

the more notable changes here. As one would expect, the New Directive pays due regard to Russell and Burch's Three Rs principles. They are mentioned both in the memorandum, as the basis for the new measures, and in the first Article of the Directive. The scope of species and developmental stages covered by the proposed Directive has been broadened. The previous Directive covered any live non-human vertebrate, including free-living larval and/or reproducing larval forms, but excluding foetal or embryonic forms. The new proposals extend this coverage to vertebrates including independently-feeding larval forms and embryonic or foetal forms from the last third of their normal development, as well as independently feeding cyclostomes, cephalopods and decapods.

Non-human primates receive some special attention. In the proposal, the use of non-human primates is permitted only for research on medical conditions with a substantial impact on humans (life-threatening or debilitating clinical conditions) or for research aimed at the preservation of the primate species. Research using great apes is allowed for such research where there is no alternative, but it requires a Commission decision. The proposed Directive also requires a move towards the use of F2 non-human primates; that is, animals that come from parents who were themselves born in captivity. In the case of macaques this must come into effect within seven years after transposition of the Directive.

The new Directive requires that member states should each designate a reference laboratory for the validation of alternative methods replacing, reducing and refining the use of animals within a year of the Directive entering into force. The Directive also requires that establishments should each have their own independent ethical review body and that each member state should set up a national animal welfare and ethics committee. Scientists may be concerned that project authorisation is for only 4 years. Currently many projects run for 5 years and the reduction will lead to an increased burden on both scientists and regulators with little apparent welfare benefit.

A number of issues remain to be clarified, not least the classification of severity of procedures. The proposal includes a category of 'up to mild' which would appear to have no lower limit. Moreover, the definitions of the three severity categories have yet to be decided. Article 15 states that the Commission should develop criteria, with stakeholder input, using existing severity classification schemes in place in Member States as well as those promoted by international organisations as the basis. Hence, the Directive could come into force with definitions of severity still undecided, and it is not clear how member states could implement such legislation. Even more disturbing is that Article 2 states that the Directive does not cover practices that are not invasive. If this Article is not corrected, procedures leading to mental states of suffering, as a result of hunger, thirst, noise, or fear would be unregulated. However, it does seem that this was not the intention of the drafters as the definition of procedures in Article 3 uses the terms: pain, suffering, distress, or lasting harm, which would include such procedures. It seems likely that confusions such as these will be tidied up

during the next stages of the Directive's progress through the EU legislative process.

However, there are more serious concerns with the draft. The first of these relates to the tables and standards concerning care and accommodation. These tables are based on the recommendations adopted by the Commission in June 2007, which were in turn based on the revised Appendix A to the Council of Europe Convention ETS123. Unfortunately, the proposed Directive's care and accommodation tables and standards omit reference to most of the species-specific text, which was in both prior documents. This omission could result in a much-reduced quality of care. For example, the proposed tables seem to permit dogs to be housed, under procedure, singly in half the space normally required to house a pair. However, the text of the revised Appendix A to the Convention and of the June 2007 Commission recommendations make it very clear that pair housing is expected to be the norm and that separation should not be for more than four hours per day. Further concerns include Article 2, which appears to exclude clinical veterinary trials and possibly rodenticide trials. Such research should be regulated. Article 14.5 suggests that post-operative analgesia is only required where animals may experience considerable pain. Clearly, there are many situations when analgesia can and should be given before animals experience considerable suffering. Article 16 only permits reuse where the procedures are up to mild. Dependant on the definition of 'up to mild', this article could result in an unnecessary increase in the numbers of animals used, for example in the case of long-term surgical models.

It is clear that there is much work to be done and there will be many interested groups lobbying for various changes so the final form of the new Directive is still unclear. However, as long as the flaws can be satisfactorily resolved, and as long as the member nations equally implement the revised Directive, then it could result in higher welfare standards across the European Union. Providing that does not result in the export of research to non EU countries, then animals used in research should be better off.

**Proposal for a Directive of the European Parliament and of the Council on the Protection of Animals used for Scientific Purposes** November 2008. Commission of the European Communities. A4. 90 pages. Available at: [http://ec.europa.eu/environment/chemicals/lab\\_animals/home\\_en.htm](http://ec.europa.eu/environment/chemicals/lab_animals/home_en.htm)

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### **Animal welfare in the UK 2007: RSPCA measures annual change**

For the third year running, the UK's Royal Society for the Protection of Cruelty to Animals (RSPCA) has published its review of the status of animal welfare in the UK. The aim of this Report is to track year-on-year change in areas that the Charity believes are of high animal welfare importance. Thirty-three areas are covered in one of five categories: generic, farm animal, pet animal, research animals and wildlife. Issues included range between those with an obvious impact on animal welfare, such as piglet mortality

levels between birth and weaning, and indicators which have a less direct association, for example the number of relevant government advisory, non-departmental public bodies on which an animal welfare specialist is represented.

