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1. Name:

2. Organisation (if applicable):

Royal Society for the Prevention of Cruelty to Animals

3. Email address:

4. Address:

5. In responding, it would be helpful if you could indicate whether you are responding as

a civil society organisation

6. Keeping in touch

Please keep me informed by email of the progress of this review, and other BIS Balance of Competence reviews.

1. 1. Where has EU action had a positive impact for the UK on research, technological development, innovation or space? What evidence is there for this? Has EU action encouraged national action in any areas?

Four areas of EU action will be examined on the use of animals in scientific procedures: i. Legislation controlling the use of animals in scientific procedures (Directive 2010/63/EU on the protection of animals used for scientific procedures) Legislation on research animals had not been radically changed since 1986 until 2010 during which time the EU had expanded from 12 to 27 member states (many of which had no previous legislation on research animals). The UK has traditionally been a leader in regulation and setting standards in this area of animal use, such that the new Directive is largely based on key aspects of the UK legislation, the Animals (Scientific Procedures) Act 1986 (ASPA). This level of good practice is seen as a benefit to animal welfare, public confidence and ultimately UK science, as it is widely recognised that better welfare and better science go hand in hand. Directive 2010/63 has lower standards in some areas (e.g. with respect to some housing standards and methods of humane killing) than the UK ASPA. Had the Directive simply been 'copied out' into UK law during the transposition process, then UK standards would have been reduced; but when implementation occurred in December 2012 the UK agreed to keep many of its existing standards. The use of animals in experiments is a controversial issue of public concern; any real or perceived reduction in legislative standards would have affected public confidence in UK regulation and the level of support for the scientific use of animals, with consequences for industry and academic research. As noted above, good animal welfare is a prerequisite for good science, so any reduction in standards would have had the potential to affect the quality of both welfare and science, which would be detrimental to the UK science base. EU actions to raise standards relating to animals in research and testing therefore benefit the UK by recognising its leadership in the field and 'levelling standards up'. Without a harmonised legislation amongst the EU-27 companies could relocate their testing or operations within the EU. Globally, there is an OIE standard on the use of animals in laboratories, which was agreed in 2009. However, the OIE has no mechanism to implement, enforce or monitor its standards and it is difficult to assess how impactful this standard has been to raise standards worldwide. To date, there has been no real evidence that the standards in the UK or EU have caused companies to migrate activities to other countries, such as China or Singapore, where animal welfare standards and the level of regulation are perceived to be lower. Indeed there appears to be more of an incentive in those countries to raise their standards in line with the EU ones. However, as is seen above with other animal welfare laws, implementation of the Directive is patchy and slow. The Directive was due to be implemented in all member states on 1st January 2013. On that date only seven countries had implemented, two partially implemented and 18 had not yet done so. By 1st March a further six countries had implemented the Directive, but there are still at least ten countries that have not or only partially implemented the harmonising legislation. The Commission therefore needs a better system to ensure timely implementation of legislation and the operation of the single market. ii. Legislation/regulations on transport of laboratory animals including primates imported from third countries Action to set higher standards for transport to, from and throughout the EU would benefit the UK's ability to ensure the welfare of animals imported into the country. Every effort should also be made to avoid transporting living animals, as this is a significant source of stress which impacts upon both welfare and science. Laboratory animal transport is also a major concern for the public, especially in the case of primates. iii. Legislation/regulations requiring animal use in toxicity and/or efficacy testing for products such as cosmetics, chemicals (e.g. REACH), biocides, pharmaceuticals and vaccines, medical products and devices, food safety, nanomaterials The UK has been a driving force in applying the 3Rs (replacement, reduction and refinement) to the testing of the classes of product listed, and for removing redundant requirements for animal tests from test batteries. However, since the majority of test regulations are set within Europe, the UK will not usually be in a position to take unilateral decisions. Greater commitment to re-evaluating regulatory test requirements, action to remove obsolete tests, and greater flexibility to refine tests, reduce the number required and ensure alternative methods are implemented without delay is essential. As action at the global level (OECD and OIE) is slow, action at the EU level can act as a

