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Beyond Compliance
Practices | Regulation | Training | Science

Leading by Example
Sharing | Implementing | Enforcing | Assessing

Open Communications
Dialogue | Reporting

Putting animal welfare principles and 3Rs into action



European Pharmaceutical Industry 2012 Update

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Open Communications — Dialogue | Reporting

Beyond Compliance

- How do we ensure that animal welfare standards and practices are put into action throughout the sector both in our industry and among the laboratory and research community more broadly?
- How do we make sure that global regulations reflect 3Rs strategies?
- What internal and external industry initiatives facilitate the implementation of training programmes on animal welfare and care?
- How do scientific advances help progressing 3Rs and Welfare? *New

Leading by Example

- How do we share and encourage good practices based on 3R principles across the pharmaceutical industry?
- How do we stimulate putting into practice global animal welfare standards?
- What is being done to rapidly implement and enforce across Europe the revised European Directive 2010/63/EU on the protection of animals used for scientific purposes?
- Are companies independently assessed on how animal welfare standards are applied?

Committing to Open Communication

- How do we contribute to an open and constructive dialogue on animal welfare?
- How is industry communicating the progress made with animal welfare activities, specifically the 3Rs?

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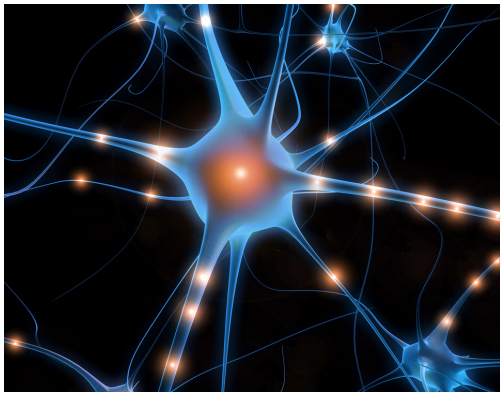
Beyond Compliance

Question: How do we ensure that animal welfare standards and practices are put into action throughout the sector both in our industry and among the laboratory and research community more broadly?

The European pharmaceutical industry's animal welfare standards and practices often go beyond those required by regulators. In addition to carrying out their own review of internal animal welfare standards and practice controls, companies also carry out regular monitoring and systematic audits of external partners.



In 2012 several of our member companies contributed to the translation of international animal welfare recommendations and guidelines to enable improved access to non–English speakers. Specifically:

- Supported the Association for Assessment and Accreditation of Laboratory Animal Care International to advance standards of animal welfare in China by organising two conferences and helping translate a guide on the care and use of laboratory animals.
- Participated in the translation of international recommendations (related to surgery and methods of administration of substances) into French for publication (STAL edited by AFSTAL) to facilitate better access (especially to technicians).
- Participation in the translation of the internet site "humane end-point".

Individuals from our member companies continue to contribute to the work of both national and international laboratory animal science and veterinary organizations. In particular they were instrumental in developing recommendations produced by FELASA on harm benefit analysis.

Fifteen pharmaceutical companies shared data on body weight loss in short term toxicity studies and based on an analysis of the data published recommendations to significantly refine these studies. This work was facilitated by the UK National Centre for Replacement, Refinement and

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Reduction of Animals in Research (UK NC3Rs).

Other activities focused on continuous improvement within our own companies: Many of our member companies continue to work on programmes to acclimatise our animals to experimental environments. Training of non-human primates, dogs, goats and pigs to voluntary cooperate with scientific, veterinary and husbandry procedures has significant benefits for animal welfare, science and staff, especially when combined with appropriate socialization, habituation and desensitization. Training methods mainly based on positive reinforcement (which reward desired behaviour) is recommended as good practice by many legislative and professional guidelines. Using training programmes as a routine minimises stress to animals, improves the safety of attending personnel, decreases sources of variability in experimental data and hence reduces the number of animals required for a given study.

The efforts of one member company in training dogs and non human primates was recognized by an award from their national Society of Animal Science.

Another company developed a welfare assessment tool for evaluating dog behaviour. This tool, which incorporates cognitive bias testing and cardiovascular analysis, was presented at several animal welfare symposia. The results indicate dogs with optimistic outlooks have lower blood pressure and more positive behavioural traits than dogs with a pessimistic outlook.

This information can be used to refine experimental procedures and to focus training on indivudual animals.

