Theme II
Policy/Law on Animal Use, Public Engagement and Ethics Review

Session II-1: Public accountability

Session II-1: Oral presentations

Strategies and tools for effective public participation
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The presentation introduces the principles and best practices of public participation, tools that can be used in the different stages of a participatory process, and strategies to assess the effectiveness of the process. Public participation is widely recognized as a critical aspect in a variety of public accountability, policy, regulatory, and environmental processes. It is sometimes a regulatory requirement. Despite this, few policy and decision makers, managers, and scientists involved in these processes have formal training or professional development opportunities to build their capacity in planning for and implementing participatory processes. Many of these professionals “do” participation every day, but many do not have the opportunity to reflect on their practice or to contemplate ways to do it better. The presentation is designed to offer this opportunity and to introduce useful knowledge and tools that could help professionals and scientists engage the public to make sound policy and management decisions. Through effective public participation, the processes and outcomes of planning, policy, and decision-making are expected to be more efficient, equitable, and sustainable. The presentation draws on a curriculum on “participation basics” developed by FORREX in 2009 to address the needs of professionals whose job requires them to engage the public but who have not had any formal training in public participation.
Openness and public accountability – the why, who, what and how of it

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In recent years, a number of expert reviews\(^1,2\) have concluded that it is desirable for the public to have access to good information about the type of research undertaken using animals and the intended benefits, along with the number and species of animals used and the implications in terms of pain, suffering and distress for the animals involved.

Openness about animal research is also promoted both by animal protection organisations and representatives of those using animals\(^3\) – albeit from different perspectives. However, there is no single “public”, and “openness” can mean different things to different people.

This presentation will consider what is meant by “openness,” who has responsibilities and interests in this regard, and, using examples, it will discuss how it may be better achieved. It will cover:

- Bodies regulating the use of animals in research and testing
- Regulators whose requirements generate a demand for animal tests
- Local or institutional ethics (or animal care and use) committees
- Pharmaceutical and chemicals companies
- Academic institutions
- Research funders
- Professional scientific bodies and journals
- The media
- Animal protection groups

Simply increasing the amount of information provided in the public domain will not lead to better understanding or a more nuanced debate. Information has to be meaningful, and it has to be honest.

The use of genetically-engineered animals in research: An exploration of stakeholder opinions

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Regulation has been developed in response to public concerns about animal-based science. However, as new developments in biological research involving animals occur, public attitudes may be shifting. Understanding public attitudes towards the shifting use of animals in science is important; public monies fund animal-based studies, and the public are often beneficiaries. Our previous studies have shown that public acceptance of animal-based science increases when regulation is in place, but to a lesser extent for experiments involving genetically-engineered animals. To better understand these earlier findings, an interview-based study was conducted to explore the in-depth views of different stakeholders (n = 20 researchers, animal care staff and members of the public) regarding the creation and use of genetically-engineered animals in research. Responses indicated that interviewees were more willing to accept genetic engineering of animals if done for biomedical research, and were less willing to accept this use if the aim was to develop food for human consumption. There was universal agreement among participants that limits to genetic engineering should be established, any resulting pain and distress for animals should be minimized, and that better communication between the scientific community and the public is needed. Together, our studies provide examples of stakeholder engagement strategies that can be employed to understand the conditions under which people consider the use of animals in research to be acceptable.
There is widespread agreement that the provision of accurate, unbiased information is essential to an informed debate about the scientific validity and ethical justifications for animal experiments. As a practice usually regulated by public institutions, often financed by government and practiced within public institutions, animal experimentation is also a legitimate subject of concern for citizens and taxpayers. While mechanisms exist to increase transparency of public institutions, direct access to primary sources of information remains the “gold standard” and the objective of Freedom of Information (FoI) provisions. Nations and political cultures have different attitudes towards openness regarding the conduct of public bodies in general and animal experimentation in particular. Comparisons are made between the practices of different nations on this issue, with a particular focus on the US and UK. Consequences of greater disclosure and greater withholding of primary information regarding both conduct and regulation of animal experiments are examined, and perspectives on the suitability of animal experimentation as a subject of FoI specifically are explored. The value of alternative or complementary sources of information such as published scientific papers and project summaries are examined as well as the limitations of this information. Disclosure of primary information, ideally by a FoI mechanism, is of particular and unique benefit to the public, the scientific community and animal welfare and governments which do not currently facilitate this kind of transparency should review their practice and laws.

