

# A Global View of Animal Experiments 2014

# 1 Executive Summary

This paper, produced as part of the Lush Prize, which rewards initiatives to end animal testing, looks at the issues surrounding animal testing globally (particularly in toxicology) and the difficulty of determining an accurate level of animal use and suffering. There are few countries where animal testing does not take place; yet, whilst in some countries a lot is known about animal research, this is not the case on a global level. Reasons for variation in data availability include tradition, politics, financial implications and culture.

For proper and transparent discussion to take place about the scientific and ethical issues surrounding animal experiments there needs to be an understanding of the level and types of experimentation, the species used and the harm done to individual animals. Only when we have this information can the impacts of regulation and the uptake of non-animal testing methods be adequately monitored.

It is clearly no easy task to accurately determine the extent of animal experiments on a global scale. Taylor et al., in their 2008 paper<sup>1</sup>, came the closest to understanding the worldwide scale of animal testing with their estimate of 115.3 million animals in 179 countries, a huge figure but still one which they concluded "is still likely to be an underestimate".

We have compared their data with new data for eight of the largest countries and used the same adjustments to get a picture of use today. This appears to show a small increase total in animal use over time across the countries concerned.

	2005 Estimate	2012 Estimate	% increase
USA	17,317,147	7 16,194,10	-6.49
Great Britain	1,874,207	2,738,50	46.12
Germany	1,822,424	1,566,37	7 -14.05
Canada	2,316,283	L 3,333,68	43.92
France	2,325,398	3 2,200,15	-5.39
Italy	896,966	5 781,81	.5 -12.84
Autralia	2,389,813	3 2,614,83	9.42
Spain	595,597	7 900,12	51.13
	29,537,833	3 30,329,59	2 2.68
Global Estimate	115,300,000	0 118,390,04	0
Estimated number used in			
toxicity tests	9,224,000	9,471,20	03

<sup>1</sup> Taylor, K., Gordon, N., Langley, G., Higgins, W. Estimates for Worldwide Laboratory Animal Use in 2005. ATLA 36, 327–342, 2008



Data on animal testing are not available for all countries that use animals. Statistics are still not available for the now significant economies of Brazil, China and India for example. Even where it does exist, it usually excludes some animals. For example, those killed to supply tissues (an additional 21% of animals); genetically-modified animals used solely to maintain established breeding colonies (an additional 34%); animals bred for use in labs but killed as 'surplus to requirements' (50% of mice and rats according to industry figures); some foetal and embryonic forms; and certain invertebrate species.

Ensuring that all countries that continue to experiment on animals publish accurate and comparable data would go a long way to aiding the important discussions of the level of animal testing, its purposes and the extent to which animals suffer. The level of toxicology testing involving animals, of particular relevance to the Lush Prize, could also then be determined.

# 2 Introduction

Animal testing takes place all over the world, using millions of animals, many in experiments causing severe pain and distress. Yet, how many animals are used? What species? What are they used for? What levels of pain do they experience? These questions are not so easy to answer on a global scale.

For proper and transparent discussion to take place about the scientific and ethical issues surrounding animal experiments there needs to be an understanding of the level and types of experimentation, the species used and the harm done to individual animals.

Accurate information is also necessary if the impacts of regulation and the uptake of nonanimal testing methods is to be adequately monitored.

Globally, there are very few countries where animal testing does not take place. Only two countries are known to have banned all experiments on animals: the European Principality of Liechtenstein in 1989 and the little heard of Republic of San Marino (an enclave situated in central Italy) in 2007<sup>2</sup>. These are amongst the very smallest countries in the world<sup>3</sup>. Another of the world's smallest countries, Malta, appears to have reported no animal use for scientific purposes until 2008, when it declared the use of 690 animals<sup>4</sup>; however, it does seem as though some experiments may have been taking place in Malta for at least a decade before it joined the EU in 2004<sup>5</sup>.

