



## Proposed EU changes in animal experimentation regulations

by Angela K. Turner

Current regulations for the protection of animals used in scientific experiments across the European Union are now over 20 years old. Since the 1986 directive (86/609/EEC) the number of member countries of the EU has more than doubled, with several others potentially joining in the near future, creating a wide range of animal welfare standards across Europe, some of which are higher than those provided by the EU directive itself. In addition, the 1997 Treaty of Amsterdam included a protocol requiring the EU to consider animal welfare in its policies. To raise standards overall, the European Commission has therefore proposed a revision of the directive [1]. This will also take into account changes since 1986 in scientific procedures, such as the development of genetically modified animals, and recent research on animal welfare, such as the possibility that some invertebrates feel pain. Most importantly, the revision will adopt the Three Rs framework (refinement of experiments to reduce suffering, reduction of numbers of animals used in experiments and replacement of animals with other material such as tissue cultures or virtual organisms). These principles have already been widely adopted in the UK and elsewhere but are not mentioned in the existing directive.

The revised directive would improve on the previous one in several respects. As well as promoting the Three Rs, it requires member countries to have a regulatory framework for licensing individuals, institutions and experiments involving animals, and for making sure institutions comply with the directive; institutions also need to have their own ethical review body. Secondly, the 'animals' covered by the directive, currently 'vertebrates', would include some invertebrates and possibly also fetuses, immature and larval stages, as well as animals bred for tissues and organs. Thirdly, the directive would restrict the use of animals, in particular non-human primates, taken from the wild. Fourthly, experimental procedures would have to be classified according to the degree of harm to the animal. Finally, the directive would lay down certain minimum standards of housing and care.

Some of these changes are mostly uncontroversial and indeed are already implemented by some EU countries. The UK for example has long had both a national framework and local committees to authorise and review scientific

**Over 12 million animals are used in scientific experiments in the EU each year**

research involving animals, although the revised directive may increase bureaucracy in this regard. The adoption of the Three Rs framework is also an important step in reducing the numbers of animals (currently more than 12 million a year) involved in scientific experiments in the EU. Other parts of the new directive, notably those concerning non-human primates and invertebrates, however, have led to major objections [2]. There are concerns that valuable fundamental research will be restricted, leading to the possibility of such research being driven away to countries outside the EU, that the development of new medicines and treatments may be hampered, and that there will be more red tape for researchers to deal with without a corresponding increase in animal welfare. To address such concerns, over 50 organisations in 19 EU member states formed the European Coalition for Biomedical Research in 2006 [3]. In the UK, in March 2009, nine bioscience organisations also produced a 'declaration of concern' [4].

A particularly controversial plan is to protect certain invertebrates. The UK already includes the common octopus in its welfare regulations but the revised EU directive would extend this to lampreys, cephalopods (squid as well as octopus) and decapod crustaceans such as crabs and prawns, and larval and embryonic forms of these and vertebrate animals. Recent research on prawns and hermit crabs suggests that they can feel pain and that crabs remember details of the painful experience [5, 6]. But it is not known

**Some research on primates may be banned**

whether other crustaceans experience pain in a similar way. In some respects, the larger crustaceans such as crabs have similar nervous systems to those of vertebrates, but critics point to the differences, in size and complexity, rather than the similarities [7]: despite the evidence, they say crustaceans may just automatically react to a painful stimulus but not feel it and be aware of it. Including these animals in the directive would hamper their use as models of humans, for example in studies of the vestibular system.

Protecting larval and embryonic forms, which are not proven to feel pain, would also create administrative problems, as it can be impractical to record, for example, the huge numbers of eggs produced by fish and frogs which are widely used in toxicological studies [8, 9, 10]. In addition this proposal may affect the development of vaccines which involves the use of chickens' eggs [10].

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➤ The revised directive indicates specific circumstances when non-human primates can be used in experiments, restricting their use in certain areas. There is thus a concern that the directive will curtail basic research on, for example, brain function and reproduction, which could eventually lead to treatments for human conditions such as autism, depression, memory and visual disorders, and early miscarriage [2, 3, 4, 8, 10]. Currently in the UK the use of non-human primates is already tightly controlled but is allowed when this can be justified on scientific grounds and there is no alternative animal model. With a few exceptions such as conservation of the species or for study of life-threatening human clinical conditions, laboratory research on great apes would be banned, as it has been in the UK since 1998. The directive provides most protection to primates but its failure to extend this to other similarly sentient species, such as pigs, is also a concern.

Plans to phase out the practice of taking animals from the wild for scientific experiments, except in certain scientifically justified circumstances, are also problematic. The aim is to use only captive bred animals and in particular primates bred from parents who were also born in captivity (i.e. the second or later generations) on the assumption that they will suffer less from being in captivity, although whether this is true is not known. However, there are currently insufficient second generation primates being bred, especially within the EU [2, 3, 4, 8, 10]. Many captive bred primates are sourced from outside the EU and the suppliers are unlikely to be able to provide second generation animals or may raise their prices if they have to change their breeding regimes to do so. At best, the costs of research in EU member states would increase; at worst, the scarcity of these primates may mean that some research is not done at all or is moved to other countries, which may have lower welfare standards. There is also no clear provision for studies of animals that cannot yet be bred in the laboratory such as marine fish and crustaceans. Banning the use of stray or feral animals also prevents research on, for example, the spread of diseases in such populations.

The revised directive requires scientific procedures to be classified according to their severity, taking into account factors such as the duration and intensity of pain or suffering and the restriction of behaviour. The four categories proposed are 'up to mild', 'moderate', 'severe' and 'non-recovery' (i.e. the animal is killed after surgery done under anaesthetic). This classification is broadly similar to that already in place in the UK although the categories are not clearly defined. However, some severe procedures where the animal suffers over a prolonged period may be prohibited and this may affect the use of non-human primates as models of, for example, Parkinson's disease and other neurological conditions in humans [8].

**Protection may be  
extended to crustaceans  
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thought to feel pain**

Some provisions of the directive might actually increase the number of animals used and increase suffering overall. Re-using animals would be limited to mild or 'non-recovery' procedures; in the UK this would be costly and result in more dogs and non-human primates being used in surgical procedures [8]. It is also sometimes impractical as one procedure may involve surgery, for example to implant a device to monitor heart rate, before the animal undergoes other procedures.

The strict standards proposed for housing and care of animals used in scientific research may also increase both costs and numbers of animals used without improving welfare and scientists would like more latitude to adapt housing to particular situations [8, 10]. Indeed, the proposed directive is inflexible in some respects in not allowing for changes resulting from advances in our understanding of what comprises good welfare for animals.

There are also important omissions in the revised directive such as the lack of guidance for marking animals. Mutilations such as cutting off toe digits, for example, would still be allowed, even though such procedures are thought to be painful. Some scientists think they should be banned outright.

Revising the directive is inevitably taking a long time and is far from complete. Work on the revision started in 2002 and included a public consultation in 2006. The European Parliament adopted the First Reading of the proposal in May this year and at the time of writing the document was with the European Council. Within the UK, a consultation process finished in July; the Lords EU Committee have held their own inquiry into the revision of the directive and were expected to produce their report in November this year [8, 9]. A number of amendments to the revision have already been proposed and there will undoubtedly be further changes by the time the final version of the directive is confirmed after a second reading in the European Parliament and by the European Council. These changes should go some way to meeting the main concerns I've discussed here. Whatever the final form of the directive, though, there will inevitably be repercussions for scientific research, as well as animal welfare, throughout the EU.

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