



INTRODUCTION RESEARCH ANIMAL INDICATORS

Estimates of the number of animals used across the world each year in research and testing usually range between 50 and 100 million. More than 12 million are used across the European Union (EU)¹. Official statistics for 2008 show² that this includes more than 3.5 million animals used in the UK, which represents a seventh consecutive annual rise and the highest number of animals used since the mid 1980s.

If progress is to be achieved in reducing animal use, reducing suffering and replacing animal experiments with humane alternatives, action is needed not only at national, but also at international level. Given the increasingly global nature of science and industry, the use of animals in one country, such as the UK, can be profoundly influenced by the legal requirements, guidelines and scientific developments in other countries. For example, a pharmaceutical company based in the UK will have to carry out animal tests according to the legal requirements of all the countries in which it wishes to market a new medicine. As a member of the EU, the UK must take particular account of European laws and standards, and work to improve them.

The international dimension offers both challenges and opportunities. Legislation regulating the use of animals in experiments can vary widely between different countries. Reaching agreement on harmonised controls, and on legal requirements for the use of animals in safety testing for example is difficult, even within the EU. On the other hand, organisations such as the World Congresses on Alternatives and Animal Use in the Life Sciences, the International Conference on Harmonisation (ICH), the Organisation for Economic Co-operation and Development and the Office International des Epizooties (OIE, also known as the World Organisation for Animal Health) provide platforms for introducing improvements for animal welfare worldwide.

The importance of the international dimension is reflected in the following list of important events of 2008 relating to the use of animals in experiments.

■ The revision of European Directive 86/609 that regulates laboratory animal care and use across the EU continued^{3,4}. Draft proposals published in November 2008 are currently under discussion between the Council of Ministers and European Parliament (EP), and national bodies are consulting with stakeholders.

- To inform decisions on the future of primate use, the European Commission's Scientific Committee on Health and Environmental Risks (SCHER) was asked to produce an opinion on the need for primate experiments, and the possibilities for their replacement. A call for evidence was made in May 2008, and a limited consultation held in November 2008.
- Meanwhile, in the UK, the government has been undertaking a general review of how European legislation is transposed in the UK, with a view to reducing unnecessary administrative burden⁵. In relation to the regulation of animal experiments, the Home Office has established a steering group of the major stakeholders which has been considering possible changes to current practices. The RSPCA is represented, and argues that any changes made must not have a detrimental effect on animal welfare, weaken the legislation or reduce public accountability.
- Following a US Food and Drug Administration (FDA) pronouncement⁶ that meat and milk products from cloned cattle, pigs, goats and their offspring were safe for human consumption, it was expected that commercial use of cloned animals and their offspring as food products could be globally widespread by 2010. In January 2008, the European Group on Ethics⁷ stated that given the current level of animal suffering and health issues involved, it is doubtful whether the cloning of animals for food is ethically justified. In September 2008, the EP voted overwhelmingly in support of a motion urging the European Commission to prohibit the cloning of animals for food.

FOOTNOTES AND REFERENCES

- 1 European Commission (2007). Fifth report on the statistics on the number of animals used for experimental and other scientific purposes in the member states of the European Union (data for 2005). Brussels.
- 2 Home Office (2009). Statistics of Scientific Procedures on Living Animals: Great Britain 2008. London: HMSO.
- 3 See: http://ec.europa.eu/environment/chemicals/lab_animals/home_en.htm
- 4 Since 2002, scientific staff from the RSPCA's research animals department have provided expert input into the revision process at various stages and on a range of issues, often on behalf of Eurogroup for Animals. The RSPCA is lobbying for many changes to the Directive. These include: extension of the Directive to cover all research that may cause animals to suffer and a clearly defined and effective system of licensing, control and inspection for all member states. This must incorporate an ethical evaluation of animal use including a harm/benefit assessment that takes into account the lifetime experience of the animals. A system of local and national ethical review processes must also be an integral part of a licensing process as must the requirement for greater focus on the 3Rs of reduction, refinement and replacement.
- 5 <http://scienceandresearch.homeoffice.gov.uk/animal-research/legislation/better-regulation>
- 6 US Food and Drug Administration (2008) 'Animal cloning: A Risk Assessment'. www.fda.gov/cvm/Documents/CloningRiskAssessment_FINAL.pdf
- 7 European Group on Ethics (2008) 'Ethical Aspects of Animal Cloning for Food Supply. Opinion No.23'. http://ec.europa.eu/european_group_ethics/activities/docs/opinion23_en.pdf

WELFARE INDICATOR: The number of non-human primates used in scientific procedures in the UK

RSPCA concern

The use of non-human primates (from here referred to as 'primates') in research and testing is a matter of particular concern to the RSPCA and the wider public. This has been recognised at a governmental¹ and regulatory level, with some countries making special provisions for primates in legislation – for example, either implementing specific bans² or emphasising the need to replace and reduce experiments on these animals³.

The RSPCA believes that the special nature of primates means that ending their use is an essential goal which governments, regulators, industry, scientists and research funders worldwide should accept and make a high priority. The Society would like to see the indicator figures showing significant reductions over successive years.

Background

In the UK about 3,000 primates (mostly marmosets and macaques) are used in research and testing annually⁴. Across the European Union (EU) this figure is around 10,000⁵ and worldwide it is estimated that more than 100,000 are used each year⁶. Much primate use is for developing or testing the safety and effectiveness of medicines and vaccines, but primates are also used in more fundamental biological research, for example in studies into brain function and behaviour.

There is no question that primates experience pain and distress and many aspects of the lifetime experience of laboratory primates can cause stress and suffering. Primates in laboratories cannot control their environment, social grouping or what is done to them⁷. Any pain or distress associated with experimental procedures is compounded by additional adverse effects resulting from the capture of wild primates, breeding practices, transport, housing, husbandry, identification, restraint, and finally, euthanasia.

