quail and ferrets, OneKind agrees that the concerns raised in Section 58 of this consultation are valid, in that deregulating the breeding and acquisition of these species might negatively impact on their care and welfare. Buying animals only from designated establishments does ensure that that the animals are bred under codes of practice and government guidance and that the establishments where they are bred can be inspected by the Animals Scientific Procedures Inspectorate. This confers a degree of protection on these animals, and allows the public to check that inspections are being carried out. We therefore support the use of Article 2 to ensure that these species are only used if they are purpose bred and continuing to list them as in ASPA (Schedule 2) at least affords some level of regulation, inspection and monitoring.

Question (13a): What impact will this have on UK breeders, suppliers and users? Will opening up the ability to supply animals have any animal welfare impact?

The restriction on stricter national measures under Article 2 (2) presents very serious implications for the welfare of all animals bred, supplied or caught from the wild and used in UK laboratories. Broadening the system to allow supply of animals across Europe also poses a great risk for transit of animals into the UK from an uncontrolled source in e.g. the Far East where animal welfare is far less considered. Animals may come via another EU member state with less rigorous controls and less regard for animal welfare. The UK must challenge this.

Article 2 (2) could also impact on UK breeders and suppliers who have higher standards of welfare in place. Without supporting the supply of any animals for scientific procedures, we acknowledge that it is better to obtain animals from within the UK rather than animals from unregulated suppliers across the world. The latter are likely to have endured greater pain, suffering and distress from capture, confinement, long term transport and storage in poor conditions.

Non-human primates

Question 14: What impact will these requirements have on UK breeders, suppliers and users? What impact, if any, is there likely to be on animal welfare?

We agree with the aim of ending the use of wild-caught non-human primates. The provisions of Recital 19 and the timetable laid down in Annex II are not ideal but they do offer progress towards ending the capture of non-human primates from the wild. The provision for F1 non-human primates in Article 10 and Annex I of the Directive is welcome.

It is likely that use of overseas breeders will have an impact on UK breeders and suppliers. As stated in out answer to Question 13 above, it is better that animals should be obtained from within the UK rather than further afield. In the face of competition from overseas where standards are lower, it is possible that current UK breeders could reduce their

standards and animal welfare in the UK would be affected. This would add further to animal suffering and would also affect research results.

Article 11: Stray and feral animals of domestic species

Question 15: Is there a case on animal welfare grounds for retaining the current UK prohibition on the use of stray and feral animals, as permitted by Article 2?

OneKind agrees that the UK should retain its current restrictions on the use of stray and feral animals, under the Animals (Scientific Procedures) Act 1986 s.10(3)(a) and (b) and Schedule 2.

Stray and feral animals should not be used for a multitude of reasons, including the stress which is involved in their capture, restraint and transportation to the designated establishment where they will be used. All animals suffer in laboratories, but animals which are not bred or used to captivity and the close proximity of humans suffer additional stress from these aspects. As well as the stress of these factors, which will make the animals an even poorer scientific model than animals bred specifically for laboratory use, scientifically, the use of purpose-bred animals with an available genetic and health background is preferred. These more homogeneous animals reduce the variation of data gathered from them, leading to improved consistency and reproducibility of data. This can reduce the number of animals that are used. There are therefore both scientific and ethical reasons for stray and feral animals not to be used in research under the Directive.

Further examples are needed to clarify the conditions under Article 11 (2)(a) and (b) for scientific justification of the use of a stray or feral animal, instead of another animal of the same species that has been purpose-bred.

5. PROCEDURES

Article 3: Definition of 'procedure'

67. … under the new Directive ... the use of a method of killing of animals not listed in Annex IV (Methods of Killing Animals) solely for the use of their organs and tissues is not a procedure and will not require project authorisation. However, exemption from using an Annex IV method of killing will be needed. A system will be required to enable exemption to be granted to individuals who are not licence holders and are outside the regulatory system.

Question 16: Do you have any proposals as to how this might be achieved?

We agree that Article 3 and Article 6 taken together suggest that killing an animal using a method not listed in Annex IV of the Directive would not be regarded as a procedure, if the animal was being killed solely for the purpose of harvesting its organs or tissues. We do not think that any system should be devised for offering the required exemption. It is important to record all animal use and the distinction between live animal use and the killing of an animal for use is rather artificial.

OneKind requests that s.2(7) of the Animals (Scientific Procedures) Act 1986 be retained, but strengthened so that all methods of killing, not only those listed at Schedule 1, are considered to be procedures and are regulated accordingly.

Article 5: Purposes of procedures

Question 17: Are there any further issues we should consider in relation to the 'permissible purposes' set out in Article 5?

OneKind believes that during the transposition of Article 5, s.5 of the Animals (Scientific Procedures) Act 1986 should be amended to prohibit the granting of a licence for any project or procedure unless a full cost-benefit analysis has been carried out, taking into account a retrospective assessment of all existing published and unpublished data.

Article 12: Procedures

Question 18: Are there any further issues we should consider in relation to the provisions on procedures set out in Article 12?

We agree that retaining the Animals (Scientific Procedures) Act 1986 ss. 3 and 6 is consistent with Article 12.

Article 14: Anaesthesia (and the use of neuromuscular blocking agents)

Question 19: We propose to transpose these provisions relating to the use of anaesthesia as they stand. Are there any further issues we should consider relating to the use of anaesthesia?

