



Theme 3

Moral Issues of Animals, Alternatives and Public Policy

Chairs:

Jon Richmond (United Kingdom)

Martin Stephens (USA)

Session 3.1

Influencing and making public policy

Lecture

The scope of international funding for research, development, validation and acceptance of alternatives to animal tests for regulatory purposes must become transparent

Sara Amundson

Doris Day Animal League, Washington, DC, USA

Attempts by the regulated industries and animal advocates to ascertain the amount of monies spent to shepherd alternatives through to acceptance have been mitigated by the lack of accountability by and the sheer number of federal agencies in many of the industrialised countries providing some funding for these activities. In addition, while Europe has provided a centralised focus for its resources and prioritisation, most countries do not have readily accessible accounting of annual spending.

In order to prioritise replacement methods and also identify immediate needs for “picking the low hanging fruit” in the field of alternatives, a document must be collated on an annual basis to provide genuine transparency of federal funding. Those members of the regulated industries that fund research, development and validation of alternative methods should also more readily present data on annual dollars allocated for this work.



Poster

Do we need an invalidation process for animal and non-animal tests?

Michael Balls and Robert Combes

FRAME, Nottingham, UK

A plethora of regulations require that many chemicals and chemical products are tested for efficacy and/or safety. When permitted to operate effectively and without bias, the ECVAM/ICCVAM/OECD validation process can be used to independently establish that new animal and non-animal test procedures are sufficiently relevant and reliable for their stated purposes and should be considered for regulatory use. However, it is clear that many currently-accepted animal tests and candidate non-animal tests do not, and could not, meet the agreed cri-

teria for necessity, test development, prevalidation, validation and acceptance. Do we therefore need an invalidation process to parallel the validation process, so that such methods could be independently reviewed and declared irrelevant and/or unreliable for their claimed purposes? Examples will be given of animal tests and candidate non-animal tests which ought to be evaluated in this way, and which could ultimately be declared to be invalid.

Poster

The Animal use barometer – an annual report

Iris Boumans and Coenraad Hendriksen

Netherlands Centre Alternatives to Animal Use, Animal, Science and Society, Utrecht, The Netherlands

In the Netherlands, laboratory animal use declined since 1978, but has slowed down since mid nineties. There are numerous factors influencing the use of animals in research. On the one hand there is a policy addressed towards the replacement, reduction and refinement of laboratory animal use, such as through financing 3R projects and regulation of animal experimentation. On the other hand recent developments, such as the EU programme REACH, may lead to an increase of animal use. In the annual report “Animal use barometer”, which is initiated by the animal welfare organisation “Sophia Vereeniging” and carried

out by the Netherlands Centre Alternatives to animal use (NCA), trends in the animal use and the affecting societal factors are evaluated, both on the national level as on the international level. Insight in these processes is aimed to result in the development of a more specific and effective policy towards a decrease in laboratory animal use. The developments in 3R research and implementation and advances that lead to either an increase or decrease of laboratory animal use are monitored specifically. Insight will be provided of trends and developments, and specific recommendations will be given.



Lecture

NIH policies and strategies

Norka Ruiz Bravo

National Institutes of Health, Bethesda, MD, USA

The National Institutes of Health is the Nation's medical research agency supporting research to improve the quality of human health in the United States and around the world. NIH develops research policies and scientific priorities using a collaborative process that involves its numerous stakehold-

ers, including policies related to the use of animals in research. We actively seek scientific and public input and strive to develop approaches that serve the interests of the NIH, the research community, and the public. Examples will illustrate the process.

Lecture

The current OECD health effects test guidelines for REACH are in urgent need of revision

Robert Combes

FRAME, Russell and Burch House, Nottingham, UK

The European Commission (EC) has stated that all testing to satisfy the new REACH legislation for chemicals risk assessment must be undertaken according to the OECD health effects test guidelines (TGs). Each guideline has been analysed with respect to its design and its scientific and animal welfare implications, the extent to which it makes use of modern techniques, and its suitability to be used in the REACH system for the testing of large numbers of chemicals. The results of this analysis were published recently (*ATLA 32*, 163-208, 2004). It was found that some of the TGs required by the EC in its annex to the REACH proposals are unnecessary and that many others need to be updated to make use of modern methods and new knowledge, and to use current approaches for applying refinement and

reduction strategies, to improve the scientific and animal welfare aspects of the procedures used. This report raises the serious question of why the OECD secretariat, and the various national co-ordinators and government experts who represent the 30 Member Countries of the OECD, have allowed the TGs to become so outdated and unsuitable. This presentation discusses the above issues, and makes recommendations for improving this highly unsatisfactory situation in the light of ongoing initiatives by the OECD to improve the process of test guideline development. It is recommended that this focuses on updating TGs, as well as producing new ones, particularly those based on advanced, non-animal approaches to testing.