In September 2007, Members of the European Parliament (MEPs) categorically backed a declaration⁸ that called for an end to the use of great apes and wild-caught primates in research in Europe, and a clear strategy for replacing all primate experiments with humane alternatives. This was an important statement, given that the European Directive regulating the use of animals in experiments across the EU is currently under revision⁹. It also reflected the principles set out in a resolution¹⁰ initiated in 2005 by the RSPCA and backed by animal protection organisations worldwide.

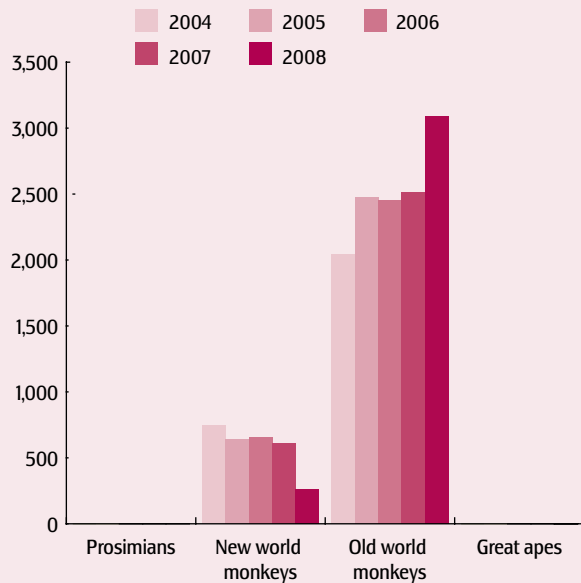
In its official response to the parliament's declaration, made in January 2008, the European Commission (EC) stated that a phase-out of primate use is not practical.

Proposals for revision of the Directive on animal experiments were published in November 2008. They contained no measures likely to lead to a phase-out of primate use. They did, however, propose a ban on the use of wild-caught primates and restrictions on the use of primates in research to experiments relating to life-threatening and debilitating human diseases. A ban on the use of great apes was weakened by a clause allowing their possible use in health emergencies. Even if accepted into the final Directive, these measures are unlikely to reduce primate use significantly.



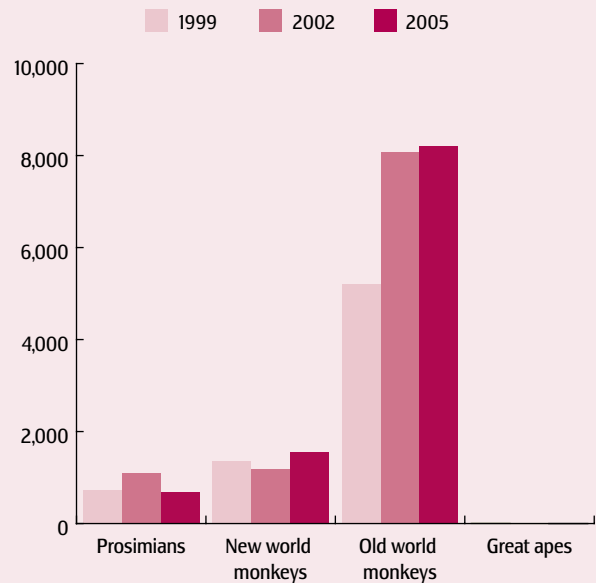
THERE IS LITTLE CHANGE FROM THE PREVIOUS YEAR.

Figure 1: The number of primates used in scientific procedures in the UK, 2004–2008



Data source: Home Office.

Figure 2: The number of primates used in scientific procedures in the EU, 1999, 2002 and 2005



Data source: European Commission.

Note: (i) the above figures represent the number of individual animals used in licensed procedures for the first time during the course of the year in question (e.g. an animal used for the first time in 2007 and then reused in 2008, will only appear in the total for 2007).

(ii) the EU figures for 1999 and 2002 relate to 15 member countries, whilst the figure for 2005 also includes the data for the 10 new accession states, thus now covering data for 25 EU members for the first time. However, with regard to the impact on trends of primate use of adding data for these 10 new EU member states, it should be noted that they were responsible for the use of just 57 of the total 10,443 primates used in 2005.

The indicator figures

The number of primates used in the UK and Europe are reported in Home Office and EU official publications respectively. The UK figures are published annually, but in the EU they are only made available every three years. Accurate figures for most other countries are not available. Data for Figure 1 have been taken from Table 1a of the Home Office annual statistics publications, 1999–2008 (published 2000–2009). Data for Figure 2 have been taken from Table 1.1 of the third¹¹, fourth¹² and fifth¹³ reports on the statistics on the number of animals used for experimental and other scientific purposes in the member states of the EU (published by the EC in 2003, 2005 and 2007 respectively). The four categories of primates are explained as follows.

- Prosimians – the most primitive group of primates, they may or may not have a tail e.g. lemurs, lorises, pottos and bushbabies/galagos.

- New world monkeys – primates native to Central or South America e.g. marmosets, tamarins, squirrel monkeys, and capuchins.
- Old world monkeys – primates native to Africa or Asia e.g. macaques and baboons.
- Great apes – all of these primates lack a tail e.g. chimpanzees and gorillas.

The need for annual statistics to be published for the EU is illustrated by the data on great apes. The official EU figures for 2002 and 2005 show no apes were used in scientific procedures in these years. This could lead people to infer that none were used in the intervening time yet six chimpanzees were used in the Netherlands during 2004¹⁴. This, and other important information, may go unreported where figures are only produced every three years.