valuable incentive in this area. The EU needs to act quickly to reduce the bureaucracy associated with the risk assessment process, and to overcome excessively risk-adverse inertia and other (already well defined) obstacles to regulatory change. Even on a single issue, the phasing out of the testing of cosmetics on animals, it took 20 years to implement the original intent of Directive 93/35 (adopted in 1993) when Directive 2003/15 was finally implemented on 11 March 2013. As discussed above, this shows the benefit of the EU harmonising legislation for products that are traded globally. In 1997 the incoming Government announced it would no longer license the testing of cosmetics on animals and, although this was a critically important statement of principle that was welcomed by the RSPCA, it only applied to the UK so its effect in practice was at best minimal. This was because companies could export their testing to any other EU member state. Only when the 2003 EU testing ban was implemented, followed by the 2013 final ban on marketing any cosmetics tested on animals, could the intent of the 1997 UK ban finally come into effect. iv. The European Partnership for Alternative Approaches to Animal Testing (EPAA), part funded by the European Commission The EPAA helps co-ordinate intra- and inter-industry activities aimed at replacing the use of animals, particularly in toxicology testing. Expediting the development and acceptance of more advanced and predictive methods would have economic, as well as animal welfare benefits to the UK, since non-animal testing is usually cheaper and faster. Undertaking this at an EU rather than UK helps coordination and pooling of resources, and also opens up funding availability (see below). v. The EU Framework Programmes for research funding

2. 2. Where has EU action had a negative impact for the UK in these fields? What evidence is there for this? Has EU action prevented potentially useful national action in any areas?

3. Getting the Commission to improve quality of and achieve centralisation of relevant information, and achieving stronger implementation and enforcement of the Directive. These are central threads that must run through attempts to improve animal welfare, as highlighted by the Commission in its 2012-5 strategy. Implementation has been discussed above. On enforcement, whilst the role of governments is obviously crucial, oversight and measurement of enforcement across the EU can only be done by the Commission. Enforcement is crucial to the operation of the internal market, and to improving welfare standards, and there is even a competitive advantage for farmers in Member States which do not ensure compliance with the legal standards, as their production costs can be generally lower. This can lead to trade distortion at intra-community level. It is difficult at present to measure enforcement as any assessment of enforcement is mainly from reports from the small number of Commission missions and self reporting from countries. Information on assessing enforcement in the EU-27 is not centrally compiled despite the fact that this would seem to be crucial in assessing future direction, especially with laws such as those on the care and use of animals in laboratories that operate 'cross border'. 4. There is a need for greater harmonisation within the Commission on animal welfare. For example, DG Sanco has responsibility for ensuring improvements in welfare standards; DG Development for providing technology transfer to developing countries to raise their welfare standards; and DG Agriculture for ensuring that any bilateral or WTO negotiations take animal welfare into account. However, there is little overarching harmonising strategy or even communication between DGs. This has negative consequences for the Commission strategy.

3. 3. How and where has UK engagement with partner countries or international bodies, both within and outside the EU, been helped or hindered by EU involvement?

Globally, there is an OIE standard on the use of animals in laboratories, which was agreed in 2009. However, the OIE has no mechanism to implement, enforce or monitor its standards and it is difficult to assess how impactful this standard has been to raise standards worldwide. To date, there has been no real evidence that the standards in the UK or EU have caused companies to migrate activities to other countries, such as China or Singapore, where animal welfare standards and the level of regulation are perceived to be lower. Indeed there appears to be more of an incentive in those countries to raise their standards in line with the EU ones

4. 4. What benefits or difficulties has the objective of a European research area (ERA) delivered for the UK?

The European Partnership for Alternative Approaches to Animal Testing (EPAA), part funded by the European Commission The EPAA helps co-ordinate intra- and inter-industry activities aimed at replacing the use of animals, particularly in toxicology testing. Expediting the development and acceptance of more advanced and predictive methods would have economic, as well as animal welfare benefits to the UK, since non-animal testing is usually cheaper and faster. Undertaking this at an EU rather than UK helps coordination and pooling of resources, and also opens up funding availability (see below). The EU Framework Programmes for research funding Over the last 20 years, the European Framework Programmes for Research and Technology Development have contributed more than €200 million towards the development of non-animal models for drug development, chemical toxicity, ecotoxicology and product safety assessment. Recently, an additional €50 million in funding has been provided under the EU/COLIPA Joint Research Initiative aimed at developing replacement approaches for repeated dose toxicity. Examples of specific EU-funded projects with the potential to shift toward new, innovative approaches in toxicology are at http://axlr8.eu/eu-funded-3rs-research/. Many of these projects will involve partners from the UK, and any UK industry that currently uses animal tests potentially stands to gain from any successful outcomes. It is better that this is done at an EU level than a member state level.