Poster

International harmonisation of testing for pharmaceuticals: animal protection at the ICH

Sadhana Dhruvakumar

People for the Ethical Treatment of Animals (PETA), Research and Investigations, Norfolk, VA, USA

Before a drug enters human clinical trials, pharmacokinetic/dynamic parameters (“ADME”) and toxicity must be assessed, and few non-animal methods are currently accepted. Animals are also used for quality control in drug production. Because of the global nature of the drug market, the International Conference on Harmonization (ICH) was established in 1990 to align regulatory requirements across key regions. ICH consists of regulators and industry groups from Europe, Japan, and the U.S., as well as several observers. Amongst its other activities, ICH publishes consensus guidelines for preclinical testing which have contributed to a decrease in duplicative animal testing across regions. However, the system is fallible: In 2001, Japan requested additional preclinical testing of Oxycontin in beagles, even though the drug had been

on the U.S. and European markets for 30 years. In addition, ICH guidelines have largely not incorporated validated 3Rs methods. The coalition of animal protection groups known as ICAPO (International Council on Animal Protection at the OECD) has formed a sister organisation, ICAPI, to address animal testing issues at the ICH. ICAPI has made a formal request for observership status at ICH meetings in order to liaise more efficiently with other global pharmaceutical stakeholders. Though ICH activity has tended to focus on the retrospective alignment of methods long accepted in all member regions, ICAPI is well positioned to help expand this focus to harmonising acceptance of emerging alternatives by bringing 3Rs methods to the table in a timely manner, thus facilitating their incorporation into ICH guidelines and their global adoption.

Lecture

Developing guidelines – the Canadian experience

Gilly Griffin and Clément Gauthier

Canadian Council on Animal Care, Ottawa, Canada

In Canada, the responsibility for overseeing the care and use of animals in science lies with the Canadian Council on Animal Care (CCAC). Each of the three programs of the CCAC (Assessment, Guidelines and Education, Training and Communication) operates through a peer-based system. The development of CCAC guidelines affords the opportunity for an interface between scientists using animals as tools to obtain scientific data; animal welfare scientists trying to understand the “needs” of animals used in science; animal care personnel; animal welfare and community representatives. The use of a peer-

review approach ensures that CCAC guidelines are based on sound scientific evidence and expert opinion that takes into consideration current societal values and the interests of the animals. Examples from recently published CCAC guidelines (the care and use of wildlife; the care and use of fish; and laboratory animal facilities) will be used to demonstrate the process in action. In particular, the development of guidelines in areas where there is a lack of scientific evidence will be discussed, including short-term and long-term strategies for addressing the need for research to support guidelines’ development.

**Poster****Biosimulation and its contribution to the 3Rs in animal and human research***Hanne Gürtler*

Living United Consult, Alleroed, Denmark

Animal experimentation and testing in human subjects are today a necessary part of the development of new drugs. The use of experimental animals and human subjects is, however, a source of concern for the European public in general.

Biosimulation holds great hopes for the future in reduction, refinement and replacement of animal and human experimentation in drug development. Biosimulation, however, is a complex and difficult research field to understand and hence to appreciate by the public.

BioSim, a new EU sponsored Network of Excellence on Biosimulation – a New Tool in Drug Development has as a vehicle for its dialogue with the public established a workpackage on Bioethics and Dialogue with Public.

The objectives of the workpackage are to establish how and to which extend biosimulation can contribute to the resolution

of bioethical issues in drug development by reducing, refining and replacing animal and humane experimentation, establish how biosimulation can contribute to the implementation of the 3Rs (reduction, refinement and replacement) in animal and human research, establish if and how the 3Rs principle in animal research can be expanded to experiments on humans, increase awareness among European research groups involved in biosimulation of the 3Rs principle in animal research and improve the knowledge and understanding of biosimulation and its potential for resolving key bioethical issues in drug development in the European public.

The objectives and the workplan of the BioSim workpackage on Ethics and Dialogue with the Public will be presented.

Poster**Living United – a new international initiative on animal welfare and animal-human relations in action***Hanne Gürtler*

Living United Consult, Alleroed, Denmark

Animal welfare is a topic which interest many people. The way we use and exploit animals today and the conditions we provide for them raise many concerns in the public in many countries.

The views on animals and their use are today much polarised in the society as a whole and among different stakeholders and have over the years led to many confrontations between protectors and users of animals. The present speed of the technological development and the globalisation will not reduce these tensions. There is therefore a need for generating a common understanding on animal welfare issues and for developing practical and applicable solutions which balance the needs and welfare of animals and humans.

The implementation of new welfare initiatives is a common challenge for all users of animals. Therefore there should be an

increased dialogue, exchange of experiences and collaboration between the different users on the implementation of new welfare initiatives.