<sup>2</sup> Knight, A. The beginning of the end for chimpanzee experiments? Philosophy, Ethics, and Humanities in Medicine 2008, 3:16

<sup>3</sup> Countries by area. One World Nations Online.

http://www.nationsonline.org/oneworld/countries\_by\_area.htm. Accessed 10.4.14

<sup>4</sup> European Commission. Sixth Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union (2010)



There is considerable variation in the availability of data on animal testing in different countries. In some, such as Europe, North America and Australasia, data on numbers of animal tests are available in the form of annual reports published by the national or regional bodies responsible for regulating animal testing. In many countries (such as China) no such gathering of statistics, or even regulation of animal use in laboratories, exists. Even where data are available they are rarely consistent in their approach, covering varying species and procedures, making comparisons and analysis extremely difficult.

A recent book<sup>6</sup> looking at global regulations on animal testing notes that there are differences in the way principles behind regulatory frameworks of animal testing are defined: "When principles are enshrined in legislation, legislators inevitably feel the need to provide definition and to establish clear boundaries between what is legal and what is not. This is the reason for the variation in standards that we so frequently find across countries or geopolitical areas."

Reasons for variation include tradition, politics, financial implications, pragmatism, culture, etc. "This creates the current situation where we all speak about the same aims and follow the same principles, but where animals are treated differently in practice"<sup>7</sup>. Although the book looks at legislation in many parts of the world it notes the difficulty in identifying specific information on regulations in African and Arabian countries.

The British Home Office, the body overseeing animal experiments, notes<sup>8</sup> that: "The overall level of scientific procedures is determined by a number of factors, including the economic climate and global trends in scientific endeavour. In recent years, while many types of research have declined or even ended, the advent of modern scientific techniques has opened up new research areas, with genetically modified animals, mainly mice, often being required to support these areas."

A 2008 study<sup>9</sup> found that, although eight of the top ten countries using animals in laboratories do produce statistics, of the total 47 countries with evidence of considerable animal use (based on a bibliographic search of published papers in 2008), "annual statistics could only be obtained for 30 of them (64%). Assuming that only those countries with specific legislation to control animal experiments produce statistics, it seems there may be minimal legislation in most countries in which animals are used in research and testing". The authors obtained confirmation that Indonesia, Nepal, Pakistan and The Philippines do not provide publicly available statistics.

<sup>5</sup> Scerri, C. Animal experimentation in Malta: regulatory processes and future perspectives. Malta Medical Journal. Mar2009, Vol. 21 Issue 1, p19-25

<sup>6</sup> Guillen, J. Laboratory Animals: Regulations and Recommendations for Global Collaborative Research. Academic Press Inc., 2013

<sup>7</sup> Guillen, J. Laboratory Animals: Regulations and Recommendations for Global Collaborative Research. Academic Press Inc., 2013

<sup>8</sup> Home Office. Annual Statistics of Scientific Procedures on Living Animals Great Britain 2012

<sup>9</sup> Taylor, K., Gordon, N., Langley, G., Higgins, W. Estimates for Worldwide Laboratory Animal Use in 2005. ATLA 36, 327–342, 2008



# 3 About the Lush Prize

The Lush Prize aims to speed the introduction of non-animal testing, particularly in toxicity testing for consumer products and ingredients. It does this by providing a £250,000 annual fund to reward effective projects and individuals working in five areas of campaign, lobbying and research.

The Lush Prize is a major initiative aiming to bring forward the day when safety testing takes place without the use of animals and complements the many projects already addressing the use of animals in medical testing.

# 4 Global data

Given the fact that many countries do not produce data on animal testing, accurately determining the extent of animal experiments on a global scale is no easy task. The most recent reliable source of data on the worldwide use of animals in labs was published in 2008 and based on statistics for 2005<sup>10</sup>. Data was collated for 37 countries that published national statistics and a statistical model applied for a further 142 countries. This resulted in a conservative estimate of global animal use of 58.3 million animals in 179 countries. Further extrapolation was conducted to produce "a more comprehensive global estimate that includes animals killed for the provision of tissues, animals used to maintain genetically-modified strains, and animals bred for laboratory use but killed as surplus to requirements" (as published data often excludes these). This resulted in a figure of 115.3 million animals, which the authors concluded "is still likely to be an underestimate".

We have compared their data with new data for eight of the largest countries and used the same multiplier to get a picture of use today. This appears to show increasing animal use over time.