THERE HAS TO BE A RADICAL SHIFT IN THINKING AWAY FROM “HOW CAN WE ENSURE WE CAN CONTINUE TO USE THEM” TO A MORE ENLIGHTENED AND HUMANE APPROACH OF “WHAT DO WE NEED TO DO TO AVOID THEIR USE”.

The available data, both for the UK and EU, show that there is no significant downward trend in primate use and there have been suggestions that primate use may actually increase in the coming years¹⁵.

The RSPCA believes there should be an immediate, internationally coordinated effort, involving governments, regulators, industry, scientists and research funders to define a strategy to bring all non-human primate experiments to an end. This needs to incorporate an effective European-wide mechanism for challenging and assessing the justification for primate use, including full assessment and recognition of all of the harms to the primates involved, i.e. from acquisition and transport, confinement in the laboratory, and from scientific procedures and their effects.

Since primate use is of such serious concern, there has to be a radical shift in thinking away from “how can we ensure we can continue to use them” to a more enlightened and humane approach of “what do we need to do to avoid their use”.

FOOTNOTES AND REFERENCES

- 1 For example:
http://ec.europa.eu/environment/chemicals/lab_animals/pdf/petitions_dir86_609.pdf
- 2 The use of great apes in scientific procedures with the potential to cause pain, suffering, distress or lasting harm is not allowed in New Zealand, the Netherlands, Sweden, the UK or Austria. Northern Ireland goes further and does not licence the use of any primate in invasive experiments.
- 3 For example, the UK Animals (Scientific Procedures) Act 1986; and Council Decision (1989) on the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes [Official Journal of the European Communities].
- 4 Home Office (2009) Statistics of Scientific Procedures on Living Animals: Great Britain 2008. London: The Stationery Office.
- 5 European Commission (2007). Fifth report on the statistics on the number of animals used for experimental and other scientific purposes in the member states of the European Union (data for 2005). Brussels.
- 6 Hau and Schapiro (2006) ‘Non-human primates in biomedical research’ *Scandinavian Journal of Laboratory Animal Science* 33, 9–12.
- 7 See: The welfare of non-human primates used in research (2002) – Report of the Scientific Committee on Animal Health and Welfare, European Commission, Health and Consumer Protection Directorate-General. Available at: http://ec.europa.eu/food/fs/sc/scah/out83_en.pdf
- 8 See: http://ec.europa.eu/environment/chemicals/lab_animals/pdf/declaration_nhp_en.pdf
- 9 See: http://ec.europa.eu/environment/chemicals/lab_animals/revision_en.htm
- 10 ‘Call to end the use of non-human primates in biomedical research and testing from animal protection organisations worldwide’ Berlin, August 2005.
- 11 European Commission (2003). Third report on the statistics on the number of animals used for experimental and other scientific purposes in the member states of the European Union (data for 1999). Brussels.
- 12 European Commission (2005). Fourth report on the statistics on the number of animals used for experimental and other scientific purposes in the member states of the European Union (data for 2002). Brussels.
- 13 European Commission (2007). Fifth report on the statistics on the number of animals used for experimental and other scientific purposes in the member states of the European Union (data for 2005). Brussels.
- 14 See page 189 (‘Comment of the Dutch authorities’): European Commission (2007). Fifth report on the statistics on the number of animals used for experimental and other scientific purposes in the member states of the European Union (data for 2005). Brussels.
- 15 For example, see Ragan C I & Chapman K L (2007) ‘Testing of biologicals: reducing primate use’ *Toxicology* 231, p91–99.

WELFARE INDICATOR: The amount of laboratory animal suffering**RSPCA concern**

The RSPCA believes that the reduction of suffering of animals used in experiments is an essential goal. The most urgent need is to end 'substantial' suffering for these animals, although the ultimate aim is to avoid discomfort, pain, or distress altogether.

Reducing suffering is central to the widely accepted principle of the 3Rs (replacement, reduction and refinement) and some progress has already been made. However, it is not currently possible to assess how much has been achieved because there is no available data on the level and nature of pain or distress experienced by each animal.

Better reporting of animal suffering would encourage more effective recognition, alleviation and prevention of pain and distress, so that progress with reducing suffering could be monitored. In addition, it would lead to greater openness and transparency regarding animal use and help to focus attention on issues of particular concern. Suffering may be caused to laboratory animals as a result of how they are sourced, transported, housed and used in experiments. However, this indicator relates only to suffering experienced during, or as a result of, experimental procedures as this is the only information currently formally recorded for publication in the Home Office (HO) annual statistics.

Background

The HO for England, Scotland and Wales¹, and the Department of Health, Social Services and Public Safety for Northern Ireland² publish annual statistics on animal use in research and testing in the UK. These provide basic information on the species and numbers of animals used, but suffering is currently only reported in terms of 'average' predictions of the amount of suffering within each project. These average assessments usually cover a range of scientific procedures, with different levels of severity, involving different numbers of animals. Furthermore, they are assigned before the research is conducted, so they are only predictions and do not convey the level, nature or duration of suffering that the animals actually experienced³.

In recognition of these issues, the Laboratory Animal Science Association (LASA) and the Animal Procedures Committee⁴ (APC) formed a working group to explore new ways of collecting and reporting data on severity. This included extensive consultation and pilot studies within industry and academia.

The final report of the LASA/APC working group was published in October 2008⁵. It recommended reporting the maximum severity actually experienced by each animal using the categories 'mild', 'moderate' and 'substantial'. This would enable data on severity to be correlated with other information in the HO statistics such as species and purpose. Linking the severity data to the project licence abstracts currently published on the HO website⁶, by 'tagging' the abstracts with severity category labels, would also increase the quality of the information available to the public.

The HO and the APC's own suffering and severity working group have agreed to work together to address some practical issues arising from the report and the APC group is expected to report in the first half of 2009⁷.

