



Interagency Coordinating Committee on the Validation of Alternative Methods

Metrics: Measuring Success in the 3Rs

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

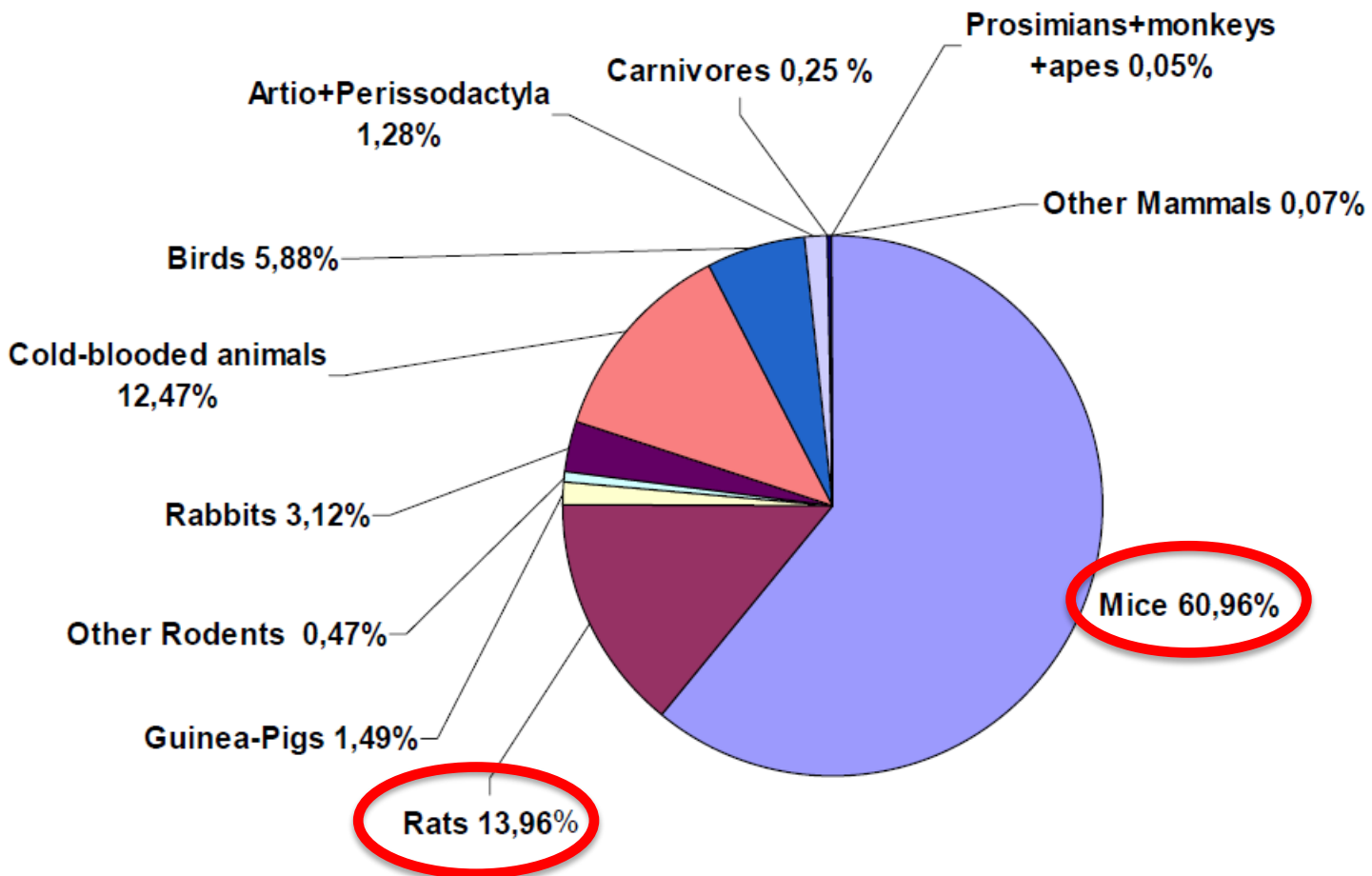
The Issue

- SACATM and multiple stakeholders have encouraged ICCVAM to develop metrics to determine the impact of the 3Rs in regulatory testing
- ICCVAM is looking into approaches to develop metrics

EU Requirements

- Council Directive 86/609/EEC
 - Laws, regulations, and administrative provisions regarding protection of animals used for experimental and other scientific purposes
- Article 13: Collect statistical information on the use of animals in experiments for scientific purposes in the EU (any live non-human vertebrate)
- Article 26: Report data every 3 years