We agree that there may be circumstances in which administration of anaesthesia may be more traumatic than the procedure to be undertaken, and in these cases the overall welfare of the animal may preclude the use of anaesthesia. However we find it difficult to accept that a procedure may be carried out without the use of anaesthesia on the grounds that administration is incompatible with the purpose of the procedure. In such cases there must be a rigorous, monitored cost-benefit assessment with a presumption against the procedure, unless there is an overwhelming argument for it to continue.

Neuromuscular blocking agents

Question 20: Should current UK provisions relating to the use of neuromuscular blocking agents in mammals be retained? Should we continue to apply the same provisions to other animals?

We support the view expressed in the consultation that, as analgesia alone does not remedy non-pain-related distress associated with procedures, there is a strong case for retaining the current UK provision on anaesthesia for mammals when neuromuscular blocking agents (NMBAs) are administered. We regret that the Directive would allow NMBA use with

analgesics, as these would not mitigate the terror and distress of a paralysed but conscious animal.

We think it is dangerous to assume that non-mammals would not suffer distress from procedures using NMBAs, and we strongly believe that the same provisions must apply, where relevant, to all animals.

Article 16: Re-use

Question 21: We propose to transpose the provisions of Article 16 relating to re-use as they stand. Are there any further issues relating to re-use we should consider?

OneKind does not believe that animals should be re-used. Re-using an animal inevitably increases the suffering of the individual and does not contribute to the principle of reduction, as the same amount of suffering is caused, even if the number of animals is lower. To allow an animal to recover from anaesthetic following a procedure in order to be used again - when otherwise the animal would have been euthanased while unconscious – amounts to prolonging or repeating its suffering unnecessarily.

In the absence of a complete moratorium on re-use, the UK should certainly maintain its stricter standards and not follow the Directive. The Animals (Scientific Procedures)Act 1986 s.14(1)(b) states that an animal should not be re-used for a severe procedure if it has previously experienced severe pain or distress. Article 16(1) appears potentially more stringent than this, in that it starts from the position of only permitting the use of an animal in a procedure causing mild/moderate pain/distress to be followed by re-use in a procedure causing mild/moderate pain/distress or non recovery – although this is only when another suitable animal is available. However, Article 16(2) of the Directive would allow animals, in exceptional but undefined circumstances, to be re-used after a severe procedure and does not explicitly require prior authorisation for re-use. The mandatory pre-authorisation of re-use is essential, given that unauthorised re-use has been known to take place and has been identified in Home Office inspections.

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?

The consultation notes that the government believes that the stricter measures relating to the welfare of animals at the end of a regulated procedure, under the Animals (Scientific Procedures) Act 1986, could be retained using Article 2.

Having had some contact with an establishment that was taking good care to re-home animals suitably, OneKind believes that this is feasible and desirable. All measures should be

taken to ensure that the maximum number of animals should be released or re-homed to a suitable natural environment, care provider or sanctuary.

Regarding animals suffering mild effects, it would be difficult to envisage a general rule to cover all of the many issues that may arise. The longer term consequences of currently mild effects would have to be considered. This means that veterinary advice would have to be taken on a case by case basis, starting with the objective of ensuring that the animal will be released or re-homed given appropriate treatment or long term care.

Article 18: Sharing organs and tissues

Question 23: How should we facilitate the sharing of organs and tissues? Are there any further issues relating to the sharing of organs and tissues we should consider?

OneKind accepts that many UK establishments make a practice of maximising the sharing and use of tissues and organs. Article 18 is therefore welcome, not only because it will improve practice in other member states, but because transposition in the UK provides the opportunity to make organ and tissue-sharing universal and provide for monitoring..

Given that issues of competition within industry are bound to affect the willingness of some laboratories to engage in sharing, an assessment of arrangements for organ/tissue sharing could also be introduced as part of the licensing process. Practical arrangements for sharing organs and tissues, such as shared storage, refrigeration and transit facilities, could be supported.

Measures should also be taken to support and promote alternative sources of organs and tissues such as human tissue banks and the continued development of artificial alternatives.

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 agree that there is an argument for retaining Schedule 1 techniques where these offer a welfare advantage over those in Annex 1V. Some measures permitted under Annex IV are likely to exact a higher welfare cost than would be permitted in the UK and, in addition to those mentioned in the consultation paper, we would highlight:

- The percussive blow method for reptiles, large birds (diving birds, for example, which have particularly thick skulls), rabbits, and neonate dogs, cats, ferrets and foxes. Not only is there a danger that the animal will not be killed by a single blow, and will suffer as a consequence, there are also significant issues surrounding restraint and achieving a stress-free kill. Assessment of the percussive blow as a technique for killing grey squirrels has shown that it is essential to restrain the animal appropriately and even then the technique has not been endorsed by mainstream animal welfare charities.

- Decapitation as a killing method for birds up to 250g, rodents and rabbits. The comparison of Annex IV and Schedule 1 methods in the consultation notes the paucity of research into this method in these species and we do not think it is acceptable to say that it is "probably OK" for rodents and rabbits. If there is any doubt, the animals should be given the benefit of it.
- The comparison also casts doubt on the practicality of electrical stunning for fish and we would add a welfare concern to this, having witnessed demonstrations of electrical stunning of trout where a small number of animals recovered consciousness.

No method should be transposed from Annex IV where there is any risk of a higher welfare cost. All measures should be taken to ensure that methods used are painless and stress free for the animals.

Regarding maceration, we note that the consultation's comparison of Schedule 1 and Annex IV methods makes reference to public perception. For most people, the concept of maceration of animals is repellent. Gathering numbers of animals and putting them conscious into the macerator must inflict terror and pain on the individuals involved even if these are of short duration. While maceration may relatively quickly achieve the necessary effects of exsanguination and destruction of the brain, and thus meet the objective standards for humane killing, in other respects this is a primitive method and we believe that the UK should ensure that alternatives are used.