At the time of writing, the proposal for the revision of Directive 86/609 (see introduction) includes a requirement for statistics on the actual severity of procedures to be collected and published annually⁸. The work carried out by the LASA/APC working group has been submitted to the European Commission and the concept of retrospective reporting of severity has been supported in principle by the Federation of European Laboratory Animal Science Associations (FELASA)⁹.



INSUFFICIENT DATA ARE AVAILABLE.

The indicator figures

The RSPCA wants to see a reporting system that will accurately convey the level of suffering experienced by individual animals. The Society therefore supports the concept of retrospective reporting and the recommendations of the LASA/APC working group.

Annual publication of the number of animals who actually experienced mild, moderate or substantial suffering would represent a significant improvement over the current situation. However, this would still only provide a basic indicator of whether laboratory animal suffering is increasing, decreasing or staying the same. Supplementary information would be necessary and the Society supports the

recommendation that publicly-available project licence abstracts should be linked to retrospective severity data. This whole approach would require changes to the gathering and publishing of the statistics⁹, which the LASA/APC group has taken into account⁵.

The proposal for retrospective reporting of severity within the 2008 draft Directive (currently under discussion) is welcome, as EU statistics have been woefully inadequate to date. The RSPCA strongly supports the concept of retrospective reporting throughout the EU, as part of the Society's goal to achieve a much more comprehensive, transparent and meaningful system of reporting animal use¹⁰.

THE RSPCA WANTS TO SEE A REPORTING SYSTEM THAT WILL ACCURATELY CONVEY THE LEVEL OF SUFFERING EXPERIENCED BY INDIVIDUAL ANIMALS.

FOOTNOTES AND REFERENCES

- 1 Home Office (2009) Statistics of Scientific Procedures on Living Animals: Great Britain 2008. London: The Stationery Office.
- 2 Department of Health, Social Services and Public Safety (2009) Statistics of Scientific Procedures on Living Animals: Northern Ireland 2008. Belfast: The Stationery Office.
- 3 Smith J A and Jennings M on behalf of the Boyd Group and RSPCA (eds) (2004). Categorising the severity of scientific procedures on animals. Summary and reports from three round-table discussions. RSPCA Research Animals Department, Science Group: www.boyd-group.demon.co.uk/severity_report.pdf
- 4 APC: The independent body that advises the government on the implementation of the Animals (Scientific Procedures) Act 1986.
- 5 Smith J A (rapporteur) (2008). Final report of a LASA/APC working group to examine the feasibility of reporting data on the severity of scientific procedures on animals. LASA/APC: www.apc.gov.uk/reference/lasa_apc_final_report.pdf
- 6 For abstracts, see: www.scienceandresearch.homeoffice.gov.uk/animal-research/publications-and-reference/001-abstracts/
- 7 See: www.apc.gov.uk/reference/December-10-2007-minutes.pdf
- 8 See: www.ec.europa.eu/environment/chemicals/lab_animals/revision_en.htm
- 9 Reed B (2004). RSPCA response to the Animal Procedures Committee consultation paper on the statistics of scientific procedures on living animals in Great Britain. RSPCA Research Animals Department, Science Group.
- 10 For further information, see: www.rspca.org.uk/directive86609

WELFARE INDICATOR: The proportion of non-animal methods in OECD (Organisation for Economic Cooperation and Development) test guidelines

RSPCA concern

More than a million animals are used in the European Union (EU) every year in tests intended to evaluate the safety of products such as new medicines, pesticides and industrial chemicals¹. The numbers of animals used for this purpose worldwide are not known, but are undoubtedly much higher. The amount of suffering caused by these tests varies according to the test, and is often unpredictable since new products may range from harmless to highly poisonous. Nevertheless, large numbers of animals, including primates and dogs, are kept in laboratory conditions, subjected to distressful dosing procedures, suffer some adverse effects from the test substances and, ultimately, are killed.

The RSPCA believes that safety tests using animals must be replaced with humane alternative methods. To achieve this end, much more effort is needed to develop non-animal test methods and to accelerate their worldwide acceptance and implementation as alternatives to the existing methods using animals.

Background

The majority of safety testing is done in such a way that the results will satisfy legal requirements for the safety of products for people, and the environment. For some types of product, testing on animals is required by law, whereas for others, the use of animal tests is recommended in guidelines issued by regulatory authorities².

Many different safety tests are used to detect or measure the wide range of effects that chemicals can have on living organisms. They include tests for irritation to the eyes and skin, acute and chronic poisoning, effects on reproduction, and the ability to cause cancer. Some tests are designed to measure chemical effects on wildlife species. There are also many possible variations in the way each test is done, for example in the range of chemical concentrations used, the species and strain of animal, and the length of time they are exposed to the chemical.

Various international bodies have attempted to standardise the methods used in safety assessment. The test guidelines produced by the OECD Test Guidelines Programme³ are the most widely accepted. If tests are done in accordance with OECD guidelines the results are ensured acceptance by regulators in the 30 OECD member countries, and probably beyond. The methods apply to all chemical products, including pesticides and medicines.

The number of test guidelines is expanding because previously unsuspected hazards of chemicals continue to be identified. For example, the possible effects of chemicals on human sex hormones have only been recognised comparatively recently. The existing tests are not considered sufficient to identify these endocrine disrupting chemicals or 'gender benders', and new ones are being developed.

There is therefore an increasingly urgent need for methods of safety testing which are more reliable than existing animal tests, and which do not involve inflicting suffering on animals.

A great deal of effort has already been put into the development of alternative, non-animal methods of safety testing, but much more needs to be done. The RSPCA promotes the development of non-animal alternative methods and, for chemical products, the acceptance of such tests into the OECD test guidelines is a crucial final step.



THERE IS NO CHANGE FROM THE PREVIOUS YEAR.