In spite of the advances made today to develop and disseminate information and guidelines for the care and use of laboratory animals in many parts of the world to improve the health, welfare, and psychological well-being of the research animals, using the Three Rs as a foundation in order to increase the accuracy, reproducibility and ensure quality control in the validity of animal based results, the trend is lacking in most developing countries. A comprehensive and systematic review of published reports revealed that adoption of the 3Rs, oversight by IACUC or an ethical committee on animal based research, and the forward looking towards alternatives to animal use in research are not visible in developing countries. These deficiencies may account for the lack of recognition of data from developing countries and be responsible for the absence of searchable reports comparable to those from the Western world and Far East. It is suggested that for developing countries to catch up on this matter, particular issues need to be addressed such as advocacy for involvement of governmental regulations, academic responsible conduct of research by investigators, institutional commitment to animal welfare in research as well as exposure to training opportunities by international resource agencies on animal care and use such as AAALAC and ILAR, before raised public awareness further worsens the already slow pace of scientific advancement in these countries.
Surveys of the UK adult population have shown that 70% agree with the use of animals in medical research. However, there are no comparable studies of young people. In 2006, the ethics of animal experimentation became part of all high school biology curricula. The aim of this study was to determine young people’s opinions on animal experimentation. A 20 minute presentation followed by the opportunity for students to ask questions on the use of animals in research was delivered in high schools within West Yorkshire, UK. Electronic voting handsets were utilised to gather student opinions before, during and after the session.

The seminar was delivered to 466 science students, aged 11-17, from 11 schools. The majority of students (78%) had never or only occasionally thought about the use of animals in research before the seminar, with only 37% either agreeing or strongly agreeing with their use. After the session, the level of acceptance had increased to 66%. When asked how new medicines should be tested, 31% thought that non-animal experimental preparations should be used, 24% would utilise animals, whilst 22% would use prisoners. Students also had serious misconceptions about practices in research laboratories, for example, 53% thought that animals were kept in small confined cages.

This study demonstrates the need for scientists to engage in outreach activities in order to provide young people with necessary information to enable them to make an informed decision for themselves as to whether the use of animals in research can be justified.

**Session II-1: Poster presentations**

**II-1-241**

**Meeting the 2013 deadline for cosmetic testing: an opinion on the status of alternative methods**

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In 2003 the European Parliament voted to end testing on animals for cosmetic purposes. The final installment of the ban is 2013 when it will become unlawful to sell cosmetics that have been tested for toxicokinetics, repeated dose or reproductive toxicity endpoints using animals outside of Europe. There is the risk however that this deadline can, and will, be extended due to a perception that these endpoints are not yet replaceable.

In an attempt to raise debate about the genuine status of alternative methods, the BUAV have produced a scientific review of the alternatives for the three remaining endpoints plus skin sensitisation and carcinogenicity which have been mistakenly included in the 2013 deadline. The report has been disseminated to European politicians and Commission experts. The report concludes that, should prevalidation studies be successful, full replacement of skin sensitisation and carcinogenicity should be possible by 2013. Toxicokinetics and reproductive toxicity studies are actually not always required for cosmetics due to low exposure and can already be replaced in part by *in vitro* methods. Repeated dose can be replaced by the implementation of strategy that combines the results from tests on key target organs *in vitro*, and in many cases can be waived through the use of the Threshold of Toxicological Concern (TTC) approach. The review concludes that the 2013 marketing deadline can be met with minimal impact to the cosmetic industry and that to extend it would undermine the excellent work done by industry to meet the deadline.
Veterinarians play an important role in the promotion and education of the 3Rs