Companies were also active in trying to improve welfare for less well characterised species for example fish. Research was conducted to assess the most appropriate forms of enrichment which vary depending on the type of fish used e.g. one piece of work that was published examined the enrichment requirements of zebrafish and showed that anthropomorphic desire to include items in the fish tank does not necessarily improve welfare measures.

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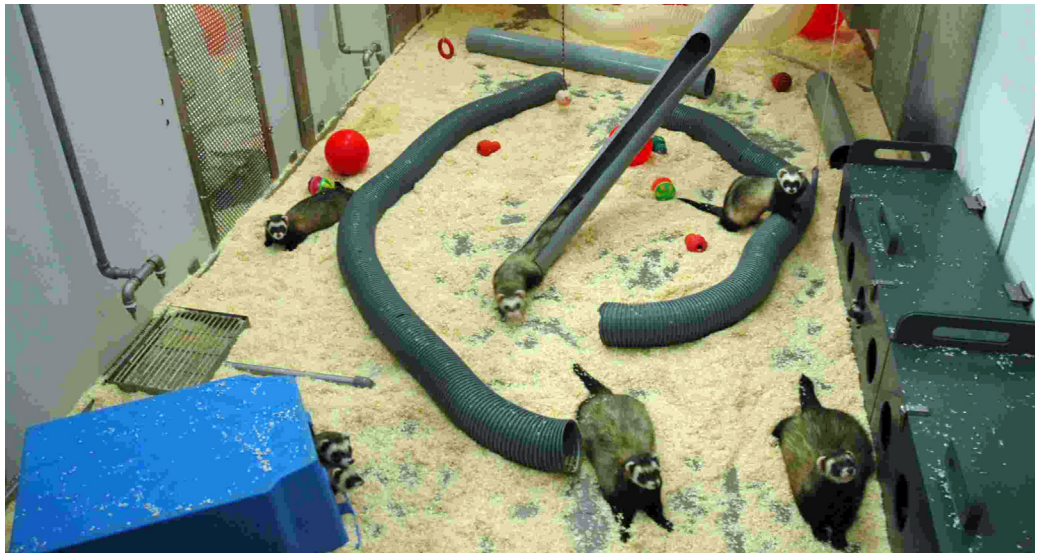
Question: How do we make sure that global regulations reflect 3Rs strategies?

We continuously contribute to reviews of European and international regulatory requirements to make sure we implement the most up to date 3R strategies across the industry.

Supporting review of regulations and international guidelines

As previously reported in the 2011 report, we continue to guide the implementation of the EU Directive on the protection of animals used for scientific purposes by participating in Expert Working Groups with the European Commission (e.g. education and training, severity assessment). In addition, many of our members contributed as professional experts to discussions with their national authorities to achieve the most appropriate transposition of the legislation. Contributions came particularly in the field of training requirements for personnel (including the designated veterinarian), ethical evaluation of projects and determining the roles and organisation of the animal welfare body. The result achieved benefit both for the science and the animal welfare.



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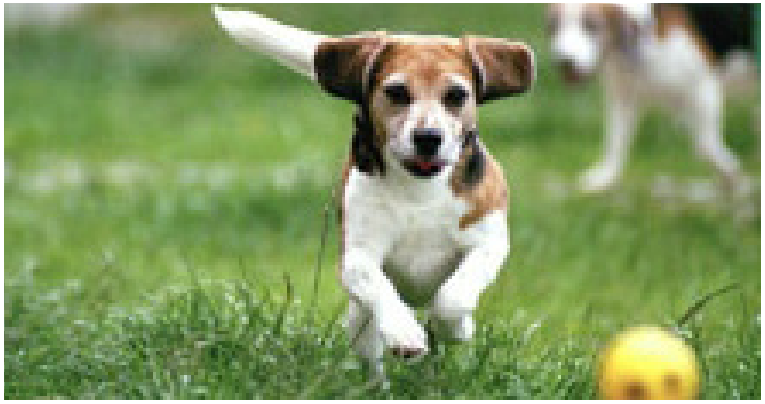
Question: What internal and external industry initiatives facilitate the implementation of training programmes on animal welfare and care?



The European pharmaceutical industry runs education and training programmes and courses on animal welfare and care for its employees.