The indicator figures

The proportions of 'animal' and 'non-animal' tests in the OECD guidelines are used as a rough guide to progress with the replacement of animals in toxicity testing. Only tests using vertebrate animals are included, and only those non-animal tests that detect an effect which might otherwise be measured in animals. The indicator is expressed as the percentage of relevant OECD test guidelines describing exclusively non-animal tests (Figure 3). The actual numbers of non-animal and animal test methods are shown in Figure 4.

- The ultimate objective is to see all the animal tests removed and replaced with non-animal tests, i.e. 100 per cent of test guidelines based on non-animal methods.
- An increase in the proportion of non-animal tests would be positive progress towards this objective.

In 2008, no new relevant tests were adopted. In the three years since these data were first used as an indicator, only one new non-animal test has been accepted – an in vitro method for measuring the absorption of chemicals by the skin – and no animal tests have been deleted.

This is very disappointing, particularly in view of the fact that since 2002 close to €100M has been invested by the EU in research on alternatives to animal testing.

The OECD Test Guidelines Programme has made progress in reducing animal use by means other than introducing completely non-animal tests. A number of methods have been introduced which use fewer animals than previously, and in some test guidelines non-animal methods can be used to reduce the number of chemicals which have to be tested on animals. However, these beneficial changes are not reflected in the indicator figures.

FOOTNOTES AND REFERENCES

- 1 The latest available data are for 2005: European Commission (2007) Fifth report on the statistics on the number of animals used for experimental and other scientific purposes in the member states of the European Union. Brussels.
- 2 For example, the European Medicines Agency (EMA) and the Scientific Committee on Consumer Products (SCCP).
- 3 www.oecd.org

Figure 3: Percentage of non-animal tests in OECD TGs, 2004–2008

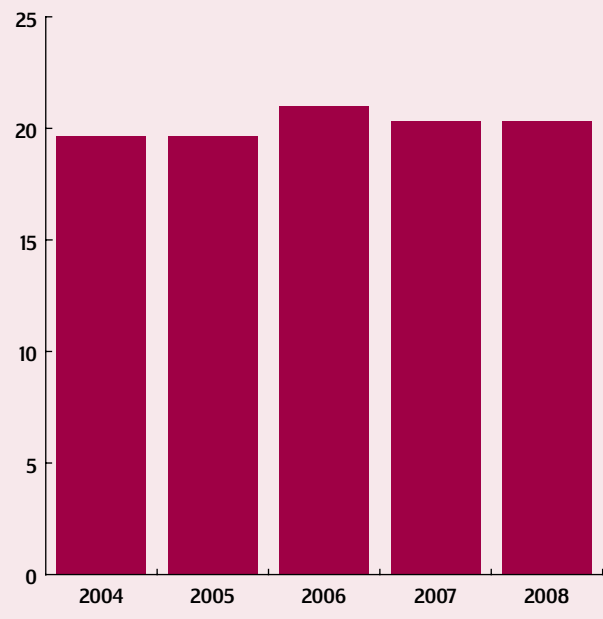
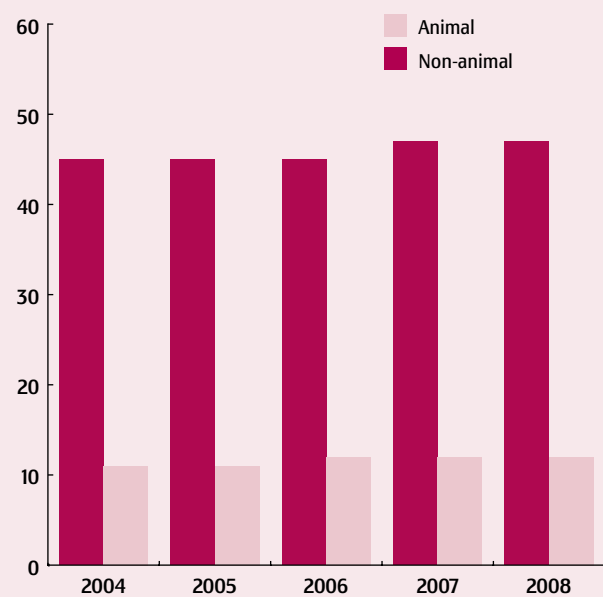


Figure 4: Number of OECD TGs using non-animal or animal methods, 2004–2008



Data source for Figures 3 and 4: OECD.

WELFARE INDICATOR: The number of animals used in quality-control tests for release of veterinary vaccines in the UK

RSPCA concern

Animals kept as companions, and those on farms or in zoos, are routinely vaccinated against common, often life-threatening, diseases¹. Some wildlife populations are also vaccinated. In addition to routine use, veterinary vaccines are also manufactured as an emergency stand-by in case they are needed to help control disease outbreaks such as Foot-and-Mouth Disease.

European regulations require that batches of veterinary vaccines are subjected to a variety of tests, some of which involve animals, before they can be released onto the market. Large numbers of animals are used and some will experience considerable suffering. Thus, whilst vaccines help safeguard the health and welfare of many animals, this is only achieved at a considerable cost to others, presenting a difficult ethical dilemma. The RSPCA believes more can and should be done to address this problem, for example by a concerted effort to develop tests that will replace or avoid the use of animals and/or substantially reduce the level of suffering and numbers involved. The adoption of more humane test methods by regulators and manufacturers internationally also needs to be accelerated.

Although some work is already going on in this area, it is difficult to assess its effect because the numbers of animals used and levels of suffering in the different types of test is not published regularly. Reporting of these figures in the public domain is an essential first step in monitoring progress on this issue.

