



Evaluation of Humane Endpoints for Pertussis Vaccine Safety Testing

Welcoming Remarks and Introduction

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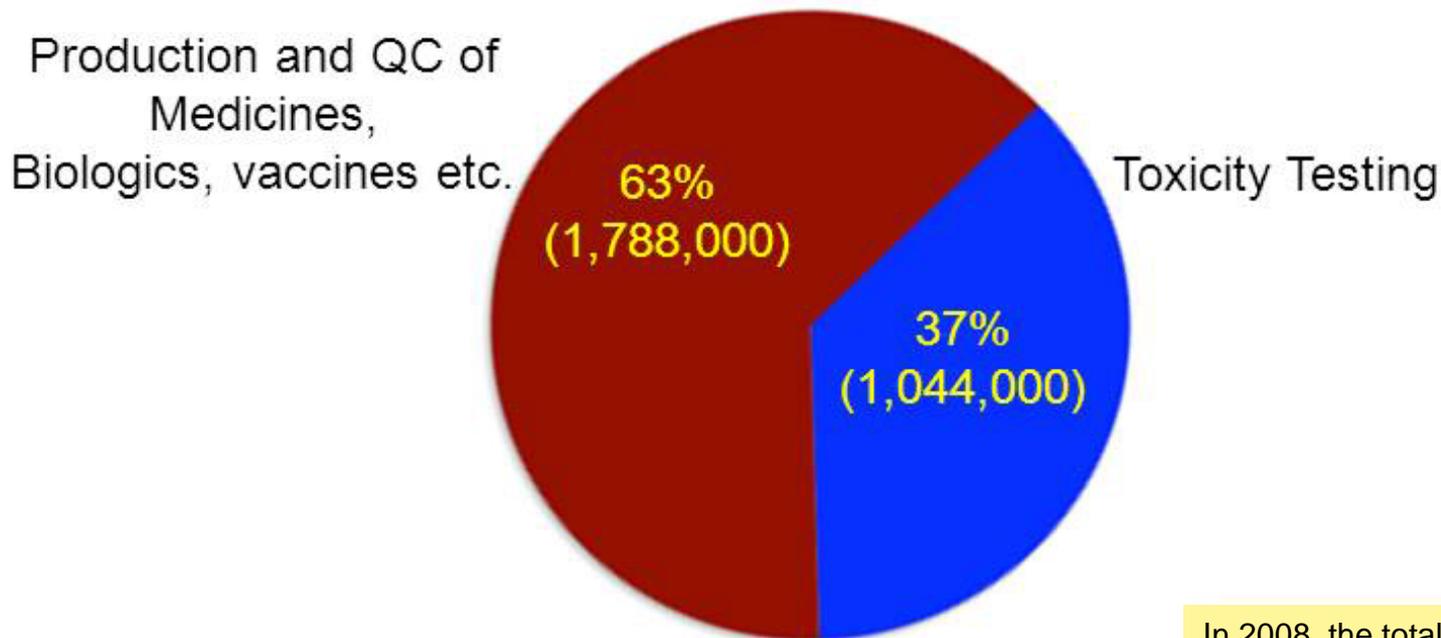
November 27, 2012

William H. Natcher Conference Center
Bethesda, MD



Animals Used for Testing by Major Categories (EU 2010)

