## Is EU legislation on animals used for scientific purposes sufficiently geared towards research using farm animal species?

## **Marcelle Holloway**

## **European Commission, DG Environment**

Around 12 million animals are used on a yearly basis in scientific procedures in the EU today. The majority of these are used in the field of pharmaceuticals in applied research as well as during product development, production and testing. Current scientific knowledge does not yet allow us to replace the use of animals for scientific purposes, which is our ultimate goal. Therefore, the EU has recently strengthened the legislation in this field. A new Directive on the protection of animals used for scientific purposes, replacing Directive 86/609/EEC, came into force in November 2010. Member States of the EU have until November 2012 to transpose the requirements of the Directive into their respective national legislation and it will take full effect on 1 January 2013.

The main innovations of the revised Directive include a requirement for a systematic project (ethical) evaluation and a project authorisation. The scope of the Directive now includes specific invertebrate species and foetuses of mammalian species in their last trimester of development, as well as animals used for the purposes of basic research and education and training. It sets minimum standards for the housing and care of the animals and puts far greater emphasis on improved transparency and enforcement through regular, risk-based inspections.

The principle of the Three Rs - the replacement, reduction and refinement of the use of animals in experiments - is the corner stone of the new Directive. The Three Rs are embedded throughout the text and must be taken fully into account during all aspects of animal use and care. The requirement to use a non-animal method instead of one using animals, when such a method is recognised by EU legislation, is explicit in the text.

Finally, more resources are foreseen for the development, validation and application of alternative methods.

To ensure that the aims set for the new Directive are achieved, there needs to be a clear understanding of the legal requirements by all those affected by it. A number of topics were identified following the adoption of the Directive which would benefit from further discussion among experts to facilitate uniform transposition and application. These topics include the development of a statistical reporting format for the use of animals; how the creation, breeding and use of genetically altered animals are to be considered; the development of a framework for mutually recognisable education and training system as well as the development of a severity assessment framework. Significant progress has been made and a number of results are already available for the benefit of a wider audience.

The fruits of the revised Directive can only be harvested following close co-operation between all those affected by the legislation together with a committed approach to its complete and correct application. The EU can claim to have the highest standards of experimental animal welfare in the world, whilst promoting high quality, competitive science and research in Europe.