								%
	Year 1	Official Stats	Estimate	Multiplier	Year 2	Official Stats	Estimate	increase
ISA	2005	1,177,566	17,317,147	' 14.71	2012	1,101,199	9 16,194,103	-6.49
ireat Britain	2005	2,812,850	1,874,207	0.67	2102	4,110,000	2,738,500	46.12
iermany	2005	2,412,678	1,822,424	0.76	2011	L 2,073,702	1,566,377	-14.05
anada	2005	2,316,285	2,316,281	. 1.00	2012	3,333,689	9 3,333,683	43.92
rance	2004	2,325,398	2,325,398	1.00	2011	L 2,200,152	2,200,152	-5.39
aly	2005	896,966	896,966	1.00	2011	l 781,815	5 781,815	-12.84
utralia	2011	6,489,005	2,389,813	0.37	2011	L 7,100,000	) 2,614,834	9.42
pain	2011	. 595,597	595,597	1.00	2011	l 900,127	900,127	51.13
			29,537,833	3			30,329,592	2.68
ilobal Estimate			115,300,000	)			118,390,040	
areat Britain Germany anada rance raly utralia pain	2005 2005 2005 2004 2005 2011	2,812,850 2,412,678 2,316,285 2,325,398 896,966 6,489,005	1,874,207 1,822,424 2,316,281 2,325,398 896,966 2,389,813 595,597 29,537,833	0.67       0.76       1.00       1.00       1.00       1.00       1.00       1.00       1.00       1.00       1.00       1.00       1.00	2102 2011 2012 2011 2011 2011 2011	4,110,000         2       4,110,000         1       2,073,702         2       3,333,689         1       2,200,152         1       781,815         1       7,100,000	<ul> <li>2,738,500</li> <li>1,566,377</li> <li>3,333,683</li> <li>2,200,152</li> <li>781,815</li> <li>2,614,834</li> <li>900,127</li> <li>30,329,592</li> </ul>	46 -14 43 -5 -12 9 51 2

<sup>10</sup> Taylor, K., Gordon, N., Langley, G., Higgins, W. Estimates for Worldwide Laboratory Animal Use in 2005. ATLA 36, 327–342, 2008



Andrew Knight<sup>11</sup>, analysing the data of Taylor et al., suggests the annual global figure of animal use in labs could be as high as 126.9 million.

Taylor et al.'s study<sup>12</sup> concluded that "the distribution of animal use appears to be concentrated in a relatively small number of heavy user countries", in particular the USA and Japan.

# 5 Reliability of official statistics

Despite the USA and Japan being by far the largest users of animals in testing (Taylor et al.'s estimations for 2005 were over 17 million animals in the USA and over 11 million in Japan; the third country, GB, used just under 2 million animals), their statistics are not the most reliable.

The USA excludes rodents, birds, reptiles, amphibians and fish from its animal labs legislation and statistics. In 2005, 17.3 million animals had been used in labs according to official records but Taylor et al.<sup>13</sup> note that a 2000 survey by the US Animal Plant Health Inspection Service yielded an estimate of 31–156 million and in another study, a laboratory veterinarian estimated that over 80 million rodents alone were bred annually for research in the USA.

In Japan, the law adopts a self-regulation system for animal experimentation<sup>14</sup> and surveys on the numbers of animals used are conducted every three years and are not mandatory<sup>15</sup>.

In Canada, not all animal labs submit data on animal use<sup>16</sup>. Participation is only mandatory for labs that receive research funding from the national funding agencies. Although some other labs still submit annual data, not all do. The number of labs using animals that do not submit data to the CCAC is not known.