In addition, we develop educational tools in partnership with the research community to help spread knowledge and good practices both in the pharmaceutical industry and amongst the wider scientific community.

New training activities have been put in place to help understand the requirements of the new Directive:
Representatives from several companies in France have developed, together with their public research counterparts, a training program for project evaluators/ethics committee members in order to try and harmonize the ethical review process throughout the different committees across the country. Courses were based on regulation, National Charter on the ethics of animal experimentation published by the "Comité National de Réflexion Ethique sur l'Expérimentation Animale" and the Guide for the ethical evaluation of experiments using laboratory animals that was approved by the French authorities.

One company carried out interviews on the ethical aspects of animal research with all new employees and students. This is especially useful to discuss the potential impact on animal welfare of activities of new employees or students who will not be directly involved with the animals (e.g.chemists/formulation specialist determining the dosing method or the properties of formulations to be administered; kineticians or staff in charge of blood clinical/ haematology analyses responsible for setting sampling volume and frequency). As a result, in their future activities, they will take into account the impact of their requests on animal welfare.
In several companies all employees directly in contact with animals were given the option to attend training on the animal behaviour/welfare from an external specialist in this domain. In another company a 3R information meeting, was held to foster a culture of 3R awareness throughout the entire value creation chain. A renowned ethicist was invited for presentation and discussion. Around 400 participants took part including animal carers, scientists and administrators as well as representatives from senior management.
One company has implemented a training course in ethical principles for all newly recruited staff.
Other companies delivered courses to develop technical skills in imaging, recognizing humane endpoints and improve surgical skills to implant telemetry devices.

Another example is the development and delivery of a professional Continual Professional Development scheme for all staff involved in working with animals.

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Question: How do scientific advances help progressing 3Rs and Welfare?

The aim of the Innovative Medicines Initiative is to speed up the development of better and safer medicines for patients. However, many of the ongoing projects in this research public private partnership have the potential to deliver 3Rs as a consequence of addressing their primary goal. Here we highlight 4 projects and illustrate how our involvement with these will lead to progress in the 3Rs.

From Science to 3Rs

StemBANCC is an academic-industry partnership uniting 23 academic institutions and ten pharmaceutical companies. Initiated by Roche and managed by the University of Oxford the project is one of IMI's largest ventures with a budget of € 55.6 million. The project started in October 2012. Currently, many drugs fail rather late in the drug development process because the tests used in the earlier stages of drug development are not precise enough. StemBANCC will generate cell lines, which will improve and speed up the drug development process, reduce the need for toxicity assessment in animals and ensure that patients benefit from more effective and safer drugs.

The aim of the StemBANCC project is to generate and characterise 1500 high quality human induced pluripotent stem (iPS) cell lines derived from 500 patients as research tools for drug discovery. iPS cells are adult cells that have been genetically reprogrammed to lose their tissue-specific qualities and become pluripotent. The iPS cells will be used to develop human disease models in vitro, in order to enhance early stage drug development. The StemBANCC project will create a solid database with numerous patients and accurate data on their disease enabling a new level of insight into disease mechanisms. The cell lines will be made available to researchers to study a range of disease including peripheral nervous system disorders, central nervous system disorders, neurodysfunctional diseases and diabetes. The project will investigate the use of human iPS cells for toxicology testing by generating liver, heart, nerve and kidney cells.

Innovative Medicines Initiative

EUROPAIN: The EUROPAIN project, active since October 2009, aims to improve the treatment of patients with chronic pain by establishing translational models in animals and humans. Such improvements of human pain modeling may lead to improved animal models or the decrease in their use.
Three renowned academic pain consortia, from Germany, Denmark and the UK, have joined forces with a Spanish SME and with Europe's most active pharmaceutical companies working on pain.

ABRISK: The ABRISK project addresses anti-drug (AD) immunogenicity- a major limitation to the use of biopharmaceuticals. At the moment, in many cases, the only way to determine the potential for immunogenicity is to test the biopharmaceutical in a non-human primate. The project will develop cell-based tools to study immune responses to biopharmaceuticals, an alternative method to animal testing.
A growing number of medicines are based on biological molecules such as proteins and monoclonal antibodies. These novel drugs have resulted in new, more effective treatments for a number of serious conditions. Yet sometimes these medicines trigger an individual response from the patient's immune system, which can decrease the effectiveness of the drug or cause severe side effects. The aim of the IMI-funded ABRISK project is to shed new light on the factors behind this immune response. The project, which represents the first concerted effort to solve this problem, will aid in the creation of new, safer biopharmaceuticals and also generate tools to determine how individual patients are likely to respond to them both in clinical trials and after release to the market.