The purpose of the Living United Initiative is to bridge science, business and society and hereby contribute to an improved dialogue between science and society on issues related to animal welfare and animal-human relations, an increased dialogue, exchange of experiences and collaboration among users and between users and protectors and a decreased polarisation in society through broad stakeholder involvement, constructive dialogue, joint efforts and innovative communication.

The objectives of the Living United Initiative and the Living United Stakeholder Forum for communication of balanced solutions will be presented.



Poster

Population control of dogs and cats: a proposal for interacting education, research and society

Stelio Luna, Alfredo Lima, Paulo Steagall and Bruno Minto

FMVZ-UNESP, Veterinary Surgery and Anaesthesiology, Botucatu-SP, Brazil

The population of dogs and cats in Brazil is growing without control, as the Brazilian people have not assimilated the concept of responsible ownership. The increased population of dogs and cats lead to several public health problems. The capture and euthanasia is expensive, difficult and ethically compromising. The ovariosalpingohysterectomy and orchiectomy are the best methods to minimise overpopulation, as well as the conscience of the owner regarding the responsible ownership, registration and identification of the animals. This study aimed to perform surgical sterilisation of dogs and cats, to reduce their population, integrating the program with education and research, by using the same animals. The animals were selected from owners of low income. The surgeries were performed by undergraduate

and graduate students and residents under supervision, in practical classes and research projects. In 2004, 1028 dogs and cats were castrated, being about 70% female and 30% male dogs and cats. This project has reduced the population of dogs and cats, has provided an alternative method for teaching anaesthesiology and surgical technique and allowed the elaboration of 15 clinical research projects as an alternative to the use of animals specifically for teaching and research purposes. The student acceptance of the method was excellent, increasing their responsibility and dedication when compared to the use of the animals from the experimental kennel. The use of animals for research was avoided, integrating a public health campaign for the population, teaching and research under ethical principles.

Lecture

The development and implementation of public policies governing the use of animals in the life sciences – influences and outcomes

Margaret Rose

University of New South Wales, Prince of Wales Clinical School, Sydney, Australia

The Australian Code of Practice for the Care and Use of Animals for Scientific Purposes is the key policy document governing such use of animals in Australia and has been the basis for similar documents in New Zealand, Singapore, and Hong Kong. First published in 1969 as an initiative of the scientific community, the seventh edition was published in 2004. Today, revision of this code is the responsibility of a diverse group representing research institutions, funding bodies, regulators and animal welfare organisations; extensive public consultation is an essential part of this process. The principles of the 3Rs, the primacy of practitioner responsibility and the oversight by Animal Ethics Committees are fundamental elements of this code which, in recent years, has been incorporated into state legisla-

tion. Since the inception of this code there have been significant changes in community involvement in and expectations of how and why animals are used for scientific purposes. The ways in which this code, associated legislative changes and other public policies governing such use of animals have evolved in Australia against a background of increasing expectations of transparency, accountability and consultation are discussed and the involvement and influence of various stakeholders in setting policies and achieving outcomes is considered. As a scientific activity where the practitioner is expected to take primary responsibility for the welfare of the animals, the use of scientific evidence to inform such policies and the involvement of scientists in their formulation also is examined.



Lecture

Challenges and opportunities of animal welfare organisations in influencing and making public policy

Ursula G. Sauer

Deutscher Tierschutzbund, Akademie für Tierschutz, Neubiberg, Germany

For ethical and scientific reasons, the German Animal Welfare Federation strives for an end to all animal experiments. Therefore political activities lately have concentrated, amongst other issues such as cosmetics testing or the use of non-human primates in research, on the new EU Chemicals Policy, REACH. Its aim to submit not only new but also existing chemicals to an extensive evaluation scheme encompasses the danger that this might lead to a substantial increase in animal testing. To avoid this, the challenge to fundamentally revise an entire area of legislation should be taken as an opportunity to bring about a change in paradigm in safety testing and evaluation. The German Animal Welfare Federation has subjected the concept of the REACH system to an in depth scientific evaluation

and has put forward detailed proposals that ensure that the new Chemicals Regulation will serve to improve human health and environmental protection without the use of live animals. These proposals are continuously being brought forward to national and European politicians and members of relevant authorities, as well as to the public and other stakeholders representing industry and environmental or consumer protection organisations. Institutions that indirectly influence the new EU Chemicals Policy are also addressed, such as the OECD – responsible for international test guideline acceptance, or national and European funding institutions who can play an essential role in promoting the further development of appropriate non-animal test methods.