5. 5. How has the EU sought to coordinate the policy instruments at its disposal across different policy areas to create an enabling environment for researchers and innovators? How successful has this been?

In some areas the UK can be seen as the 'driver' in improving standards, resulting in higher standards in the UK than in some other member states. The care and use of animals in laboratories is a prime example of this. With respect to animals used in research, given the importance that the UK places on animal welfare, and the link between good welfare and good science, better practice in the UK should be seen as a benefit. Indeed, the UK government, industry and academia regularly talk proudly about the UK's 'high standards'. Any action within the EU to drive towards similar higher standards should therefore be seen as a benefit to the UK as well as to the EU as a whole. The UK has been a driving force in applying the 3Rs (replacement, reduction and refinement) to the testing of the classes of product listed, and for removing redundant requirements for animal tests from test batteries. However, since the majority of test regulations are set within Europe, the UK will not usually be in a position to take unilateral decisions. Greater commitment to re-evaluating regulatory test requirements, action to remove obsolete tests, and greater flexibility to refine tests, reduce the number required and ensure alternative methods are implemented without delay is essential. As action at the global level (OECD and OIE) is slow, action at the EU level can act as a valuable incentive in this area. The EU needs to act quickly to reduce the bureaucracy associated with the risk assessment process, and to overcome excessively risk-adverse inertia and other (already well defined) obstacles to regulatory change. Even on a single issue, the phasing out of the testing of cosmetics on animals, it took 20 years to implement the original intent of Directive 93/35 (adopted in 1993) when Directive 2003/15 was finally implemented on 11 March 2013. This shows the benefit of the EU harmonising legislation for products that are traded globally. In 1997 the incoming Government announced it would no longer license the testing of cosmetics on animals and, although this was a critically important statement of principle that was welcomed by the RSPCA, it only applied to the UK so its effect in practice was at best minimal. This was because companies could export their testing to any other EU member state. Only when the 2003 EU testing ban was implemented, followed by the 2013 final ban on marketing any cosmetics tested on animals, could the intent of the 1997 UK ban finally come into effect.

1. 6. What could the EU most helpfully do to promote scientific and technological progress and innovation (including in the space sector)? - How could the EU use its existing competence differently to deliver more in your area? - How might a greater or lesser degree of EU competence

deliver more in your area? - How could improvements to existing EU activities make them more effective and efficient?