7. CHOICE OF METHODS

Article 4: Principle of replacement, reduction and refinement

Question 25: We propose to transpose the requirements of Article 4 as they stand. Are there any further issues relating to replacement, reduction and refinement we should consider?

We support the transposition of Article 4. However the only genuinely alternative approach is to move towards replacement as soon as possible, which is in the spirit of the Directive as stated at Recital 10. Reduction and refinement are only partial interim solutions and cannot be considered as genuine alternatives.

The UK should take the opportunity as a key member state to accelerate the use and validation of alternatives, request feedback on regulatory approval and make the promotion of non-animal research data an ongoing priority for all UK and EU review bodies. This should also be communicated to all UK researchers regularly to encourage and champion non-animal methods, innovation and new research initiatives.

Measures taken with regard to use of alternative methods for any procedure should be detailed in the non-technical summary and made available in the public domain, with qualitative explanation of why humane alternatives were not used.

Article 13: Choice of methods

Question 26: Is our analysis of the impact of Article 13 correct? Are there any further issues relating to the choice of methods we should consider? Are there any currently permitted testing methods which will be prohibited?

We believe that the analysis of the impact of Article 13 is correct. We support transposition of the more stringent provisions of Article 13 to prohibit animal testing in response to regulators from outside the EU.

We welcome the requirement in Article 13(1) to use a non-animal method when recognised under the legislation of the Union, and we urge the government to press for further progress in recognising these alternative procedures. Article 13 (2) still places the emphasis on reduction and refinement and here, too, we believe the UK could take a lead – moving the agenda further and faster towards replacement,.

Question 27: We propose to transpose the provisions of Article 13 as they stand. Are there any further issues we should consider relating to the use of death as an endpoint?

Use of death as endpoint runs the risk of intensifying the pain, suffering, distress and lack of dignity for animals, especially where use of anaesthesia or analgesia is restricted if it interferes with the purpose of the procedure. We agree with Article 13(3) in that it recommends that the use of death as an endpoint should be avoided as far as possible. In transposing this section therefore we believe it would be valuable to create a non-exhaustive list of circumstances where the use of death as an endpoint would be prohibited, with all other circumstances to be considered on a case-by-case basis, with a presumption against permitting it.

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?

We agree with the principle of Article 46 but it is general in nature. Compulsory data sharing is vital for the reduction of animal testing. This will also contribute to transparency of animal testing and accountability of licence holders. Given the estimated extent of duplication in regulatory testing (estimated at approximately 160,000 animals each year by the European Commission) we believe that this is another area where the UK can usefully take a lead. A UK database should be created to collect information on animal experiments and share data including review of all EU-wide available research evidence, whether published or not; retrospective assessment of all related procedures to ensure that objectives are being met and there are tangible links to human disease or medicine.

The safeguard clause in Article 46 for when: ' further procedures need to be carried out regarding the data for the protection of public health, safety or the environment' needs to be clarified further. Specific examples are necessary to illustrate when and why further procedures would be necessary.

Chemical testing is likely to form part of this category and this would benefit from requiring cost-benefit assessment of the purpose of testing, and comparison of chemical data from previous testing in the UK, EU and beyond.

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?

Replacement is the only authentic alternative approach.

It would be valuable to establish a UK co-ordinating body for the development and validation of non-animal methods and ensure their implementation. This would be wider than the scope of the present National Centre for the 3Rs, and would require the participation of specialist animal welfare organisations.

Issues for the body to cover would include: funding, resourcing and training in use of existing validated alternative methods and review and acceptance of new methods in development.

We believe that 'like for like' replacement is not necessarily needed for every animal test. Animal tests can simply be stopped or removed from regulatory guidelines as they are unnecessary. For example, an acute toxicity test was recently deleted from the European Medical Association (EMA) test guidelines as these data could be obtained from repeat dose toxicity tests.

Similarly, it may not be necessary to devise one alternative test directly to a specific animal test, but instead to use a 'battery' of alternatives. For example, testing of chemicals for absorption, irritation and corrosion of the skin may be tested with several assays. As the reliability of animal tests is often questionable, modern non-animal methods can improve on, as well as replace, conventional animal testing. We understand that no animal test has been validated.

Article 48 and Annex VII: Union reference laboratory

Question 30: Are there any further issues we should consider in relation to the Union reference laboratory?

OneKind welcomes the commitment to give full support to the Union reference laboratory and its activities. We believe that the Union reference laboratory must be primarily

orientated towards the replacement of animals in research, rather than the refinement and reduction of their use, and we would like UK support to be on that basis.

The laboratory could also incorporate a human tissue bank and database in order for researchers to be able to obtain tissue for their research. Making human tissue more widely available would encourage the use of human tissue and cells and promote the replacement of animal use. The UK could also provide feedback on progress on alternative methods.

9. SEVERITY OF PROCEDURES

Article 15 and Annex VIII: Classification of severity of procedures

Question 31: Are there any areas in which the Annex VIII severity classification is unclear? Are there any additional examples of severity that might be included in guidance on the application of the proposed severity classification system? [See also questions relating to Article 55 below.]

To function effectively and meet its objectives, severity classification needs must be clear, consistent and easily understood by researchers and those processing and authorising applications. The system must clearly link common procedures and practices to categories of pain and suffering which are readily understood by the public. The severity classifications in Annex VIII are general in nature and open to interpretation by researchers who may underestimate (and therefore exceed) the severity limits set for animals used in their procedures. It would be helpful to provide specific examples of procedures under each category.