Poster

The ethics of research involving animals

Harald Schmidt

Nuffield Council on Bioethics, London, UK

The issue of animal research has aroused intense debate, particularly in the UK. It is unhelpful to view the discussion as being only between those who are in favour of research and those who are against it, since between these two poles of the spectrum there are a range of further positions. In May 2005, the Nuffield Council on Bioethics, an independent UK body examining ethical issues raised by new developments in biology and medicine, published a report on “The ethics of research involving animals”. This talk will focus on the conclusions made in the report, and present recommendations for future policy and practice. The principal ethical question considered is: is it permissible for one species to cause pain, suffering and death to another

to achieve aims that benefit primarily the former species? The report discusses the ethical arguments to foster an understanding of the debate, identify areas of agreement and understand what lies behind the remaining disagreement. The report concludes that further moral argument alone cannot provide a universal answer as to whether or not research on animals is justified, but practical advances in scientific method can reduce areas of conflict. For this reason, the importance of the 3Rs, and especially of the need to find replacement alternatives, cannot be overstated. Considering this, the report makes recommendations on improving access to information, the role of funding bodies, ethical review processes and implementation of the 3Rs.



Lecture

The role of national associations in promoting animal welfare

Ann Turner

American Association for Laboratory Animal Science, Memphis, USA

Voluntary associations play a significant role in the United States and globally in deliberating issues and establishing societal policies. Effective associations have advanced knowledge, skills, and attitudes in the arts and sciences because they promote research; disseminate information; provide education, training, and a forum for deliberation; and influence public policy in the governmental and private sectors. This presentation will enhance the understanding of how associations function and reach consensus on important society topics. A taxonomy of associations will be presented and the major functions of each type of association will be explored.

The role of the American Association for Laboratory Animal Science (AALAS) in advancing animal welfare will illustrate the impact of national associations on animal welfare and further

clarify how associations function. AALAS is the largest and oldest voluntary association in the United States devoted to the advancement of responsible laboratory animal care and use to benefit people and animals. The association encourages research; publishes research findings, opinion articles, and educational materials; develops position statements on animal science topics; provides education and training in print and electronic formats; promotes professional standards through certification; and sponsors an annual conference devoted to scientific and practice excellence. These endeavours promote the philosophy of the Three Rs (refinement, replacement, and reduction). Specific examples of how AALAS has promoted animal welfare throughout its 55-year history will be used to illustrate the dedication to implement the Three Rs philosophy.

Poster

The importance of understanding societal expectations and awareness on animal testing and alternatives

Sonja Van Tichelen

Eurogroup for Animal Welfare, Brussels, Belgium

The debate on animal welfare and in particular animal testing contains many different views, variations of tolerability, knowledge and emotions but it is widely recognised that the use of animals in research is a huge and growing social and political concern.

The opinion of a society and its citizens are and should be a key driver for policy makers. Legislation is a reflection of the values and morals of a given society in a given time. For policy makers it is essential to understand what citizens know and expect in order to produce laws which are accepted and respected. For politicians their popularity can depend on their stance for a particular cause.

Understanding societal expectations is of interest to all other stakeholders. Consumer research informs producers about what

their clients know and feel about animal testing. Differences between regions, age and social profile give international corporations the opportunity to fine-tune marketing messages and to adapt their animal testing policy.

For the animal welfare movement, the views of its members and society are an integral part of its advocacy work. It assists in deciding priorities, manage expectations and deliver information needs.

An overview of recent opinion polls and consumer research will attempt to give a insight in what citizens and consumer in this day and age think about the use of animals for scientific purposes and what the consequences are for policy makers, industry, scientists and other relevant stakeholders.



Lecture

International efforts to identify data gaps for the development of science-based guidelines for laboratory animal care

Joanne Zurlo¹ and Hilton Klein²

¹National Academy of Sciences, Institute for Laboratory Animal Research, Washington, DC, USA;

²Merck Research Laboratories, Laboratory Animal Resources, West Point, PA, USA

The goal of guidelines and regulations for laboratory animals is to provide for optimal animal welfare while facilitating the best science. While many guidelines are based on published data and scientific principles, others are based more on expert opinion and can vary widely among countries. In 2003, ILAR hosted an internationally-sponsored workshop on the Development of Science-based Guidelines for Laboratory Animal Care. The purpose of the workshop was to bring together experts from around the world to assess the available scientific knowledge that impacts current and pending guidelines for laboratory animal care. Platform presentations focused on issues ranging from mechanisms of regulation development across different countries to data-based studies on the effects of environmental enrichment on research outcomes. In discussion sessions, par-

ticipants were tasked with evaluating the current scientific literature on animal housing and environmental enrichment, identifying gaps in the current knowledge in order to encourage future research endeavours, and assessing the effects of current and proposed regulations on facilities, research, and animal welfare. During the point/counterpoint session to discuss the pros and cons of harmonisation of standards, most of the panel members expressed positive attitudes about working toward some form of harmonisation. There was a consensus among participants to continue the dialogue and to pursue an international effort to both identify data gaps and address the challenge of filling the gaps through additional research. Several activities have emerged as a follow-up to the workshop, and these will be discussed.