OrBiTo: Most drugs are taken orally, as tablets or capsules for example. However, designing these pharmaceutical products in such a way that the active ingredient is absorbed at an appropriate rate and extent by the gut is far from easy. The OrBITO project aims to enhance our understanding of how orally-administered drugs are taken up from the gastrointestinal tract into the body, and apply this knowledge to create new non animal laboratory tests and computer models that will better predict the performance of these drugs in patients. This will further reduce the need to carry out such studies in animals.

www.imi.europa.eu

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• Microsampling

One specific area where the pharmaceutical industry has been involved in developing and exploring the potential of a new technology is microsampling. This ability to collect and analyse components of samples as small as 5-20ul has led to re-examination of the way in which blood samples need be taken in both the clinic and in animal studies.

Technical developments in measuring equipment (e.g. high performance liquid chromatography mass spectrometry HPLCMS/MS) and increased sensitivity of detection have increased the feasibility of us of microsampling. This has led to an opportunity to refine the way in which the animal studies required prior to human dosing can be conducted. An example of where this technology has contributed to 3Rs progress is:

When applied for Toxicokinetic (TK) or pharmacokinetic (PK) sampling in rodent studies, these techniques serve to reduce animal use and also add scientific advantages by allowing a direct comparison of potential adverse effects with compound exposure in the same animals. To date, the implementation of these microsampling approaches in exploratory nonclinical studies has the potential to enable a reduction of 60% in the number of mice required for stand alone to TK/PK studies and of 80% in the number of samples to analyse.

In the future, these efforts associated with bioanalytical micro-methods (e.g., Dried Blood Spot, Capillary MicroSampling) will avoid the need to use satellite animals in regulatory toxicology studies.

Our members have been involved in several initiatives to further explore the potential of this new technology. Of note are:

• In 2012, the development and validation of several microsampling techniques were communicated globally by several presentations across company sites and departments.
• A Drug Metabolism Discussion Group Short Meeting hosted by AstraZeneca in March 2012 in UK. This attracted over 140 delegates and a strong line up of presenters of respected scientists within the field. This meeting focused on the potential refinements of taking reduced sample volumes from both animal, or later in the clinic, particularly in neonates.

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From 3Rs to Good Science

3Rs Awards – Common practice is for companies to have internal 3Rs awards run annually.
These awards recognize staff having put 3Rs commitments into action progressing both science and animal welfare. The output from these award processes are often shared internally e.g. through posters, oral presentations, awards ceremonies, 3Rs newsletters and by publishing winning initiatives on the company website or through Corporate Social Responsibility reports.

Specific examples of 3Rs projects

Companies continued to report examples of changes to protocols and technical improvements, which resulted in better scientific output as well as improved animal welfare. For example:

• Replacement of the monkey kidney primary cells with L20B cell line for the inactivation testing of polio vaccines. A multidisciplinary team developed an innovative method using L20B cells that contain the human poliovirus receptor gene, thus totally eliminating the need to use animals. In addition to addressing the ethical concerns this new method is very easy to replicate, optimizes the vaccine yield price, and reinforces the industrial agility of the company. Developed methods to isolate individual cell types from the pancreas of rats to assess pancreatic toxicity. This has reduced animal use by over 95% and improved the team's ability to identify the best compounds. The team is now successfully applying the techniques to other cell types.

• Development of a rat aortic tissue based assay, which can replace whole animal studies in evaluation of unwanted effects on blood pressure (raised or lowered) can limit the usefulness of new medicines and stop their development. Relaxation or contraction of the aortic muscle provides a direct measure of compound effects and the in vitro preparation allows the team to apply sophisticated genetic techniques to understand the mechanism for unwanted effects. In this way the team has reduced animals use previously required by approximately 90%.

• Use of an end-point grid based on clinical signs, to facilitate a possible decision to stop/decrease dose or to take another decision.