Procedures which cause both severe and prolonged suffering should not be grouped together within a single “severe” category. A “severe and prolonged” category must be created allied to a list of procedures which are prohibited. This must be compiled and adhered to without safeguard clauses

An upper limit of pain and suffering must be set, for scientific and ethical reasons. In modern scientific procedures, animals should not suffer severe and prolonged pain, and death should not be an acceptable end-point. Without this category to report unauthorised prolonged suffering, the “severe” category has the potential to be open-ended, and animals could endure suffering without limits.

Article 55 safeguard clauses that would potentially allow severe pain and suffering should not be transposed.

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?

The more stringent standards of the Animals (Scientific Procedures) Act 1986 ss.6 and 7, in relation to authorisation of breeders, suppliers and users, must be retained. The requirement to notify the Home Office of any changes must also be retained.

Article 21: Suspension and withdrawal of authorisation

Question 33: We propose to transpose the provisions of Article 21 as they stand. Are there any further issues we should consider relating to the suspension and withdrawal of authorisations?

The provisions of Article 21 appear broadly to reflect current arrangements under the Animals (Scientific Procedures) Act 1986. However it is requested that the specific time frames and processes outlined in ss.11 and 13 of the Act, with regard to withdrawal and suspension, are retained.

Article 22: Requirements for installations and equipment

Question 34: Are there any further issues we should consider in relation to the requirements for installations and equipment set out in Article 22?

We agree that Article 22 is broadly consistent with current provisions in the Animals (Scientific Procedures) Act 1986 s.10(6B) and that all other conditions under s.10 (6B-6D) should be retained. It is also noted that s.10(6C) will be updated to reflect Annex III of 2010/63/EU, replacing Annex II of the previous Directive 86/609.

Article 28: Breeding strategy for non-human primates

Question 35: Are our assumptions relating to Article 28 correct? Are there any further issues we should consider in relation to the requirements for a breeding strategy for non-human primates set out in Article 28?

The strategy defined under Article 28 is a positive step to banning the capture of wild caught primates. It would be helpful to establish for certain that UK-based establishments supply only F2 animals, and to place this information in the public domain.

Article 19: Setting free of animals and re-homing

Question 36: We propose to transpose the provisions of Article 19 as they stand. Are there any further issues relating to the setting free and re-homing of animals we should consider?

We agree that Article 19 is broadly in line with the Animals (Scientific Procedures) Act 1986 s.10(3C).

Section 10(3B) relates the release or re-homing of animals to the conditions of the project licence. It would be preferable for s.10 to be amended so that the release or re-homing of animals would be the rule after use in procedures, based only on the conditions in Article 19.

Article 29: Scheme for re-homing or setting free of animals

Question 37: We propose to transpose the provisions of Articles 28 and 29 as they stand. Are there any further issues we should consider relating to these issues?

We agree that it is desirable for breeders, suppliers and users of animals to have a scheme that ensures socialisation of animals to be re-homed or, where appropriate, the rehabilitation of wild animals about to be returned to their habitat (providing this does not cause undue additional stress by delaying their release). Very often these animals have specific needs and behaviours which must be the subject of expert input.

Article 30: Animal records

Article 31: Information on dogs, cats and non-human primates

Article 32: Marking

Question 38: We propose to transpose the provisions of Article 30, 31 and 32 as they stand. Are there any further issues we should consider relating to these Articles?

We agree that Articles 30, 31 and 32 should be transposed in full and we would like to see information from animals histories included as part of the published annual statistics.

However, when an animal is imported from outside the European Union, we believe that there must be a requirement for it to be accompanied by full records documenting its origins, health and welfare history and other relevant information to safeguard its interests. We do not think it acceptable for the animal's history only to be established on arrival in the UK.

Regarding Article 32, a list of marking methods should be made available with recommendations as to the most appropriate and 'least painful' method for the animal in question.

11. CARE AND ACCOMMODATION

Article 33: Care and accommodation

Question 39: We propose to transpose the provisions of Article 33 as they stand. Are there any further issues we should consider relating to the issues covered by Article 33?

We agree that Article 33 is generally consistent with the Animals (Scientific Procedures) Act 1986 s.10(6B) with the addition of a requirement for appropriate conditions of transport and that it is desirable to transpose the Article. However the specific condition of 'freedom of movement' in s.10(6B)(a) must be retained as this is not specified in Article 33.

Examples should be given of the exemptions envisaged under Article 33(3). Actions nominally taken in the interests of animal welfare – such as depriving animals of food or water – must be explained, justified and assessed in the context of the animal's welfare in general, not simply in the context of the procedure. Such actions should also be documented in the non-technical summary.

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?

UK guidance on the use of Annex III is welcome and we hope this would be updated on an ongoing basis to optimise care and accommodation standards, with best practice exceeding those standards wherever possible.

Where differences exist between higher UK Code of Practice standards and those stated in Annex III, we would support retention of the former, using Article 2 where applicable.

The requirement at Recital 34 for the care and accommodation of animals to be based on the "specific needs and characteristics of each species" needs to be extended to cover the different stages of animals' lives. Younger animals may require more space to explore and play whereas older animals may require adaptations to their cages to reflect their advanced age. This is especially relevant where animals are used in long-term studies.

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?

The UK should retain its strict three tier licensing system for establishments, personnel and projects, administered by the Home Office.