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The veterinary profession has continued to develop since 2500 BC when the first evidence of the awareness of diseases in animals was found in Chinese writings. Today, veterinarians are highly trained in multispecies biology and comparative medicine and enjoy broad public support, are highly respected, and are consistently ranked among the most trusted members of society. As the veterinary medical profession continues to adapt to the needs of a changing society, the veterinarian has the ability to become a 3Rs advocate and educate the public on the importance of animal research alternatives. Veterinarians may be in the best position to educate and engage the public in the 3Rs because of their understanding of comparative animal health, their knowledge of animal welfare and behavior, and their ability to form a positive doctor-patient-client relationship. Veterinarians have the necessary experience to suggest valid options for replacement and reduction techniques in research. Their education in animal behavior, husbandry, disease control and welfare allows them to assess the need, importance, and effect of refinement in experiments. Finally, their ability to cultivate a doctor-patient-client relationship allows the veterinarian’s professional opinion to be taken seriously by the public. This support, led by veterinarians, could result in additional publicity, funding, and advocacy for the continued development and implementation of 3Rs protocols. A partnership-based cooperation among veterinary schools in the US and Canada to develop and implement alternative methods, and inclusion of study courses promoting 3R principles at undergraduate levels may help disseminate this knowledge further.

Activities of Ethics Committee on Animal Use (CEUA) of Oswaldo Cruz Foundation, Brazil

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The Oswaldo Cruz Foundation’s Ethics Committee on Animal Use (CEUA/FIOCRUZ) was established in 1999 to evaluate, from an ethical point of view, institutional activities involving animal use. These activities are related to animal breeding, research, drug and vaccine production, quality control and teaching. Nowadays CEUA/FIOCRUZ is composed of professionals from different areas such as veterinary, biology, statistics, medicine, pharmacy and a representative of animal rights. CEUA/FIOCRUZ works by receiving online protocols that contain an introduction, relevance of the projects, aims, crew and a detailed description of procedures. CEUA/FIOCRUZ receives around 100 projects per year, but, 3 to 5% of these protocols are not approved due to different reasons, for example, they do not comply with ethical principles or the coordinator of the project does not respond to required alterations. Despite all efforts to reduce the running time for evaluation of a project, CEUA/FIOCRUZ takes from 4 to 7 months to analyze a protocol. In order to guide researchers, a basic Guideline of Procedures is available at the website with information about anesthetics, routes of bleeding and injection, euthanasia, etc. CEUA/FIOCRUZ is working toward ensuring that researchers are conscious about using alternative methods when available, reducing animal number to a minimum required and improving the welfare of the animals when animals must be used.
In the vaccine industry, the main target population is healthy children and adults. Safety and efficacy of vaccines should be ensured to protect people against infectious diseases. For the development of novel vaccines (R&D) and the quality control of commercialized vaccines (industrial operations) (10% and 90% of the use, respectively), although major alternative methods have been and are being developed, the use of laboratory animals is still necessary and mandatory. However, in the last decade, the Reduction efforts achieved by Sanofi Pasteur appeared to be clear and important: absolute decrease of number of animals. The progresses are even better if the increase of the business and the R&D investments are considered in the meantime.

The presentation aims at explaining the Reduction initiatives and achievements, and the associated indicators.

- Effective reduction was gained by replacement methods, optimization of study design, waiving approach (removal or replacement by in vitro assays), and consistency.
- Relative reduction is highlighted by the internal indicators. For instance, the improvements of vaccine production and testing induced a drop of number of animals required to release vaccine batches. Also, the integrated research strategy provides more data to document the safety and the efficacy of novel vaccines with the same number of animals.

The commitment to reduce the use of animals is a long-term development. In addition to the animal care and use program, an institutional 3Rs program has been set up to focus on the ultimate goal, Replacement.

Public opinion surveys about animal experimentation that have been conducted by independent polling organizations, as well as those commissioned by groups for and against the practice, uniformly indicate that approval for it has declined significantly in the United States. The first national survey on the subject conducted in the late 1940s showed 84 percent of the public supported the use of animals in experiments. Today, depending on demographic factors, multiple sources suggest that support rests somewhere between 40 and 60 percent.

Since 2001, the Gallup Organization has annually conducted a national “Values and Beliefs” survey of approximately 1000 adults ages 18 and above to collect opinion data on 16 different controversial social issues, including “medical testing on animals.” An analysis of the data from the past ten years reveals a significant increase in moral opposition to medical testing on animals, as well as marked differences in attitudes toward the practice based on gender, age, political affiliation and level of education completed.

This paper discusses the 2001-10 Gallup data and offers possible explanations for these demographic differences and the general changes in the public’s attitude about this contentious issue.