• Decreased the size of needles used for blood sampling in non-rodents (especially non human primates: smaller trauma, less sensitive, with decreasing risk of hematoma at the site of sampling), in collaboration with the blood chemical unit to check the absence of impact of this change on blood clinical chemistry parameters

• We have continued our ambition to constantly improve welfare and housing conditions and several initiatives have been implemented. A study investigating the impact of oestrous cycle in Pharmacokinetic studies resulted in a shift from male to female mini-pigs allowing to group house the mini-pigs.

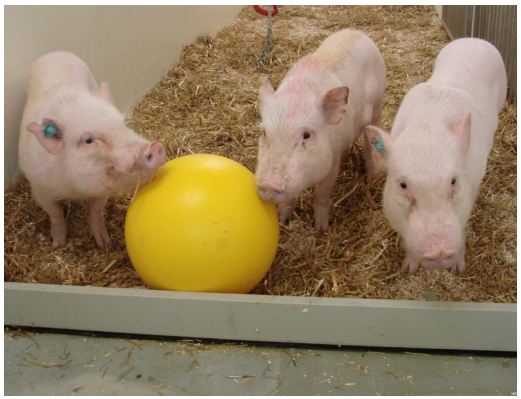
• Signed an agreement with Simulations Plus, to develop software that simulates the absorption of drugs through the skin in humans and animals, and could potentially reduce experimentation.

• A reduction in the fasting time in rats and mice for charcoal meal studies is a refinement leading to less aggressive behaviour in mice, thus allowing group housing. It requires no additional expenditure on equipment or time and no additional training of technicians.

• Developing a validated method for identifying potential effects of new medicines on male fertility. Rather than carrying out traditional standalone fertility tests, the approach combines male fertility assessment with 6 month general toxicity studies, so sparing around 80 male rats for every compound tested, down from 140 to approximately 60 males. The combined approach also provides richer, better-integrated data thereby improving the risk assessment of longer-term effects on fertility, and better supports the development of medicines for adolescents as well as adults.

• An alternative approach for testing the safety of three new monoclonal antibody medicines designed to combat infectious diseases resulted in a 57% reduction in the use of non-human primates.

• Until recently, a major limitation for in vitro assessment of cardiovascular effects was that healthy myocytes could only be maintained for 24 hours. Company scientists made a breakthrough that enables them to keep the myocytes healthy for about 2 weeks, meaning that many more compounds can now be tested using cells supplied from a single dog. The method for preserving the myocytes has been published ensuring that it can be used around the world, so making a global contribution to the 3Rs.



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Leading by Example

Question: How do we share and encourage good practices based on 3R principles across the pharmaceutical industry?

The European pharmaceutical industry collaborates within and cross sectors to identify opportunities to implement the 3Rs (i.e. to systematically and verifiably Replace, Reduce and Refine) and increase the welfare of animals used for scientific purposes.

We continue to exchange information about methods and refinement initiatives both between sites within a single company and across different pharmaceutical companies. Specific examples in 2012 include: In one company a network of animal ethic committees (animal welfare bodies) shares 3R initiatives and offers training in refinement methods established within the company.

Another company reports that an internal Global Animal Welfare Auditing System is in place. The concept calls for annual inspection visits at each site by Animal Welfare specialists from another site. The assessments provide valuable advice on 3R improvements and allow for best-practice sharing.

Many companies exchanged information on improvements to established methods or work to develop new ones via different networks and/or publications. In 2012 this included information on toxicogenomics, development of in vitro methods, the "dried blood spot" method for toxicokinetic analysis, ways in which to reduce numbers in toxicology studies. We also share information with other industries e.g. through the European Partnership for Alternatives to Animal Testing (EPAA) and academic researchers.

Several companies worked with the European Center for the Validation of Alternative Methods (ECVAM) to validate the 3T3 cytotoxicity test to identify non-toxic chemicals (LD50 > 2000 mg/kg). This test has been implemented for safety data sheet (safety of workers) testing and replaces most of the in vivo experiments when applicable. Animal use is reduced by 80%. This is definitely another step forward in the reduction of animal toxicity testing and recognition of this test for regulatory purposes.

Member companies have actively participated in:

- The UK NC3Rs initiatives, e.g. micro-sampling; use of recovery animals in safety studies; use of human tissue in safety pharmacology and refining body weight loss limits in toxicology studies. In addition they have sponsored and participated in 'Crack It' initiatives also organized by the UK NC3Rs. These will connect scientists from different disciplines to encourage innovation in the 3Rs.

