

## **TOXBANK Public Forum**

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## **An Ethical Perspective**

#### **Emily McIvor**

Policy Director, Research & Toxicology Department, Humane Society International emcivor@hsi.org | hsi.org











#### **About HSI and our affiliates**







#### Research and Toxicology Department actively engaged with:

- The Be Cruelty-Free campaign: ending cosmetics testing world-wide
- OECD Test Guidelines, Chemicals & AOP development programs
- EU Competent Authorities for REACH and Classification and Labelling
- European Chemicals Agency Member State Committee, Endocrine Disruptors Expert Group, etc.
- USTR Trade and Environment Policy Committee & TTIP negotiations
- NTP Scientific Advisory Committee on Alternative Toxicological Methods
- European Union Reference Laboratory for Alternatives (EURL-ECVAM)
- European Partnership for Alternative Approaches to Animal Testing
- International Cooperation on Cosmetics Regulation & national laws
- International Conference on Harmonization (via ICAPPP)
- Human Toxicology Project Consortium
- Implementation of EU Directive 2010/63
- Replacing animals used in biomedical research
- ... and many others



#### Statistics on Animal Use UK 2014

- 3.87 million procedures were completed;
- 8% (150 thousand) were assessed as severe;
- Tox studies frequently require death as an endpoint.

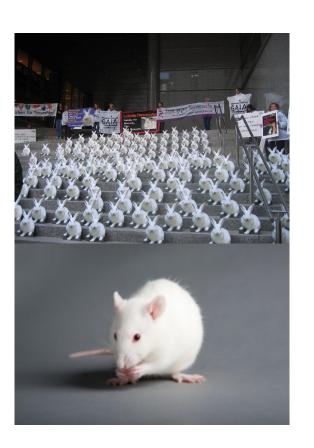
#### Severe classification (EU categories) includes:

- (i) use of metabolic cages involving severe restriction of movement over a prolonged period;
- (j) inescapable electric shock (e.g. to produce learned helplessness);
- (k) complete isolation for prolonged periods of social species e.g. dogs and non-human primates;
- (I) immobilisation stress to induce gastric ulcers or cardiac failure in rats;
- (m) forced swim or exercise tests with exhaustion as the end-point.



## **Public Opinion: IPSOS/MORI Survey**

#### Attitudes to animal research in 2014



Commissioned by the Department for Business, Innovation & Skills (BIS):

- 68% agree acceptable 'so long as it is for medical research purposes and there is no alternative';
- 37% endorse use of animals for all types of research;
- 69% can accept such research 'as long as there is no unnecessary suffering to the animals';
- Almost a quarter of the public (23%) believe that the UK Government should ban the use of animals for any form of research.



## **Ethical approaches: 3Rs at EU Level**

- Treaty for the Functioning of the European Union, 2009
- Article 13: animals defined as sentient beings
- Animal welfare a "European Value"
- Animal Welfare Action Plan (broad strategy)
- Directive 2010/63: 3Rs legal requirement
- Product safety laws: comply/complement
- 2015 Citizens' Initiative "Stop Vivisection"
- 2016 EU Commission conference
- Questioning validity, evaluating plans



## EU Directive 2010/63 EU: 3Rs Requirements + Drivers

#### 1) 3Rs implementation

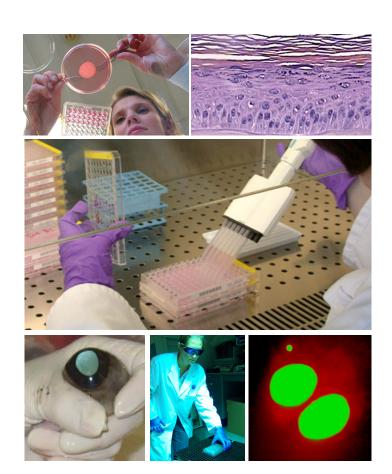
- Required by law
  - Includes breeders, suppliers and users
  - Covers housing, procedures, euthanasia

#### 2) 3Rs innovation

- European Union Reference Laboratory (EURL includes ECVAM)
  - Extended remit from reg. tox to biomedical
  - Network of contact points

#### **Member State contributions**

- Strategy setting, national and EU
- Promote development and uptake





## EU product safety legislation: supporting 3Rs

#### 1) 2006 'REACH' chemicals regulation

- lists 'promotion of alternative methods for assessment of hazards' as one of three main objectives
- requires data-sharing, one substance one registration (OSOR)
- Requires updates to test requirements
- Requires updates to list of accepted tests
- 2) 2003 cosmetics directive "7th Amendment"
- Phase out animal testing, phase in marketing ban (complete 2009 + 2013)
- 4) 2012 biocides reg. and pesticide data requirements
- 3Rs best practice, data sharing









## Drug development without animals?

- 95% new drugs deemed safe and effective in animal studies fail at clinical trial stage.
- Toxicology undergoing transformation: 2007 US National Institutes of Health, "Toxicology for the 21st Century";
- Efficacy testing under growing scrutiny:
  - Asthma: two new classes of drugs in 50 years;
  - MS: 99% candidate medicines failed;
  - AD: no progress . . .







(Photo credits: MatTek; NIH)

## **UK "Delivery Plan": Goals and Problems**

2010 UK "Coalition Agreement": included promise to reduce animal use identified problems:

- "Exporting" tests to overseas countries where welfare standards may be lower;
- Need for as yet undiscovered technologies;
- Conservatism and a risk- averse approach to adopting change;
- Conservatism on the part of journal editors and peer-review panels to accept publications based on non-animal techniques in lieu of the "traditional" animal models;
- Global market can mean repeat testing using animal method.

#### **Opportunity:**

 Recogition of significant economic benefits associated with new technologies.





# Stepping back: the humanitarian tradition Henry Salt (1892):

"We have to decide, not whether the practice of foxhunting, for example, is more, or less, cruel than vivisection, but whether *all* practices which inflict unnecessary pain on sentient beings are not incompatible with the higher instincts of humanity."

## **Leo Tolstoy:**

"As long as there are slaughterhouses there will be battlefields."



### **Conclusion**

- Changing attitudes, new technologies;
- Changing relationships: environment; animals, each other;
- Political change reflecting public opinion where next?



## Thank you for your attention



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hsi.org

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Humane Society International

emcivor@hsi.org