Even competent handling can cause stress in laboratory animals and regrettably it has been shown that handling can vary from competent and caring to careless and negligent, or worse. Therefore it is fundamental that, throughout their entire lifetime, animals are handled by competent personnel.

The requirement for a personal licence issued by the UK authorities is a basic protection against bad practice and offers an immediate and straightforward sanction (as well as a reporting mechanism) if breaches should occur. We do not think that reducing the administrative burden is adequate reason to reduce protection for animals. Registration of personnel would not be an adequate substitute, especially bearing in mind that many procedures involve actions that would be illegal in another context.

Breeders, suppliers and users are subject to commercial and competitive pressures to maximise supply of animals for use in laboratories or meet the objectives of their research. Relying on local control could make the system more vulnerable to being influenced by these considerations.

Education and training

Question 42: What specific features would you like to see in a UK or European training system? What elements of current UK training could be omitted whilst still complying with Annex V? How should the quality of individual training and supervision be assured so that new employers are confident about training and competence and to facilitate the transfer of individuals within the UK and across Europe? Would such a system result in any additional costs? If so, please specify. How might the requirement for continuous professional development best be met?

We welcome the commitment to publish updated UK requirements for training in the forthcoming guidance on legislation, and to press for common training standards across Europe, as long as these are at the highest level.

Training should prioritise the use of alternatives in all areas and encourage new research strategies and ideas in non-animal methods.

While all the items listed in Annex V are important, we believe that specialist training with input from animal welfare groups would be particularly valuable for consideration of item 2 (Ethics in relation to human-animal relationship, intrinsic value of life and arguments for and against the use of animals for scientific purposes). Where item 10 (Requirement of replacement, refinement and reduction) is concerned, the emphasis must be on replacement, in line with the intention of the Directive.

Article 24: Specific requirements for personnel

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

Paragraph 131 of the consultation suggests that the certificate holder responsible for compliance in an authorised establishment may delegate the day-to-day work of ensuring competence. While we understand the need for training to be appropriate for local situations and personnel, we suggest that this should be in addition to, rather than instead of, a centralised training process.

Article 24 (2) (a) requires the person responsible for project implementation and compliance (Article 42(2)(b)) to *stop* any unnecessary pain, suffering, distress or lasting harm, being inflicted in the course of the procedure. This is a lower level of protection than currently offered by the Animals (Scientific Procedures) Act 1986, which imposes a responsibility to *prevent* pain or avoidable suffering, distress or lasting harm. We believe that these are not sufficiently similar to warrant direct transposition and that Article 2 should be invoked to ensure that the current standard is maintained.

Article 25: Designated veterinarian

Question 44: Are there any further issues we need to consider regarding the requirement for a designated veterinarian or other suitably qualified person?

We have no further issues to raise on this question.

13. PROJECTS

Article 36: Project authorisation

Article 37 and Annex VI: Application for project authorisation

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 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?

All information about project evaluations should be made public to ensure accountability and public confidence. Publication of technical details of project licence applications (with private information excluded) would allow wider scientific scrutiny of proposals to use

animals and consideration of non-animal alternatives or other sources of the information required.

Ethical evaluation reports and retrospective reviews should also be made available to the public.

The new national committee should safeguard and promote the principle of replacement, and should consider all cases where there is doubt as to whether this has been applied.

Article 39: Retrospective assessment

Question 46: Should we extend the requirement for retrospective assessment to some or all projects involving procedures classified as "mild" or "non-recovery"? What should be the process for retrospective review and should this involve the animal welfare body?

All projects must be retrospectively assessed to establish what has actually happened to the animals, as opposed to what researchers predicted might happen. Retrospective assessment can help to demonstrate whether animal procedures have been conducted within the terms of the project licence and can inform future cost-benefit assessments and define priorities for replacement techniques.

Procedures classed as “non-recovery” should certainly be retrospectively assessed to ensure that animals were not deprived of life without at least scientific justification. We believe that the animal welfare body should be involved in review to ensure that procedures have been appropriately classified and avoidable pain, distress or lasting harm has been prevented.

Review should cover:

- all aspects of the procedure design, set up and completion
- scope for use of alternative methods to animals
- comparison of outcomes to predicted results and what was achieved in relation to the project area, such as its relationship to drug development or study of disease
- suggested modifications to the procedure and reasons for these
- publication of the review decision in the public domain (allowing for removal of genuinely confidential information) and whether similar procedures would be permitted or refused in future
- scrutiny of the use of animals instead of non-animal methods

Extra costs required for retrospective assessment of all procedures should be taken from the budget allocated for decentralisation of the licensing system. Many stakeholders and the public would see this as a more scientific and ethical use of budget than transfer to local control.

Article 40: Granting of project authorisation

Multiple generic projects

Question 47: Are there any other categories of project that should be covered by these provisions?

We would oppose any authorisation of multiple generic projects. We feel that it increases the risk of unnecessary duplication and even though the methods may be established, they may still cause suffering. Ensuring the competence of personnel is not something that can be done on a "generic" scale.

The use of high numbers of animals in transgenic breeding adds to the risk for the individual animal, rather than reducing it, and it would be inappropriate to allow multiple authorisation of these projects.

Article 41: Authorisation decisions

Question 48: How should 'complex and multidisciplinary projects' be defined for the purposes of Article 41?