The report uses a traffic light system to give an 'at a glance' impression of the RSPCA's assessment as to whether welfare issues have improved (green), remained relatively unchanged (amber), worsened (red), or to indicate that there are insufficient data on which to make a judgement (grey). The traffic light does not reflect the absolute level of animal welfare but the direction of change. This year, five areas affecting animal welfare are reported to have improved since the 2006 figures, including a substantial reduction in the number of wild-caught CITES-listed birds imported into the EU. Many areas show little change from last year and four are reported to be worse, two areas of concern being a large increase in the number of reports and convictions for animal fighting in the UK and an increase in the number of reptiles being imported into the UK.

The RSPCA hope that *The Welfare State: Measuring Animal Welfare* will provide a snapshot picture of animal welfare in the UK and allow comparison between years, thereby highlighting where more attention is required if animal welfare is to be improved, and also to illustrate where encouraging progress has already taken place. The report provides an interesting introduction to a varied set of issues affecting animal welfare today.

**RSPCA Report on the Welfare State: Measuring Animal welfare in the UK 2007** 2008. A4. 106 pp. Available from External affairs, RSPCA, Wilberforce Way, Southwater, Horsham, West Sussex RH13 9RS and at <http://www.animalwelfarefootprint.com/>

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### **European Commission launch website to track the development of alternative methods to animal testing**

A new website: Tracking System for Alternative test methods Review Validation and Approval (TSAR) has recently been set in motion by the European Commission. TSAR is managed by the Joint Research Centre's Institute for Health and Consumer Protection and has been designed to provide greater transparency of the review process for alternative test methods that replace, reduce and refine the use of animals in research (the 3Rs). It is anticipated that interested individuals will soon be able to track the progress of review from initial submission of a new method for pre-validation all the way through to approval and final adoption into EU legislation and/or related Guidance Documents.

The site is straightforward to navigate and offers clear, simple explanations of the development process, which has been broken down into two parts: i) Review and Validation, and ii) Regulatory Approval. To enable a rapid launch, some areas of the website are still under construction and currently only the area dealing with regulatory approval of methods in the field of chemicals is functional. Areas of animal testing where alternative test methods are being

developed, or are already available, include: skin irritation and corrosion, eye irritation, skin sensitivity, mutagenicity, acute system toxicity, reproductive toxicity and others. A drop-down menu allows users to display information on individual alternative methods which are colour coded according to where they are in the review process: test methods shown in green are those that are already incorporated within EU legislation or other regulatory use; orange indicates that the method is currently undergoing the process of being included in the EU regulatory context, and purple shows that no regulatory use has been identified.

TSAR will be of interest to both individuals working in the field, who will be able to consult the website to check for available alternative methods for use in their research, and also to individuals not active in research but interested in how the replacement, reduction and refinement of animals in laboratory testing is progressing. TSAR is a positive step forward in the advancement of laboratory animal welfare.

**TSAR: Tracking System for Alternative Test Methods Review, Validation and Approval in the Context of EU Regulations on Chemicals** November 2008. Managed by the Joint Research Centre's Institute for Health and Consumer Protection. Website available at: <http://ihcp.jrc.ec.europa.eu/tsar>

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### **UK Farm Animal Welfare Council Report on policy instruments for protecting and improving farm animal welfare (in the UK)**

The objectives of this FAWC Opinion is to advise the Government about the range of policy instruments available to it for protecting and improving farmed animal welfare and to identify where the application of these instruments should be considered further.

The Report identifies 14 categories of 'policy instrument', including primary and secondary legislation, inspections by relevant authorities, financial incentives, education and training, research, permit schemes and farm assurance schemes. The 14 types of instrument are outlined in the Report and examples provided of their current, past or potential use. During the development of this Opinion, FAWC undertook a consultation with a variety of stakeholders and key points arising from this are noted in the Report.

The first conclusion listed states that: "To achieve the levels of animal welfare that people want requires a co-ordinated approach to the use of policy instruments to achieve desired behavioural change..." In addition to the need for animal welfare legislation and enforcement, other instruments are important: "...serious consideration needs to be given to the provision of appropriate information to consumers to allow them to make informed choices... based on animal welfare provenance"; "There is a need for a nationally- or internationally-agreed system for welfare assessment..."; "The provision of balanced animal welfare educational teaching materials for schools should be facilitated and incorporated to best effect within the school and college curriculum".