The relevance of legal frameworks governing use of animals in laboratories

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http://www.hsi.org/issues/advancing_science/
About HSI

- Among the world’s largest & most respected animal protection organizations
  - 11 million supporters worldwide
- Offices/personnel in Australia, Brazil, Canada, China, Costa Rica, Europe, India, Japan & the United States
  - Global network of partner organizations
- Constructive & science-driven approach
  - Working with companies, academic scientists, elected officials, regulators & civil society stakeholders
Protecting animals used in laboratories: a global perspective

• Where are animals used, and which species?
• How many animals, and what are they used for?
• How to ensure basic welfare standards are met?
  • trade; legislation; self-regulation (CSR/voluntary codes); OIE;
• How to ensure use of 3Rs test methods
• How to identify the best systems and means of enforcement?
How many animals?

• 2008 Taylor *et. al* estimate 115+ million globally.
  • *Known figures* *(eg EU member states)*
  • *Extrapolations* *(eg types of animal used and species)*
  • *Publications* *(proportions of animals used to publication)*

* More conservative estimates 60 million, no exact figures.
Increasing numbers and locations

- UK statistics on animal use show increasing numbers; UK and Canada over 4 million last year.
- AAALAC reports growth in Pacific Rim labs seeking accreditation.
- New countries being added to OECD Mutual Acceptance of Data arrangements, signalling competence for international regulatory test involvement (Argentina, Brazil, India, Malaysia, South Africa and Singapore).
‘Self Regulation’?

• AAALAC: accreditation requires effort on the part of user establishments to apply basic welfare standards and demonstrate knowledge.

• Institution-level ethical committees and oversight mechanisms eg: India.

• Corporate Social Responsibility charters: mention AAALAC, training, understanding that contractors are as responsible as contracting company.
Legislation

- EU Directive 2010/63 (compulsory 3Rs application; prior authorisation; classification of pain distress and suffering; objective of reducing and eventually eliminating animal use).
- India: Prevention of Cruelty to Animals Act with delegated powers to institution-level through the and Supervision of Experiments on Animals (CPCSEA).
**OIE guidance on ‘oversight mechanisms’**

- **OIE Terrestrial Code**
  - Chapter 7.8: use of animals in research and education
  - Advice on elements to incorporate including
    - application of the 3Rs
    - prior authorisation
    - standards for housing and care
    - inspections
    - veterinary care
    - procurement
Public Values and Advocacy Campaigns: Be Cruelty-Free

South Korea: 7 out of 10 people support a national animal testing ban for cosmetics
Brazil: Two out of 3 people support a national ban
Japan: (source: LUSH Japan) Nearly 90 percent responded that “I don’t want manufactures to use ingredients in cosmetics whose safety cannot be determined unless they are tested on animals.”
Canada: 8 out of 10 people support a national cosmetics animal testing ban
‘3R Best Practices’

- Some sectoral requirements prescribe redundant animal testing (e.g., pesticides, pharmaceuticals)
  - Multiple exposure routes (oral + skin + inhalation)
  - Multiple species (rodent + dog or rabbit)
### Case Study: Revision of European Pesticide Industry Data Requirements

<table>
<thead>
<tr>
<th>1. Toxicokinetics</th>
<th>11. 28-day dermal CR</th>
<th>21. Chronic (1y) dog</th>
<th>31. Avian acute oral*</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. Skin sensitization*</td>
<td>17. Mouse spot CR</td>
<td>27. Neurotoxhen CR</td>
<td>37. Fish lifecycle CR</td>
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<tr>
<td>8. 90-day oral rat</td>
<td>18. Vivo cytogen. CR</td>
<td>28. Dermal absorpt.</td>
<td>38. Fish bio[ ]</td>
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<tr>
<td>10. 28-day oral CR</td>
<td>20. Chronic (2y) rat</td>
<td>30. Livestock feed*</td>
<td>...</td>
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</tbody>
</table>

*ACTIVE INGREDIENT + FINISHED PRODUCT  CR = CONDITIONAL REQUIREMENT
3R Progress Through Revision of EU Pesticide Data Requirements

More than 80 3Rs amendments were adopted by the EU Parliament & Member Countries

- All OECD 3R guidelines taken up
- Deletion of 1-year dog study
- Shift from ‘unconditional requirements’ toward flexible testing

Potential for animal use reduction of ±50% without compromising human health or environmental protection

Possibly largest-ever one-time reduction in in vivo data requirements in a regulated product sector
3Rs Best Practices: Uptake Globally

CANADA
- HSI in discussions with Health Canada

INDIA
- HSI & FIAPPO meeting with Central Insecticides Board
- Revision of test guidelines

UNITED STATES
- HSI/HSUS, PCRM, PETA, IIVS & industry in discussions with US EPA
- Progress toward endpoint-combining, reduced LLNA, waiving fish bio-[], etc.
Case Study » Brazil

REGULATORY SCIENCE WORKSHOP

-> 29-30 Nov 2012, Brasilia – Satellite to COLAMA Congress

• Pre-workshop satellite meeting on 21st century toxicology
  • Presentations from US EPA, AXLR8, Fraunhofer Institute, others

• Overview of cosmetics regulation in ICCR regions
  • ANVISA, European Commission, US FDA

• Present current state-of-the-art re. use of non-animal methods for cosmetic safety assessment
  • Case studies by L’Oréal, BASF, ABC Brazil, IIVS, SeCAM, others
• FP7 DG RTD health-funded coordination action

• To fulfill the growing need for coordination among predictive safety assessment projects

• To provide tools for increased networking, strategic planning & collaboration with the goal of accelerating the transition toward more predictive, non-animal approaches in toxicology in line with the NRC “pathway paradigm”
Challenges and ambitions

- Identify the bottlenecks, sector by sector.
- Advocate for a joined-up approach so that the most advanced testing strategies are always used.
- Find the right ways to introduce appropriate flexibility and opportunities to improve.
- Create new mechanisms to discuss and agree practical applications worldwide.
Research /regulatory applicability

- Focus research establishing Adverse Outcome Pathways on meeting regulatory need.
- Use the best existing structures and create new ones where necessary.
- Continue to involve all stakeholders and regulators: independent research is needed that benefits all users.
- Remind regulators that animal methods are not ‘gold standard’.
Legislation: collaboration needed

- Use OIE guidelines.
- Encourage companies through CSR and AALAC to advance regulatory ambitions.
- Underline shift to non-animal approaches in regulatory testing and biomedical research.
- 115 million animals, high levels of pain distress and suffering, both deliberate and accidental.
- Animal welfare advocates, veterinarians, regulators and citizens.
Thank You!

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Our Objectives

- Near-term reduction in animal use through uptake of ‘3R best practices’ in product sector regulations
- Accelerated shift toward a (predominantly) non-animal testing approach based ‘adverse outcome pathways’
- Global policy shift
  - ‘Mandatory alternatives’ measures
  - Ending animal testing for cosmetics
  - Coordinated action to maximise benefit of further research.