- Center for Alternatives to Animal Testing (CAAT-EU) by participating in their activities, e.g. refinement initiative, information day on high content imaging information day and workshop

- In 2012 EFPIA Research and Animal Welfare group established a link with the 3Rs Leadership group of the International Consortium for Innovation and Quality in Pharmaceutical Development (IQ). The aim of the interaction is to capitalize on synergies and to look for ways to collaborate and coordinate our 3Rs efforts and avoid duplication.

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Leading by Example

Question: How do we stimulate putting into practice global animal welfare standards?

One company shares experiences between different global sites by having animal caretakers and veterinarians stay in other facilities within the company and transfer 3R knowledge between these sites.
To ensure alignment of global standards and to ensure a global transfer of 3R knowledge and sharing, employees working with laboratory animals are exchanged between parts of the worldwide organization. To further strengthen this sharing culture a governance structure has been established connecting the local ethic committees (e.g. IACUC's and Animal Welfare Bodies) and animal facilities among the global sites.

Several companies exchange information on practices (dosing methods, sampling methods, material used for examinations, end-point criteria, ethical review etc…) with Contract Research Organizations from different countries as part of the organisation of subcontracted studies.

The use of fish in environmetal and patient safety studies is a specialized but growing area. Many adverse effects can be detected using live fish and fish celles early in the development process therefore reducing the need to test in other species. Many of these scientific advancements in the use of fish in development of medicines have been published. For example:

• A new fish spheroid liver cell model was developed. Regulatory required bioaccumulation tests assessing whether chemicals that enter the aquatic environment can accumulate in fish tissues. These tests take more than 4 weeks to complete. Traditional fish liver cell-culture methods are not suitable alternatives because the cells stay healthy for only 4 days. But the newly developed spheroids thrive and maintain liver functions for around 40 days – making them strong candidates to reduce and replace the use of live fish in these studies, and in future perhaps other toxicological tests too. Significant modifications were implemented in another regulatory required fish study, which provided robust data for the environmental risk assessment and was accepted by the regulators. It used 50% fewer fish and took 35% less time.

• A potential model was developed in fish to assess hearing loss in safety assessment. There are no other specific models for this. Failure in clinical trials of a potential medicine due to hearing loss could mean that significant pre-clinical testing will have been conducted before the liability is detected. The fish test has the potential to discover this liability earlier in the development process and thus reduce the number of animal studies conducted before development is stopped.

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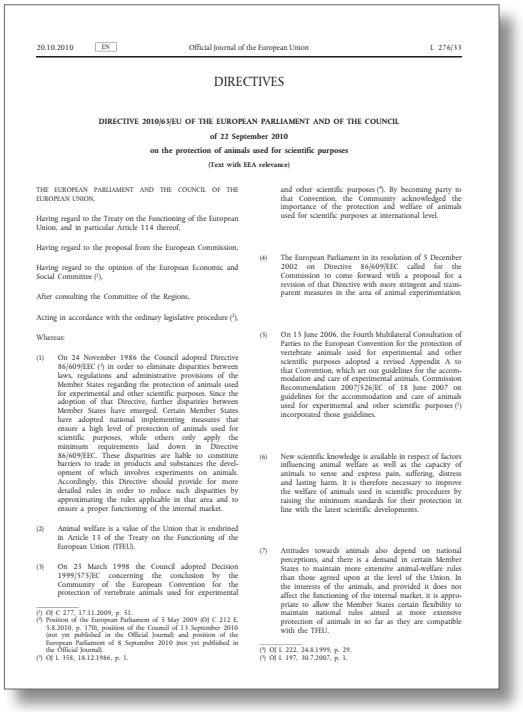
Leading by Example

Question: What is being done to rapidly implement and enforce across Europe the revised European Directive 2010/63/EC on the protection of animals used for scientific purposes?

In 2012 EFPIA members continued to support and stimulate implementation and enforcement of the revised Directive 2010/63/EC within the EU.