Criteria for defining complex and multidisciplinary projects might include:

- Use of several procedures of varying complexity, duration or length
- Projects with a number of objectives or dependent stages/'critical path' steps
- Projects which cross a number of study/research areas

'Complex and multidisciplinary projects' would warrant additional scrutiny of:

- the justification for numbers of animals intended for use
- the severity of procedures involved
- a full cost benefit analysis of each part of the project
- retrospective assessment
- mandatory and comprehensive non-technical summaries
- review of alternatives and use wherever possible for all or part(s) of the project
- maximised sharing of organs and tissues
- duplication of procedures

Article 42: Simplified administrative procedure

Question 49: Should the UK adopt a simplified administrative procedure for relevant categories of project? What form should the simplified administrative procedure take?

The UK should not simplify the current administrative procedures. All procedures undertaken using animals, with the animals bearing the cost of the procedure, should undergo a rigorous and robust assessment.

We believe that the fact that there is no equivalent provision under the Animals (Scientific Procedures) Act 1986 amounts *de facto* to pre-existing stricter national measures and accordingly the UK would be justified in deciding not to transpose Article 42.

Article 43: Non-technical project summaries

Question 50: Should we waive the requirement for non-technical summaries for some projects involving only mild or moderate procedures? Or, should we continue to aim to publish non-technical summaries for all authorised projects? What details should be included in non-technical summaries?

The UK should continue to publish non-technical summaries for all authorised projects. Waiving the requirement for non-technical summaries for mild or moderate procedures would incorrectly give the impression that these procedures are of less concern, and that less information is required about them. In addition, if there are different rules for different severities of procedure, this could encourage researchers to attempt to classify their work into lower categories so that they would not be summarised and would undergo less public scrutiny.

Summaries should clearly outline what will be done to the animals, numbers of animals used, duration of the project, types of sampling/testing/surgery that animals will undergo and also whether any animals will be re-used and how. The objectives of the project must be fully clarified, and an account must be given of the research into alternative methods for the project.

Article 44: Amendment, renewal and withdrawal of a project authorisation

Question 51: Are there any risks involved in limiting the requirement to amend or renew project authorisations to changes that may have a negative impact on animal welfare? If so, how might the risks be mitigated?

The difficulty that might arise is that project licence holders could incorrectly assess that their proposed change would not have a negative impact on animal welfare, and that there was no requirement to amend or renew the project authorisation. ASPI reports have identified incidents where project authorisation details and amendments have been overlooked at the expense of animal welfare.

The precautionary principle would suggest that all changes should trigger re-evaluation. However if this is too onerous, the risk could be mitigated by providing that any incorrect assessment would be a breach warranting withdrawal of the project licence, on a strict liability basis. Such a provision would ensure that proposed changes were thoroughly reviewed by the projects and if there was any doubt, advice would be sought.

14. ANIMAL WELFARE BODIES

Article 26 and Article 27: Animal Welfare Body and Tasks of the Animal Welfare Body

Question 52: Is there a case for animal welfare bodies to have more extensive membership and functions than the minimum requirement set out in Articles 26 and 27? If so, what additional members and functions should be required or recommended in guidance? Might animal welfare bodies play a role in advising on training and competence? How might 'small' establishments be defined and how might they meet the requirements for animal welfare bodies 'by other means'?

We respectfully disagree with paragraph 165 of the consultation which states that animal welfare bodies (AWB) and ethical review process groups (ERP) are essentially similar. There are philosophical and functional differences between a process of ethical review which involves lay members and has a role to play in project authorisation and review of applications prior to submission, and an animal welfare body with a limited, technical, non-ethical remit. The latter does not have a role in assessing the grounds, effects and justification for a project, rather it oversees certain aspects of the project which is going ahead anyway.

There is therefore a strong case for animal welfare bodies to replicate more features of the ERP. AWBs should have wider membership and functions than required under the Directive, which specifies only the person responsible for the animals' welfare and care and (if in a user establishment) a scientific member, with advice from the designated veterinarian or expert.

This limited number of members cannot be expected to deal effectively with the range of tasks allocated to the AWB including application of the 3Rs, awareness of the existence of animal alternatives and following through the outcome and development of projects. In order to ensure that the 3Rs are considered fully, a representative with extensive knowledge of these issues should be included as a member of the AWB. It may also be beneficial to have a lay person as part of the AWB in order to gain an unbiased and unscientific opinion.

AWBs should incorporate the current wider provisions for the ethical review process under the Animals (Scientific Procedures) Act 1986, including the attendance of Home Office inspectors, the inclusion of lay members and named animal care and welfare officers involved.

"Small" establishments could be defined by the number of employees or the number of animals used or bred each year. If an individual establishment was unable to set up an AWB, it could be possible for an AWB made up of staff from different establishments, lay members and alternatives experts to carry out their duties for a number of "small" establishments in the same region.

15. NATIONAL COMMITTEE FOR THE PROTECTION OF ANIMALS USED IN SCIENTIFIC PROCEDURES

Article 49: National committees for the protection of animals used for scientific purposes

Question 53: Should the Animal Procedures Committee form the basis for the new National Committee? Are there any models other than the APC on which the National Committee might be based? What should be its membership and what range of expertise will the National Committee require to enable it to meet the requirements set out in Article 49? How might this expertise be accessed?

The current Animal Procedures Committee (APC) provides a good model for a National Committee, with the provision to retain its wider ethical scope.

The potential for the APC to become more directly involved with designated establishments through oversight of AWBs is a positive step in transparency, feedback and evaluation of projects. It may be necessary to increase the size of the APC to fulfil this role. Animal welfare experts and lobbyists, animal policy researchers, scientists, ethical advisors legal experts and organisations that fund and develop alternatives to animal experiments could all play a useful part in the enlarged committee.

