

The International Symposium on Regulatory Testing and Animal Welfare: Recommendations on Best Scientific Practices for Animal Care in Regulatory Toxicology

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Introduction

An experienced and diverse group of toxicologists, animal care specialists, veterinarians, animal welfare advocates, and regulators met in this Breakout Group to review animal care best practice in regulatory toxicology. Participants (listed at the end of this report) had previously reviewed a number of key background references (also listed at the end of this report), which had been selected by the group's leaders before the meeting.

Report on Group Discussions

From the group's initial discussions, it was apparent that a significant change in the information available on best practice had occurred over the last 10 yr. Acceptance and implementation of best practice by those using animals and regulatory testing authorities had been hampered in the past by perceptions that there was a relatively small body of robust published studies. Much of best practice was perceived as anecdotal, making it difficult to convince some investigators and regulators that changes were needed. Over the last 10 yr, however, a much greater focus on animal care, an increase in resources to fund studies and greater international information exchange, often facilitated by the Internet, has greatly expanded the information available. This expansion is evident from the background reference list and other presentations at this meeting (Fillman-Holliday and Landi 2002; Gauthier 2002; Guittin and Decelle 2002). The key conclusion from the group's initial discussions was that enough information was now available to make robust recommendations for animal care best practices. Implementation, not information, is therefore the critical issue.

The group's discussion then focused on the best practices for animal care that should be prioritized for implementation. It was recognized that recommendations should take into account diversity of animal care and testing regu-

latory environments, public concerns regarding animal use, different cultural perspectives, and in some cases the resources available. The group unanimously agreed on the following principle: "There is an unequivocal link between good animal welfare and high quality science."

Recommendations

The recommendations listed below are considered current priorities that would focus greatest benefit on animal welfare.

Housing and Environment

- Do not normally house social animals singly (Dean 1999). This practice should apply to rodents and rabbits as well as dogs, pigs and non-human primates (Dean 1999).
- Ensure that animals are compatible. Promptly manage any antagonistic interactions that do occur in the short term, but also address the underlying reasons for the occurrence (Jennings et al. 1998; Reinhardt and Reinhardt 2000).
- The need for single housing of rodents to allow dietary optimization to ensure survival in long-term studies should be justified on a study-by-study basis. Further work is recommended to examine this issue (Boyer et al. 2000; Hooks and Harling 2001).
- House rodents normally in cages with solid bottoms, bedding and environmental enrichment (AAALAC 2000; Manser et al. 1998).
- Well-implemented enrichment may reduce variability rather than increase it (Knight 2001; personal communication, 2001, based on information on the effect of environmental enrichments on variation and group sizes on the outcomes of scientific procedures, submitted by Federation of Veterinarians of Europe, Royal Society for the Protection of Cruelty to Animals, International Society for Applied Ethology to the Working Party for the Preparation of the Fourth Multilateral Consultation of Parties to the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes).

Conduct of Experimental Procedures

- Select methods of sample collection and substance administration based on current scientific information.

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- High-quality information that balances welfare and practicality exist (Diehl et al. 2001; Morton et al. 2001).
- Retro-orbital blood collection in rodents should be authorized only on a study-by-study basis and only under exceptional circumstances (van Herck et al. 2001; van Herck 1999).
- International fora to share best practice within the regulatory toxicology community, especially from internal studies, are important.

Control of Pain and Distress

- Animal pain and distress should be only the minimum necessary to carry out the procedure.
- There is general public support for the necessity of animal use to ensure substance safety, even when opposition is perceived to be high (RDS 2000). However, any resulting pain and distress from safety testing is of great concern (Aldhous et al. 1999; HSUS 2001).
- Animal Care Committees (ACCs¹) should ensure that any pain and distress are absolutely necessary for the study, that procedures are refined (Morton et al. 2001), and that humane end points are used (OECD 2000).

Implementation

- All stakeholders should adhere to the principles of the 3Rs.
- ACCs, also known as institutional animal care and use committees or ethical review committees, should require robust and current scientific justification for exceptions to these positions.
- Authorities regulating animal use should ensure that ACCs meet this responsibility.
- The International Council for Laboratory Animal Sciences (ICLAS) should promote these positions and encourage other organizations to add their support.
- Regulatory testing authorities should publicly support these positions.
- All information should be shared internationally.

Recommendations for Future Work

- Regulatory testing authorities and authorities regulating animal use should jointly ensure a continuing mandate for animal use by direct public dialogue.
- Comparison studies are needed for a wider range of different sampling and dosing techniques.
- A wider range of different enrichment methods and bedding materials require validation and certification to en-

sure a range of enrichment options are acceptable to regulatory testing authorities.

- Studies that compare survival, body weight, and clinical observations of different rodent strains in social and enriched environments for long-term protocols are needed.
- Discussion of new positions should include international perspectives.

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¹Abbreviation used in this presentation: ACC, animal care committee.

- periments provided that certain criteria are met. News May 2000. <http://www.rds-online.org.uk/aboutrds/news_may00_01.html>.
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