Background

There are two main types of test that are performed on batches of veterinary vaccines – for potency (strength and effectiveness) and for safety. Some potency tests require animals to be infected with harmful bacteria or viruses, which can result in substantial suffering. For example, the potency test for *Clostridium chauvoei* vaccine (given routinely to sheep to protect against gas gangrene) involves injecting guinea pigs with bacteria, resulting in painful infections. The guinea pigs are usually euthanased to end their suffering. Such tests are of greatest concern, and it is important that efforts are concentrated on developing alternative methods to replace them that either do not involve animal tests, or use animals in ways that cause less suffering and use smaller numbers. For example, for many vaccines it is now possible to replace traditional, infection-based potency tests with less harmful methods, where the strength of the vaccine is assessed by measuring antibody levels in vaccinated animals. This reduces the level of suffering to the animals and fewer are needed.

Until recently, regulations required that tests on animals had to be used to check the safety, as well as potency, of every batch of veterinary vaccine. Tests to assess safety can involve injecting animals with relatively large volumes of vaccine, which may cause discomfort or pain. Even when tests involve relatively mild procedures, these may involve housing animals in a laboratory environment that can, in itself, be a source of distress. However, the legislation has changed and under certain conditions veterinary vaccine manufacturers can apply for permission to discontinue such tests². Manufacturers now have a clear opportunity to significantly reduce the numbers of animals used, and it is important that they seize this chance. However, it is by no means certain that they will.

In 2008, the RSPCA produced a report³, which takes a critical look at testing requirements for veterinary vaccines. Aimed at regulators, policy makers and vaccine manufacturers, it is hoped that if these parties take forward the report's recommendations it will have a significant impact on the numbers and suffering of animals used. For example, the report recommends that particular tests should be discontinued; that the process of incorporating more humane tests into the regulations is speeded up; and that research efforts should focus on replacing or modifying tests that involve lethal infectious disease agents, to reduce the suffering of those animals involved.

The RSPCA believes that there is considerable scope for a reduction in the number of animals used to test each batch of vaccine and for refinement of the tests to reduce suffering and the development of alternative test methods that do not require animals. This will require serious commitment from regulatory authorities and manufacturers.



INSUFFICIENT DATA ARE AVAILABLE.

The indicator figures

Although some efforts are already being made to reduce the suffering of animals in veterinary vaccine testing, it is difficult to assess its effect because the numbers of animals used and levels of suffering in the different types of test are not published regularly. Publication of these figures is essential if future progress is to be monitored.

In particular it is important to be able to calculate the:

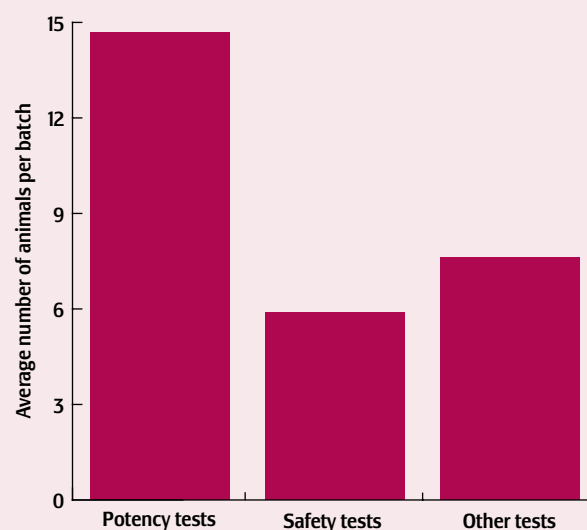
- total number of animals used to test each batch of veterinary vaccine
- number of animals used in different types of batch potency tests
- number of animals used to test the safety of each batch
- number of animals used in other batch tests⁴.

In the UK, manufacturers must submit details of the methods and results of tests performed on each batch of vaccine to the Veterinary Medicines Directorate (VMD) before the batch can be released. In 2005, the VMD released statistics relating to the number of animals used in tests for batch release in the UK during 2003. The data included the total numbers of animals used and batches released with a breakdown of how many animals had been used for each type of test. During 2003, quality-control tests for release of batches into the UK involved the use of more than 31,000 animals⁵.

No data for subsequent years have been published. However, in 2007, Defra acknowledged⁶ that making information available on the number of laboratory animals used in the production and regulatory testing of vaccines "...is necessary if government is to focus attention on priority areas for the development of alternatives to animal testing and to encourage a reduction in the use of laboratory animals and severity of testing for regulatory purposes". Defra has since commissioned work to this end.

The RSPCA is hopeful that more up-to-date data will be available for inclusion in next year's report.

Figure 5: Number of animals used in quality control tests for release of veterinary vaccines



Note: The average total number of animals used per batch in all tests = 28.2 (based on 31,047 animals used to test 1,101 batches).

Data source: Veterinary Medicines Directorate.

FOOTNOTES AND REFERENCES

- 1 For example, dogs are routinely vaccinated against canine distemper, cattle against cattle blackleg and pigs against swine pneumonia.
- 2 Manufacturers can apply for permission to discontinue the batch safety test for a particular vaccine if 10 consecutive batches have previously passed the test and providing there have been no major changes to the manufacturing process.
- 3 RSPCA (2008). *Advancing animal welfare and the 3Rs in the batch testing of veterinary vaccines*. RSPCA, Horsham.
- 4 Other batch tests may include tests for extraneous agents, toxoid contents etc. inactivation etc.
- 5 Spagnuolo-Weaver M, Ilott M and Price S. 2005. Animal usage in quality control tests for the release of immunological veterinary medicinal products in the United Kingdom. *Proceedings of the 5th World Congress on Alternatives to Animal Experimentation, Berlin, August 2005*, p223 – ALTEX Volume 22, Special Issue.
- 6 Defra (2007). *Animal Health and Welfare Research Requirements Document 2008/2009*. Available at: www.defra.gov.uk/science/funding/historical.htm

WELFARE INDICATOR: The percentage of scientific journals with ethical policies and guidelines relating to the use of animals in research and testing

RSPCA concern

Effective ethical review of animal studies is an integral part of the scientific process. It encompasses the identification and evaluation of harms, the assessment of harms versus benefits, and provides an opportunity to ensure that the 3Rs – reduction, refinement and replacement – are fully implemented.