16. INSPECTIONS

Article 34: Inspections by the Member State

Question 54: What system of inspection would best meet UK needs? What impact would adoption of a detailed and more formal, but less frequent audit-style approach to inspection have on (a) establishments; (b) public confidence? What aspects of the current UK inspection system should be retained? How might it be improved?

The current system of inspections in the UK is preferable to that proposed under the Directive. Two ways to increase the strength of the current inspection system would be to increase both the frequency of visits and the proportion of these which are unannounced.

The consultation estimates that for some establishments there could be periods of between 3 to 5 years between inspections. This is far too long and could allow controls, procedures and facilities at establishments to deteriorate significantly, with increased animal suffering as the inevitable consequence. There could be wholesale staff changes over such a long period and self-reporting of infringements could fall.

ASPI annual reports for 2007-2010 show a year-on-year decrease in inspections, an increase in infringements and a reduction in self-reporting.

The current level of UK inspections appears to be welcomed by industry, giving access to advice and information from inspectors which can pre-empt problems before they take

hold. Reduction in inspections would also reduce public confidence that animal welfare is being monitored in establishments.

More inspectors are needed to increase the network of staff, reduce travelling time and maximise each inspector's 'on-site' contact. This again is a more justifiable use of budget than decentralisation of the licensing system.

17. REPORTING

Article 54: Reporting

Question 55: Should the UK continue to publish a full range of statistics as in the current annual statistics report? Is there scope for streamlining UK statistics? Are there additional statistics it would be useful to publish?

The UK must at least retain the current system for reporting and data collection and could do this using Article 2. To reduce the reporting and publication of statistics would damage public confidence in the transparency of the system.

It would also be useful for statistics to be published concerning:

- Severity of procedures
- Numbers and types of procedures performed on non-human primates
- Numbers of animals bred and killed for organs/tissues
- Numbers of animals killed as surplus to requirements
- Numbers of animals re-homed or released
- Numbers and species of animals of endangered species used
- Numbers and types of procedure performed on endangered species

18. SAFEGUARD CLAUSES

Article 55: Safeguard clauses

Question 56: Is our analysis of the likely need to invoke the provisions of Article 55 correct? Are there any areas of work currently authorised that you believe may require reference to the Commission under Article 55?

Given that the UK currently operates a policy ban on the use of great apes and does not intend to change this, and given that great apes are not used in the EU, we cannot see any reason to transpose Article 55 in respect of Article 8.

Regarding transposition of Article 55 in respect of Article 15, envisaging situations where procedures involving severe pain might possibly be used could be seen as, in some way, condoning such use. It should be a principle that these procedures will not be used in the

UK and to transpose Article 55 on a precautionary basis would send out entirely the wrong message.

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 would not object to the incorporation of the civil sanctions under Part 3 of the Regulatory Enforcement and Sanctions Act 2008 into the transposing legislation, providing the penalties under s.22 of the Animals (Scientific Procedures) Act 1986 also remain available. Under the current range of sanctions no-one is likely to suffer injustice as a consequence of error or oversight, but serious breaches can still be the subject of criminal prosecution, and this can be appropriate in some cases.

We are not particularly interested in the use of monetary penalties as these often have little impact on large commercial organisations and indeed might simply be offset in their budgets as necessary costs for proceeding in the way the organisation views as most efficient.

20. OTHER PROVISIONS

Article 50: Adaptation of annexes to technical progress

Article 56: Committee

Article 59: Competent authorities

Article 63: Amendment of Regulation (EC) No 1069/2009

Article 64: Transitional provisions

Question 58: Are there any issues we should consider in relation to Articles 50, 56, 59, 63 and 64?

Article 59: we note that there are no plans to designate any competent authorities other than the Home Office and the Department of Health, Social Security and Public Safety (Northern Ireland). Nonetheless paragraph 185 of the consultation additionally states that animal welfare bodies are precluded from acting as competent authorities for project evaluation on the basis of conflict of interest. We assume that the same judgment regarding conflict of interest would be made for bodies that represent the research industry.

Article 64: We would not support the provisions of this Article for 'grandfathering-in' of projects and we believe this is superfluous in the UK where the authorisation of projects is so well established.

Article 58: Review

183A. Article 58 requires the Commission to review the Directive by 10 November 2017 taking account of developments in the 3Rs and to propose amendments, where appropriate.

183B. Article 58 also requires the Commission to conduct periodic thematic reviews of the application of the 3Rs, paying specific attention to non-human primates, technological developments, and new scientific and animal welfare knowledge. The Commission is to conduct these periodic thematic reviews in consultation with Member States and other stakeholders.

Question 58A: We strongly support the requirement for periodic thematic reviews. What structure would you like to see to the thematic review process? Are there any further issues we should consider in relation to Article 58?

OneKind also strongly supports the requirement for periodic thematic reviews and believes that these must involve all stakeholders including animal welfare groups. The thematic review process, allowing the gradual removal of the procedures of most concern, is essential to the spirit of the Directive, as outlined in Recital 10 which refers to 'the final goal of full replacement of procedures on live animals for scientific and educational purposes as soon as it is scientifically possible to do so'.

The UK, as one of the most progressive member states and one which carries out a very large number of scientific procedures using animals, is well placed and morally obliged to take a lead on thematic review. Consideration by stakeholders and then the submission of five specific procedures for review is a manageable number for an annual review. Subject areas should include: use of alternatives; use of non-human primates; ongoing developments in technology and animal welfare; extent of publication in given areas.

We recommend that this be the subject of a separate consultation process.