Total EU annual animal use for testing: 2,832,000



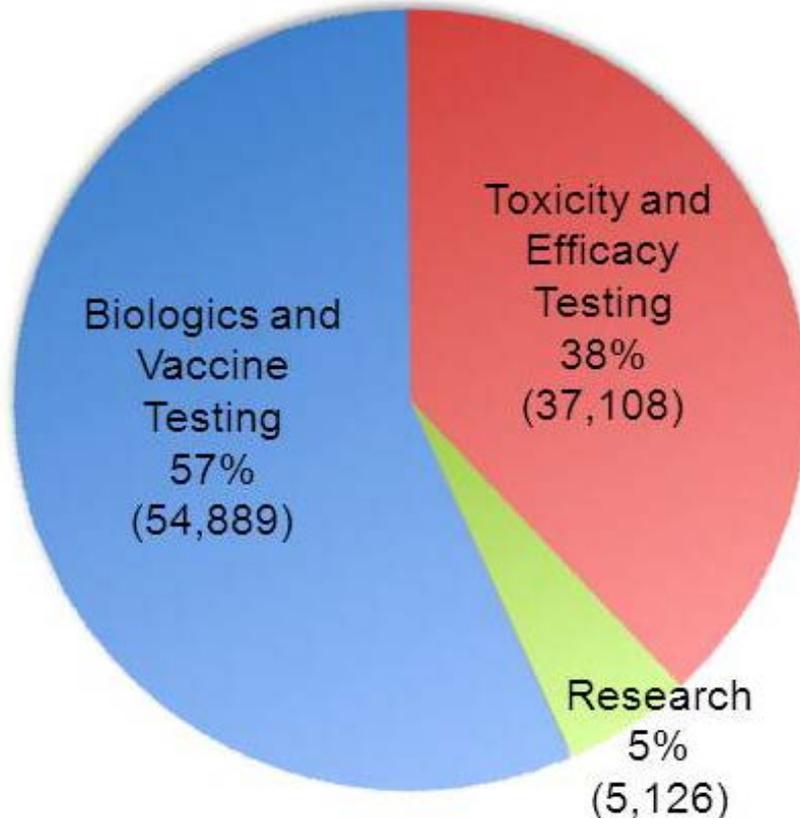
In 2008, the total number of animals used for experimental and other scientific purposes amounted to just over 12 million

Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union COM(2010) 511



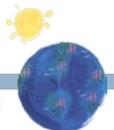
Use of Animals for Testing that Involves Unrelieved Pain and Distress (No Pain Relievers Used)

Animals by Testing Type
Reported to USDA (2010):



- 57% (54,889) of the animals reported to USDA that experience unrelieved pain and distress are used for testing Biologics and Vaccines
- Including rats, mice, and birds (not reported to USDA):
 - Est. 2 million animals used for testing that involves unrelieved pain and distress (in the U.S.)

Data for all states with all animal data for Column E of APHIS Form 7023; USDA. 2010. Annual Report - Animal Usage by Fiscal Year. United States Department of Agriculture. Animal and Plant Health Inspection Service. Available at: http://www.aphis.usda.gov/animal_welfare/efoia/7023.shtml



Humane Endpoints for HIST



Evaluation of Humane Endpoints for Pertussis Vaccine Safety Testing

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November 27, 2012 – 2:00-4:00 p.m.
William H. Natcher Conference Center
National Institutes of Health
Bethesda, Maryland, USA

Organized by members of the International Cooperation on Alternative Test Methods:
NICEATM - National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods
ICCVAM - Interagency Coordinating Committee on the Validation of Alternative Methods
EURL ECVAM - European Union Reference Laboratory for Alternatives to Animal Testing
JaCVAM - Japanese Center for the Validation of Alternative Methods
KoCVAM - Korean Center for the Validation of Alternative Methods
Health Canada

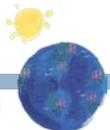
For more information, please contact NICEATM:
<http://iccvam.niehs.nih.gov/> — (919) 541-2384 — niceatm@niehs.nih.gov

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ICCVAM Agencies:

• Agency for Toxic Substances and Disease Registry	• Department of Energy	• National Institute of Environmental Health Sciences
• Consumer Product Safety Commission	• Food and Drug Administration	• National Institutes of Health
• Department of Agriculture	• National Cancer Institute	• National Library of Medicine
• Department of Defense	• Department of Transportation	• Department of the Interior
	• National Institute for Occupational Safety and Health	• Occupational Safety and Health Administration
		• Environmental Protection Agency

- The most widely used (US and EU) test for absence of residual PTx activity in acellular pertussis containing vaccines is an *in vivo* test based on a lethal histamine sensitizing effect in mice (HIST)
- As an alternative to the lethal end-point assay a more sensitive histamine sensitization test based of measurement of rectal or body temperature in mice has been developed
- Use of body temperature as an endpoint is currently approved in Japan and by the WHO

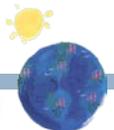


First Presentation

Highly Sensitive Histamine-Sensitization Test for Residual
Activity of Pertussis Toxin In Acellular Pertussis Vaccine
Using Body Temperature Monitoring

Masaki Ochiai, PhD

National Institute of Infectious Disease, Japan



Second Presentation

In Search of a Humane Endpoint for the Histamine Sensitization Assay

Juan Arciniega, DSc,

Center for Biologics Evaluation and Research, U.S. FDA

Open Discussion