16 Canadian Council on Animal Care. 2011 Animal Use Statistics.

Knight, A. Estimates of Worldwide Laboratory Animal Use. Letters, ATLA 36, 494-495, 2008
 Taylor, K., Gordon, N., Langley, G., Higgins, W. Estimates for Worldwide Laboratory Animal Use in

<sup>2005.</sup> ATLA 36, 327-342, 2008

<sup>13</sup> Taylor, K., Gordon, N., Langley, G., Higgins, W. Estimates for Worldwide Laboratory Animal Use in 2005. ATLA 36, 327–342, 2008

<sup>14</sup> Shoji, K. Japanese concept and government policy on animal welfare and animal experiments. AATEX 14, Special Issue, 179-181. Proc. 6th World Congress on Alternatives & Animal Use in the Life Sciences

<sup>15</sup> Kagiyama, N. and Nomura, T. Japanese Regulations on Animal Experiments: Current Status and Perspectives. In: The Development of Science-based Guidelines for Laboratory Animal Care: Proceedings of the November 2003 International Workshop International Workshop on the Development of Science-based Guidelines for Laboratory Animal Care Program Committee, National Research Council

http://www.ccac.ca/Documents/Publications/Statistics/CCAC\_Animal\_Use\_Statistics\_2011.pdf. Accessed 13.4.14



# 6 Difficulties in compiling global statistics on animal testing

Animal testing in the European Union is governed by Directive 2010/63/EU<sup>17</sup>. This requires all Member States to record statistics on animal use in the same format and submit them for publication. These are the only figures collated on a multi-national basis.

Taylor et al.<sup>18</sup> noted the difficulties in compiling global statistics. Not only do many countries not produce statistics, but where they do they are generally not collated and presented in the same way, with varying species and types of experiments included. As such, they compared each country's statistics, the definitions of 'protected animal', recognised 'purpose' and 'experiment' with those used in the EU, "since these constitute a significant proportion of the publicly-available statistics".

#### 6.1 Animals not included in annual statistics

Taylor et al.<sup>19</sup> set out several reasons for the differences in national statistics between countries, based on the inclusion and exclusion of certain kinds of animals and uses, such as:

- animals killed solely to supply tissues for ex-vivo or in-vitro research
- genetically-modified animals used solely to maintain established breeding colonies
- conventional animals bred for scientific purposes but killed as surplus to requirements
- foetal and embryonic forms
- certain invertebrate species, such as cephalopods
- purely observational studies
- fish tagging and other environmental studies on wild animals

These, and other reasons, are discussed in more detail below.

#### 6.1.2 Tissue and organ supply

In its consultation on transposing Directive 2010/63/EU into national law, the British Government noted<sup>20</sup>: "This Directive shall apply where animals are used or intended to be used in procedures, or bred specifically so that their organs or tissues may be used for scientific purposes." There was no existing equivalent provision in UK law on this and the government recognised that the numbers of animals bred specifically so that their organs and tissues may be used for scientific purposes was "not necessarily counted".

<sup>17</sup> Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes

<sup>18</sup> Taylor, K., Gordon, N., Langley, G., Higgins, W. Estimates for Worldwide Laboratory Animal Use in 2005. ATLA 36, 327–342, 2008

<sup>19</sup> Taylor, K., Gordon, N., Langley, G., Higgins, W. Estimates for Worldwide Laboratory Animal Use in 2005. ATLA 36, 327–342, 2008

<sup>20</sup> Home Office. Consultation on options for transposition of European Directive 2010/63/EU on the protection of animals used for scientific purposes. Summary report and Government response. May 2012



Data collected for EU Member States excludes animals killed solely to supply tissues for exvivo or in-vitro use. For the six countries that Taylor et al.<sup>21</sup> obtained data, the average percentage of animals killed for their tissues was 21.1% (range 2.4% - 50.1%). The new format for EU Members to submit data, which began in January 2014, still excludes recording animals killed for tissues and organs<sup>22</sup>.

The Netherlands and Sweden are current examples of countries that do collect statistical data on animals killed for organs and tissues. In the Netherlands, "the rationale of this is that the Inspectorate must have the power to supervise the killing of laboratory animals"<sup>23</sup>. In 2011, 67,196 animals were killed "without previous intervention", e.g. for organ/blood collection.

#### 6.1.3 GM animals

Under the EU Directive, strains of genetically-modified animals and their use in procedures are counted as experiments "but not their maintenance through breeding of such strains". Taylor et al.'s<sup>24</sup> study found that data on the numbers of GM animals used solely to maintain established GM strains were available from Great Britain and The Netherlands. For GB, this represented an additional 33.7% over and above the total number of animals submitted to the EC that year.