21. CONFIDENTIALITY (ASPA SECTION 24)

Question 59: How might ASPA 24 be amended to provide greater flexibility regarding disclosure of information while protecting proprietary rights and intellectual property?

The use of animals in experiments is an issue of great public concern and information should be readily available in order to allow the public to make an informed judgment on the issues. There is no justifiable reason why all information regarding the procedure and animals used should not be disclosed at a suitable time, yet the current position is that all information on animal experiments is withheld indefinitely.

Only genuinely sensitive personal or confidential information of the type that is withheld in most Freedom of Information requests needs to remain protected. The existing protections and exemptions under the Freedom of Information Act 2000, and the provisions of Articles 38 and 43 of the Directive provide ample protection for intellectual property and confidential information. Section 24 of the Animal (Scientific Procedures) Act 1986 should simply be repealed.

22: ASPA PROVISIONS NOT COVERED BY THE DIRECTIVE

Definition of 'death'

Question 60: Should ASPA section 1(4) be retained? What would be the effect if it were not retained?

Section 1(4) of the Animals (Scientific Procedures) Act should be retained to provide a formal definition of death. Removal of this definition could result in varying interpretations of the death of animal(s) during procedures, a reduction of verification procedures and possible consequences such as the premature withdrawal of analgesia or anaesthesia. These could cause serious suffering to animals, unnecessarily.

Use of animals in public exhibitions

Question 61: Should restriction on public exhibition be retained?

We support retention of the prohibition on the use of animals in procedures for exhibition to the public or for live television. These are not scientific reasons for using animals and there are considerations of ethics, how the material may be disseminated and whether it is suitable for all audiences.

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?

Where sedation is in the welfare interests of the animal, it should always be used.

Rodents: Inert Gases

Question 63: Concerns have been expressed that there is currently insufficient evidence of humaneness for this method: should it require specific justification?

Given the lack of evidence on the use of inert gases for rodents, they should not be authorised for use.

APPENDIX II: COMPARISON OF ANNEX III AND THE CURRENT UK USER AND BREEDER CODES OF PRACTICE

Table 1.2: Rats

Question 64: Is there a welfare need/benefit for retaining 20cm cage height for rats that are >250g and that are post-weaned stock or being used?

The optimum space allowance for freedom of movement and standing on hind legs must be maintained and is an obvious welfare benefit.

Table 1.4: Hamsters

Question 65: Is there a welfare need/benefit for retaining 15cm cage height?

The optimum space allowance for freedom of movement and standing on hind legs must be maintained and is an obvious welfare benefit.

Tables 2.1 to 2.4: Rabbits

Question 66: Is there a welfare need/benefit for retaining current UK CoP minimum floor areas for some weights of rabbits over 10 weeks of age? Is there a welfare need/benefit for retaining current UK CoP minimum enclosure sizes for does without litters?

The optimum space allowance for freedom of movement, jumping, hopping and standing on hind legs for rabbits must be maintained and is an obvious welfare benefit. It is not acceptable for does to be kept in cages or enclosures smaller than currently permitted in the UK, for significant periods of time, without nesting boxes.

Tables 4.1 and 4.2: Dogs

Question 67: Is there a welfare need/benefit for retaining the larger minimum enclosure size? Is there a welfare need/benefit for retaining the larger minimum enclosure size?

Dogs in cages, enclosures, kennels or confined spaces display signs of distress including biting of bars, scratching and repetitive stress behaviour, as well as fighting and aggression when confined in groups in inadequate space. Where the requirements of the Directive allow greater height, floor space and space for groups of dogs, these should be transposed, but where current UK allowances are greater, they should be retained.

Tables 6.1 to 6.4: Non-Human Primates

Question 68: Is there a welfare need/benefit to retaining the slightly larger minimum floor area for breeding pairs of marmosets?

Where the requirements of the Directive allow greater height, floor space and space for groups of dogs, these should be transposed, but where current UK allowances are greater, they should be retained.

Table 7.1: Cattle

Question 69: Is there a welfare need/benefit to retaining current minimum trough space allocations for ad libitum feeding of individual polled cattle?

Currently higher standards of minimum trough space for cattle under the Animals (Scientific Procedures) Act 1986 must be retained. Cattle in enclosed spaces are prone to fighting or bullying and some animals might not get access to sufficient food and water without adequate space.

Table 7.2: Sheep and goats

Question 70: Is there a welfare need/benefit to retaining current space allocations for most weights of sheep and goats?

Currently higher space allocations for sheep and goats under the Animals (Scientific Procedures) Act 1986 must be retained. Particularly at lower numbers, the allocation under the Directive is far lower than that currently provided and would oblige sheep to be in close proximity to each other for extended periods.

Minimum trough space for restricted feeding for sheep and goats over 35kg must be transposed from the Directive as these exceed current UK requirements. As with cattle, there can be competition for access to food.

Table 7.3: Pigs and minipigs

Question 71: Is there a welfare need/benefit to retaining the current minimum floor area per animals and are there likely to be welfare issues if minimum water flow rates and trough space allowances are not specified?

Current floor area allocations for pigs and minipigs must be retained. Even though pigs often crowd together from choice, they are also prone to aggression and habits such as tail-biting, particularly in barren conditions and space must allow them to separate when necessary. Pigs can suffer greatly from overheating and thirst. Minimum water flow rates

and trough space allowances must be specified to provide consistent standards in establishments and reduce welfare issues.

Table 7.4: Equines

Question 72: Is there a welfare need/benefit to retaining the current space allocations for equines?

The current standards of space allocations for equines including single occupation, in groups and for mares with foals allow a degree of natural behaviour and should be retained.