Contributing to the debate – EFPIA members are playing a leading role in guiding the implementation of the EU Directive on the protection of animals used for scientific purposes not only at EU level, and also within Member States. This being done by contributing to responses to national consultations, participating in Expert Working Groups with the European Commission (e.g. statistical reporting) and actively participating as members of Scientific Coalitions, such as the UK Bioscience Coalition. EFPIA is also part of a wider scientific community coalition, which provides input into EU level discussions on implementing guidance required by Directive 2010/63/EC (statistical reporting, genotyping, education and training). As was the case in previous years, in 2012, this "transposition coalition" contributed to important discussions about application of 3Rs principles and promotion of 3Rs information, education and training of personnel, including continued professional education.



20.10.2010 EN Official Journal of the European Union L 276/33

DIRECTIVES

DIRECTIVE 2010/63/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 22 September 2010
on the protection of animals used for scientific purposes
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee (1),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure (2),

Whereas:

(1) On 24 November 1986 the Council adopted Directive 86/609/EEC (3) in order to eliminate disparities between laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes. Since the adoption of that Directive, further disparities between Member States have emerged. Certain Member States have adopted national implementing measures that ensure a high level of protection of animals used for scientific purposes, while others only apply the minimum requirements laid down in Directive 86/609/EEC. These disparities are liable to constitute barriers to trade in products and substances the development of which involves experiments on animals. Accordingly, this Directive should provide for more detailed rules in order to reduce such disparities by approximating the rules applicable in that area and to ensure a proper functioning of the internal market.

(2) Animal welfare is a value of the Union that is enshrined in Article 13 of the Treaty on the Functioning of the European Union (TFEU).

(3) On 23 March 1998 the Council adopted Decision 1999/575/EC concerning the conclusion by the Community of the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes (4). By becoming party to that Convention, the Community acknowledged the importance of the protection and welfare of animals used for scientific purposes at international level.

(4) The European Parliament in its resolution of 5 December 2002 on Directive 86/609/EEC called for the Commission to come forward with a proposal for a revision of that Directive with more stringent and transparent measures in the area of animal experimentation.

(5) On 15 June 2006, the Fourth Multilateral Consultation of Parties to the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes adopted a revised Appendix A to that Convention, which set out guidelines for the accommodation and care of experimental animals. Commission Recommendation 2007/526/EC of 18 June 2007 on guidelines for the accommodation and care of animals used for experimental and other scientific purposes (5) incorporated those guidelines.

(6) New scientific knowledge is available in respect of factors influencing animal welfare as well as the capacity of animals to sense and express pain, suffering, distress and lasting harm. It is therefore necessary to improve the welfare of animals used in scientific procedures by raising the minimum standards for their protection in line with the latest scientific developments.

(7) Attitudes towards animals also depend on national perceptions, and there is a demand in certain Member States to maintain more extensive animal-welfare rules than those agreed upon at the level of the Union. In the interests of the animals, and provided it does not affect the functioning of the internal market, it is appropriate to allow the Member States certain flexibility to maintain national rules aimed at more extensive protection of animals in so far as they are compatible with the TFEU.

(1) OJ C 277, 17.11.2009, p. 51.
(2) Position of the European Parliament of 5 May 2009 (OJ C 212 E, 5.8.2010, p. 170, position of the Council of 13 September 2010 (not yet published in the Official Journal) and position of the European Parliament of 8 September 2010 (not yet published in the Official Journal).
(3) OJ L 358, 18.12.1986, p. 1.
(4) OJ L 222, 24.8.1999, p. 29.
(5) OJ L 197, 30.7.2007, p. 1.