Figure 1.1
Percentages of animals used by classes in the Member States

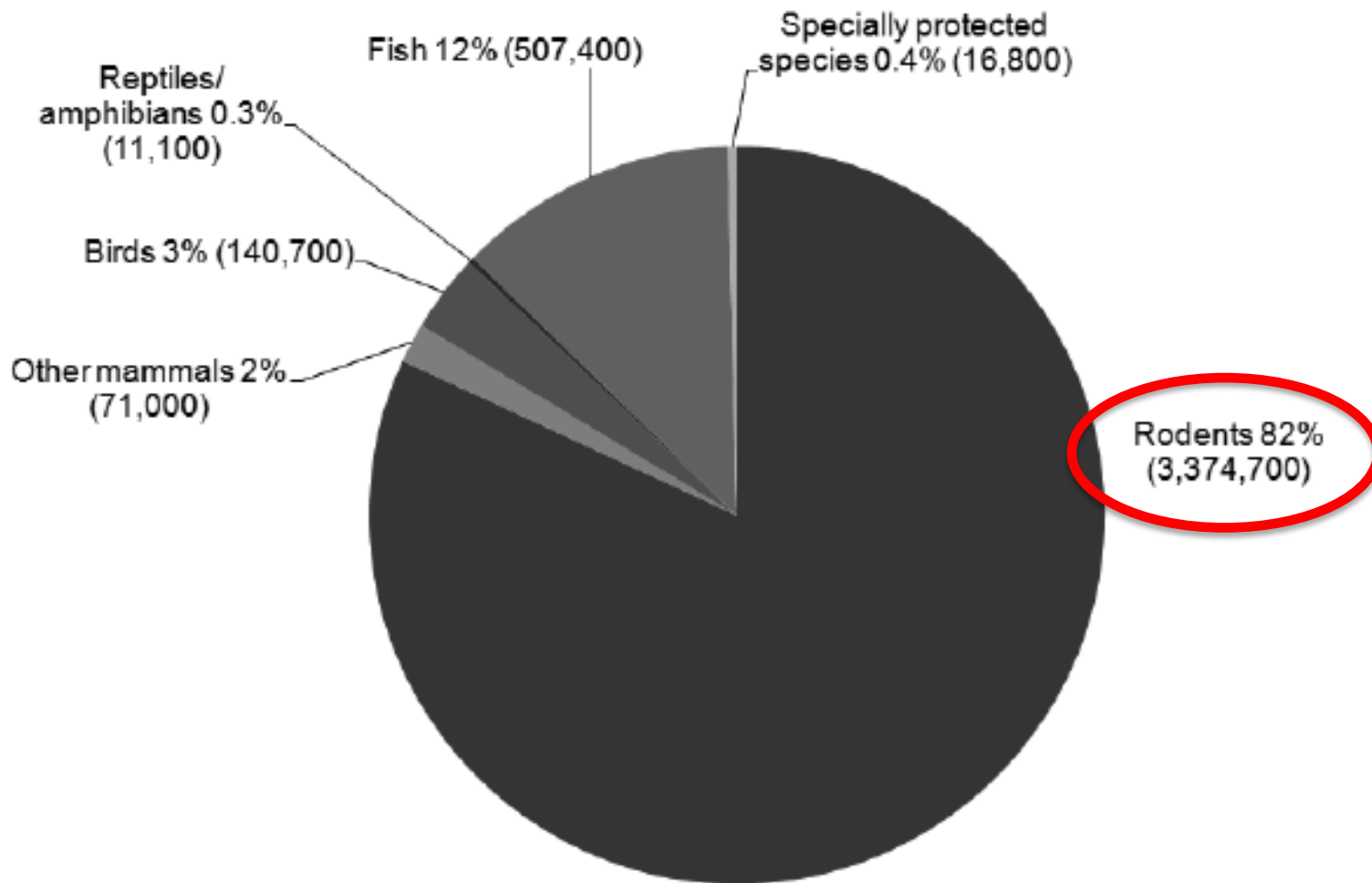


From: Seventh Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union

UK Requirements

- Animals (Scientific Procedures) Act 1986
 - Applies to any living vertebrates other than humans
- Section 21(7): “The Secretary of State shall in each year publish and lay before Parliament such information as he considers appropriate with respect to the use of protected animals in the previous year for experimental or other scientific purposes.”

Figure 3: Procedures by species of animal, 2013



U.S. Animal Welfare Act

- United States Code (USC)
Title 7 – Agriculture
Chapter 54 – Transportation, Sale, and Handling of Certain Animals
Sections 2131 – 2159
- Covered species includes: Dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warm-blooded animal
- Covered species does not include: Birds, rats of the genus *Rattus* and mice of the genus *Mus*, bred for use in research
- Based on EU and UK numbers, likely missing >70% of the animals used in research and testing

Challenges in Developing U.S. 3Rs Metrics....Here a few

Developing metrics & interpreting metrics

- Different regulatory structures among U.S. agencies
 - E.g., degree to which submitted data can be made publically available
 - Testing performed under regulatory schedules vary
- R&D testing done within companies (i.e., not submitted to regulatory agencies) which may not be submitted
- Testing done in other countries and submitted to U.S. agencies
- Outdated filing/data submission systems
- Data requirements in other countries: Studies not required in the U.S. but still required other places

Charge Question for SACATM

- Please provide comments or suggestions related to methods and approaches that could be used by ICCVAM to prioritize activities and measure their subsequent success.