The UK would benefit from more EU action in four areas: 1. In some areas the UK can be seen as the 'driver' in improving standards, resulting in higher standards in the UK than in some other member states. The care and use of animals in laboratories is a prime example of this. With respect to animals used in research, given the importance that the UK places on animal welfare, and the link between good welfare and good science, better practice in the UK should be seen as a benefit. Indeed, the UK government, industry and academia regularly talk proudly about the UK's 'high standards'. Any action within the EU to drive towards similar higher standards should therefore be seen as a benefit to the UK as well as to the EU as a whole. 2. Introducing harmonised legislation in areas where there is none 3. Getting the Commission to improve quality of and achieve centralisation of relevant information, and achieving stronger implementation and enforcement of the Directive. These are central threads that must run through attempts to improve animal welfare, as highlighted by the Commission in its 2012-5 strategy. Implementation has been discussed above. On enforcement, whilst the role of governments is obviously crucial, oversight and measurement of enforcement across the EU can only be done by the Commission. Enforcement is crucial to the operation of the internal market, and to improving welfare standards, and there is even a competitive advantage for farmers in Member States which do not ensure compliance with the legal standards, as their production costs can be generally lower. This can lead to trade distortion at intra-community level. It is difficult at present to measure enforcement as any assessment of enforcement is mainly from reports from the small number of Commission missions and self reporting from countries. Information on assessing enforcement in the EU-27 is not centrally compiled despite the fact that this would seem to be crucial in assessing future direction, especially with laws such as those on the care and use of animals in laboratories that operate 'cross border'. 4. There is a need for greater harmonisation within the Commission on animal welfare. For example, DG Sanco has responsibility for ensuring improvements in welfare standards; DG Development for providing technology transfer to developing countries to raise their welfare standards; and DG Agriculture for ensuring that any bilateral or WTO negotiations take animal welfare into account. However, there is little overarching harmonising strategy or even communication between DGs. This has negative consequences for the Commission strategy. The EU provides the right balance between business and protecting animal and human health. There has been a lot of misinformation on the effect of EU legislation on animal welfare and business - claims that any impending legislation will render business uncompetitive in (e.g. as made by the pharmaceutical industry in 2009 in discussions on the new legislation on laboratory animals) are frequently not realised, whereas other industries where there is no harmonising legislation (such as the dairy industry) have seen huge declines in producer numbers. The EUPAW report (www.eupaw.eu), undertaken in 2010 for the European Commission as part of its discussions on how effective European legislation has been on improving animal welfare, centralises (for the first time) in one place clear economic information on the effects of the EU animal welfare programme on the competitiveness and sustainability of the sectors analysed (pages 46-50 and pages 97 -104). Much of the information on effects is gathered from interviews with stakeholders and scientific research. The report clearly states that there is no observable correlation between the level of welfare standards and the numbers of animals. Nor do the cited data show that raising standards has any effect on the competitiveness of the industry, as they clearly show that there are business benefits to be gained from improving standards relating to animal care and use. The EUPAW report concludes that animal welfare policies "have not impacted negatively on the sustainability of activities at the EU level" (p. 97). This is a critically important conclusion when assessing how the EU takes further legislation forward and counters industry claims that raising welfare standards always brings disadvantages. The report correctly states that most analyses of the economic effects of improving welfare standards focuses on the costs with very little (if any) emphasis on the economic benefits that can result, and urges that this omission needs to be rectified in future analysis. The RSPCA does agree that more, well constructed and clear EU and national guidance on how legislation should be interpreted in practice would be helpful. The cascading of robust, validated welfare outcome measures into different sectors will help to enable effective assessment of the impact of legislation on animals. For example, the EU expert working groups set up to provide guidance documents on issues such as severity of suffering, statistical reporting, and education and training in relation to Directive 2010/63 are a useful model. Although it is important that such groups include a range of stakeholder perspectives, truly 'expert' input is essential. Guidelines need to be developed by people who have appropriate expertise in the issues to be addressed. Guidelines also have the advantage over legislation of being easier to update and they therefore can take proper account of current understanding of animal welfare including the scientific literature. However, if they are to be of value, there needs to be an 'expectation' that guidelines will be implemented.

2. 7. Where might future EU level action be detrimental to your work in this area?

No Response

3. 8. Where might action at national rather than EU level be more appropriate / effective?

No Response

4. 9. How could EU and national policies and funding streams interact better?

No Response

5. 10. What impact would any future enlargement of the EU have on this area of competence?

Future enlargement will have an impact in two areas: 1. it will make the adoption of harmonised legislation more difficult in the future. The increase in the EU over the past two major enlargement cycles (2005 and 2007) has slowed down decision making and made it harder to adopt more stretching legislation. The impasse in the cloning legislation in 2011 highlights the difficulty of agreeing new legislation. 2. it will be beneficial in improving legislation and standards in the incoming country - so the 13 new member states went from having no legislation managing the use of animals in laboratories to implementing the new Directive within a period of some 12 years. This does bring challenges in implementation and enforcement but overall it raises welfare standards. Any future enlargement to countries such as Turkey, Serbia or even Ukraine would bring massive advantages to animal welfare once the aquis is applied and enforced.

6. 11. Are there any other points you wish to make which are not captured above?

The future challenges with respect to animal welfare will be: 1. Increasing globalisation in animal research and testing. Bilateral agreements will be the main way of ensuring EU producers are not undercut by imports produced at lower standards. 2. Advances in science might raise new and additional ethical concerns relating to what should be permissible. For example, the genetic engineering of primates, and the acceleration and commercialisation of animal cloning, is taking place in some countries around the world. The UK should have the right to determine how it will regulate such uses of animals and retain its ability to veto applications of emerging technologies to animals on ethical and welfare grounds, regardless of whether another member state may decide to allow them. Similarly, as knowledge of animals' cognitive abilities and even their emotional needs improves, pressure will increase to improve their housing, husbandry and care – and to reconsider how harms and benefits are identified and considered. 3. More, well constructed and clear EU and national guidance on how legislation should be interpreted in practice would be helpful. 4. Agreement on new global standards on animal and more effective ways of informing the consumer through labelling or procurement

initiatives would facilitate support for higher welfare standards through the marketplace, complementing legislative rules and ensuring the competitiveness of European research in the global marketplace.