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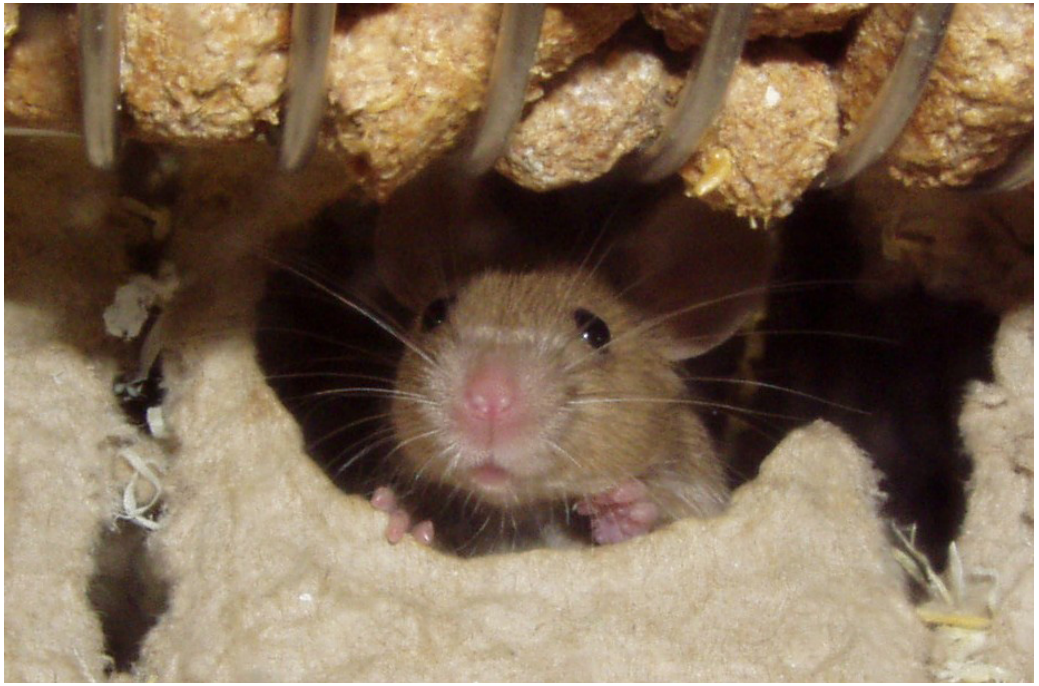
Leading by Example

Question: Are companies independently assessed on how animal welfare standards are applied?

We are independently assessed and we encourage improving existing external and independent assessments of internal animal welfare standards and facilities on a European and global level.



Many companies work with external partners.

A common approach to select these often involves an assessment of animal welfare standards.

One company reported that "over the past four years their animal quality assurance group has assessed the care and welfare programmes of more than 500 contractor and supplier organizations. The vast majority of these have either met their principles for animal welfare or responded to their recommendations for improvements to their animal care programmes.

On occasion the companies decided not to work with a contractor either because they have chosen not to adopt their recommendations or because it was clear, following a site visit, that they were not committed to continuous improvement".

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Commitment to Open Communication

Question: How do we contribute to an open and constructive dialogue on animal welfare?

The pharmaceutical industry understands the sensitivities around the issue of animal research. For this reason, we actively seek to engage in dialogue. We contribute to a continuous, open and constructive dialogue on animal research and welfare, with the public, legislators, policy makers, and interested parties.

Collaborative projects at EU level

We recognise that talking about the contribution that animal research makes to the development of new medicines and treatments and the care we take of the animals in this research, is an important factor in maintaining public support for this essential research. In 2012 specific initiatives that were undertaken to support this continued communication were:

Several companies with facilities in UK signed up to UK Declaration on Openness on Animal Research with the aim of establishing a Concordat that will develop principles of openness, practical steps and measurable objectives, which will underpin a more transparent approach to animal research.

Another company conducted weekly tours of the animal facilities both for employees within the company and for students.

Member companies presented the results of their cross industry/NC3Rs project on acute toxicity as a case study at the UK NC3Rs July 2012 Parliamentary Event. The event which was hosted by Lord Willis of Knaresborough was intended to raise the profile of the work of the NC3Rs among UK MPs and Peers and to launch the publication of their new report on evaluating progress in the 3Rs.

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Useful links

Accreditation of Laboratory Animal Care International (AAALAC) - **www.aaalac.org**

Alternatives Approaches to Animal Testing (EPAA) - **www.epaa.eu.com**

European Centre for the Validation of Alternative Methods (ECVAM) – **www.ecvam.jrc.it**

Federation of Laboratory Animal Science Associations (FELASA) - **www.felasa.eu**

Innovative Medicines Initiative (IMI)- **www.imi.europa.eu**

Institute for Laboratory Animal Research (ILAR)- **www.dels.nas.edu/ilar**

Laboratory Animal Science Association (LASA) - **www.lasa.co.uk**

National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs) - **www.nc3rs.org.uk**

3R Foundation - **www.forschung3r.ch**

For more information, contact

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Photos have been sourced from a number of sources, including EFPIA and Understanding Animal Research. EFPIA would like to thank the members of the EFPIA working group on Research and Animal Welfare for the valuable contributions to this report.

December 2013