Ethical review should be a continuous process throughout the life of every project, but there are a number of defined stages when a more formal consideration of the issues it encompasses should be addressed. These include when the research is funded, when it is authorised by the relevant legislative body (for example, the Home Office in the UK), and when it is considered for publication in a scientific journal. Funding organisations, legislative bodies and scientific journals can all have an important role in ensuring that the objectives of ethical review are fully met, but each will have a different focus and extend its influence in a different way.

The RSPCA believes that every journal publishing research involving animals should have a publication policy that (i) recognises the importance of ethical review and animal welfare, and (ii) describes the factors relating to these that will be taken into account when considering manuscripts for publication. Each journal should also require authors to include information on issues relating to animal welfare, and how the 3Rs were applied, in the papers they submit for publication. This information is essential for a proper description of the scientific protocol as well as animal welfare.

Background

Scientific journals, have a significant opportunity to influence both the ethical acceptability of research and how it is conducted. This opportunity arises because publication is essential to the success of research teams and future research funding. Journals can act as a driving force to improve standards worldwide, by requesting the inclusion of specific animal welfare and 3Rs information in scientific papers, for example species, numbers, details of housing and care provided, analgesia and anaesthesia. By ensuring that adherence to the publication policy is a requirement for publication, journals will facilitate the uptake and implementation of the 3Rs and, in turn, contribute to the development of more humane science. By publishing more information, journals can also stimulate informed discussion of the ethical and welfare issues that are integral to the use of animals in research and testing. This helps to ensure that such issues are addressed and, in turn, contribute to greater openness and transparency regarding the use of animals in science.

In 2007 (using data for 2005/6), the RSPCA began an annual review of journal publication policies to assess whether, and how well, these issues were addressed. The results of the 2009 (using data for 2007/2008) survey are described here.

The indicator figures

There are currently nearly 12,000 scientific journals in circulation worldwide. Between July 2007 and June 2008, 2,342 of these published, in English, primary data originating from the observation and/or investigation of any non-human animal; collectively publishing around 121,436 articles.

In this survey period 2,046 journals published four or more articles involving the use of animals in research and testing¹. A statistically representative sample of 324 journals was randomly selected from this pool, and the publication policies of these were collated directly from each journal's website. Where a policy relating to animal use was not given on the journal's website, the presence or absence of such a policy was confirmed by e-mail to the editor.

The journal policies were then scored out of a maximum of 12 according to the following criteria.



THERE IS LITTLE CHANGE FROM THE PREVIOUS YEAR.

Table 1: Scoring criteria

	Points awarded
Having a policy relating to the use of animals in research	1
Stating that adherence to the policy was a requirement for publication	1
Referring authors and provided links to specific guidelines, codes of conduct or legislation relating to research involving animals	1
Having an overall considered, positive statement regarding animal welfare or the ethics of animal use	1
Requiring that research submitted for publication has:	
■ undergone ethical review	1
■ implemented the 3Rs	1
■ followed contemporary good practice (and improved upon minimum standards set out in the relevant legislation) for animal housing and care	1
■ used appropriate anaesthesia and analgesia to minimise discomfort, distress and pain	1
■ defined and implemented humane endpoints	1
■ been carried out by investigators and personnel who are appropriately trained and qualified to handle and use animals	1
■ carried out euthanasia according to best contemporary practice	1
■ included all information that is suitable for publication, such as species, strain and numbers of animals and other pertinent details including refinements in husbandry and procedure	1
Total	12

Data source: RSPCA.

This year's survey achieved a high response rate of 95 per cent (309 journals), on a par with last year's 97 per cent, and was met with much openness, interest and encouragement on the part of the journals' staff and their publishers.

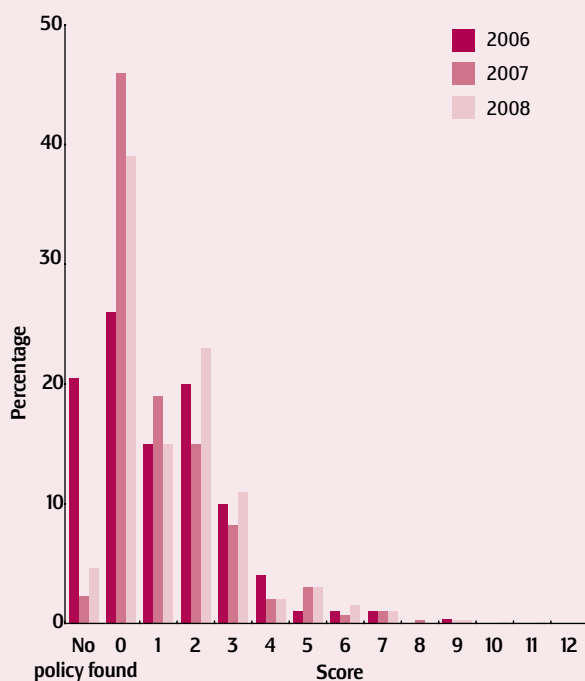
It was not possible to confirm the presence of an editorial policy for 15 (4.6 per cent) of the journals sampled. Out of the remaining 309 journals surveyed, 40.5 per cent (125 journals) had an editorial policy but did not include a section relating to the use of animals in research and testing. This is of great concern to the RSPCA, given that they collectively published a total of 8,133 articles involving animal use in the year surveyed.

The remaining 59.5 per cent (184 journals) did have a relevant

editorial policy. Although the highest score achieved was nine out of 12, this was by one journal only. The average score was just 2.4, a minimal increase over the average scores of the previous two years (2.04 in 2005/6 and 2.23 in 2006/7).

20.1 per cent (62 journals out of 309) referred authors to and provided links for specific guidelines, codes of conduct or legislation relating to research involving animals. Although this is important, it is insufficient on its own. Legislation and guidelines can be very variable in scope, level of detail and standards required, and complying with the law is a necessity, not an option. It does little to ensure that a robust ethical review has taken place, or that the 3Rs have been implemented.

Figure 6: The percentage of journals, for which no publication policy could be found, those confirmed to have no policy relating to the use of animals in research (score 0), plus those with a policy achieving the range of possible scores (1–12)

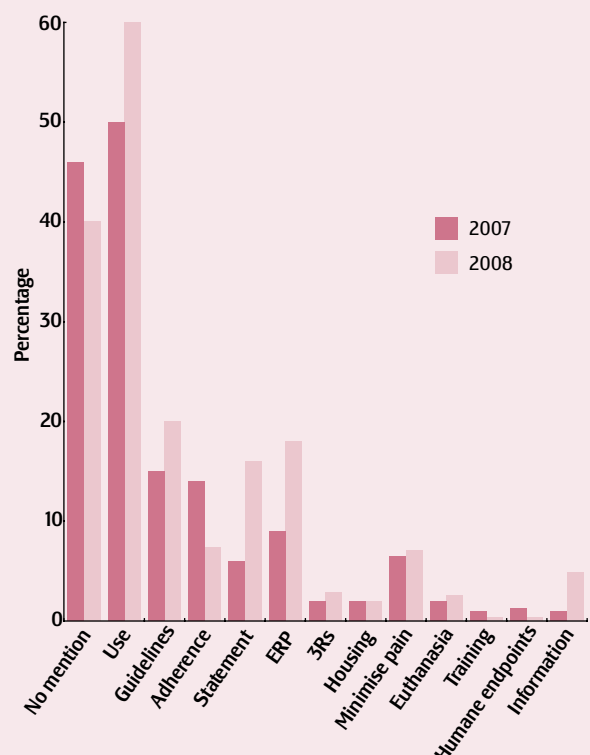


Data source: RSPCA

Furthermore, only:

- 17.8 per cent (55 journals) required that the research submitted had undergone ethical review (including the weighing of the likely adverse effects on the animals against the benefits of the work).
- 15.5 per cent (48 journals) had an overall considered, positive statement regarding animal welfare or the ethics of animal use.
- 7.12 per cent (22 journals) required that appropriate anaesthesia and analgesia had been used to minimise discomfort, distress and pain.
- 4.9 per cent (15 journals) stipulated that information relevant to the interpretation of the data should be included within the article (such as species, strain, housing conditions etc).

Figure 7: The percentage of journals whose publication policies cover each of the points in the survey criteria



Data source: RSPCA

- 2.8 per cent (eight journals) required any euthanasia of an animal to have been carried out according to best contemporary practice.
- 0.3 per cent (one journal) required authors to confirm that individuals involved in the care and use of animals were trained and skilled to an acceptable level of competency.
- Moreover, only 7.4 per cent of journals (23 journals) required adherence to the editorial publication policy as a condition for publication, meaning that irrespective of what stipulations they detailed within their policy, it was not a requirement to conform to them in order for an article to be published in their journal.

This is of concern to the RSPCA as these 184 journals collectively published a total of 25,274 articles, covering a substantial number of animals, of a variety of species, with a range of severity limits.

The RSPCA believes that editorial policies should contain more specific requirements, if they are to realise their potential in contributing to more robust ethical review and better implementation of the 3Rs.

On a more positive note, as a direct result of our correspondence, 21 journals (6.8 per cent) of the 309 found to have an editorial policy in this year's survey, either adapted or are in the process of adapting their policies to include details relating to the use of animals. Furthermore of the 82 journals that had been assessed previously (25 per cent), four journals had changed their policies and showed an improvement on their scores from previous years.

The RSPCA would like every scientific journal publishing research involving the use of animals to:

- acknowledge that the use of animals in scientific procedures raises serious ethical and welfare issues
 - define the nature of the research that editors consider is acceptable/unacceptable for publication on ethical grounds
 - request confirmation from authors that research has undergone a rigorous harm-benefit analysis as part of an ethical evaluation, and that animal welfare and other 3Rs issues have been properly addressed
- be prepared to publish sufficient information on experimental design, the 3Rs and animal welfare in order to help disseminate this to the wider scientific community
 - clearly explain what information authors need to include in papers for the research to be accepted for publication and make instructions easily accessible
 - require reviewers to make sure the above points are taken into account in the papers they review
 - require adherence to the editorial policy as a stipulation for publication.

The RSPCA has produced a leaflet outlining what is believed to be included in journal publication policies. A number of journals and publishers have shown an interest in it and are working with us to adapt their editorial policies.

In the coming year the Society will be working with journals and publishers on a separate project with the hope of encouraging journals to adopt policies, tailored to their own particular publications, which relate to the use of animals in research and testing. By developing journal policies, the RSPCA believes that significant advances can be made in the welfare of the many animals used in research each year.

LESS THAN 20 PER CENT OF JOURNALS REQUIRED THAT RESEARCH SUBMITTED HAD UNDERGONE ETHICAL REVIEW.

FOOTNOTES AND REFERENCES

- 1 This information was obtained using Michael Newman's (Stanford University, USA) protocol to undertake a targeted interrogation of the Entrez Pubmed records database (www.ncbi.nlm.nih.gov/PubMed), searching for English language journals which have published original research articles tagged as involving animal use.