Although EU data excludes GM colonies, the UK includes them in its own national report. Therefore, the UK has to amend the figures to meet the requirements of its submission to the EU. This creates a large discrepancy between what is reported in EU Member State data<sup>25</sup> as the UK's level of animal experimentation – 2,050,458 – and the figure reported in the UK's own statistical report<sup>26</sup> – 3,790,000. This means that 1.7 million animals are bred for the maintenance of colonies of genetically modified or harmful mutant animals.

<sup>21</sup> Taylor, K., Gordon, N., Langley, G., Higgins, W. Estimates for Worldwide Laboratory Animal Use in 2005. ATLA 36, 327–342, 2008

<sup>22</sup> Consolidated Commission Implementing Decision 2012/707/EU as corrected by Decision 2014/11/EU

<sup>23</sup> European Commission. Commission Staff Working Document. Accompanying document to the Report from the Commission to the Council and the European Parliament. 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. 2013. 4/5

Taylor, K., Gordon, N., Langley, G., Higgins, W. Estimates for Worldwide Laboratory Animal Use in 2005. ATLA 36, 327–342, 2008

European Commission. Commission Staff Working Document. Accompanying document to the Report from the Commission to the Council and the European Parliament. 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. 2013. Part 5/5

<sup>26</sup> Home Office. Annual Statistics of Scientific Procedures on Living Animals Great Britain 2011



The German organisation, Doctors Against Animal Experiments, claims<sup>27</sup> that, for Germany, "the number of animals that do not have the desired genetic modification is estimated to be 90 - 99%. These animals are killed and will not appear in the statistics".

#### 6.1.4 'Surplus' animals

The breeding of animals for use in labs often leads to a surplus of animals not needed; when these are killed their numbers are not included in data collated under the EU Directive. Reasons for this surplus include constant or regular breeding to meet a demand for constant availability, rather than breeding for specific requirements<sup>28</sup>, a biological surplus due to a marked difference in the requirement for either males or females<sup>29</sup> or a managed surplus such as age or bodyweight<sup>30</sup>.

A 1998 survey by the (UK) Laboratory Animal Science Association<sup>31</sup> found a marked trend in sex preference in orders supplied by labs for both rats and mice. In rats, the preferred sex for use was male and for mice was female. Due to gender preferences, approximately 32% of all male rats and 68% of female rats become surplus to in-vivo requirements. With mice, the surplus figures were 65% male and 35% female. LASA concluded that "in order to satisfy current scientific requirements, twice as many animals are bred than are actually required" and it disputed earlier government claims that up to three times as many rodents were killed as surplus than were used in experiments at the government weapons research lab Porton Down.

Another LASA survey reported that, in addition to the numbers counted in the official statistics, 5% of dogs, 0.5% of cats and 0.6% of primates were produced but not used in experiments. Based on these reports, Taylor et al.<sup>32</sup> state that these additional animals add 80.3% to the GB statistics in 2005 – an extra 1,504,749 animals. Norway did reported surplus animal figures in 2005 and they constituted an extra 38.2% (382,285 animals)<sup>33</sup>.

<sup>27</sup> Aerzte Gegen Tierversuche. Tierversuchsstatistik. <u>http://www.aerzte-gegen-tierversuche.de/index.php?</u> <u>option=com\_content&view=article&id=22:versuchstierstatistik-2006&catid=1:allgemein&Itemid=6</u>. Accessed 16.4.14

Hawkins, P. et al. Working Party Report, Husbandry refinements for rats, mice, dogs and non-human primates used in telemetry procedures. Laboratory Animals (2004) 38, 1–10

<sup>29</sup> NC3Rs. Breeding and supply. <u>http://www.nc3rs.org.uk/category.asp?catID=16</u>. Accessed 11.4.14

<sup>30</sup> Laboratory Animal Science Association. The Production and Disposition of Laboratory Rodents Surplus to the Requirements for Scientific Procedures. 1998

<sup>31</sup> Laboratory Animal Science Association. The Production and Disposition of Laboratory Rodents Surplus to the Requirements for Scientific Procedures. 1998

<sup>32</sup> Taylor, K., Gordon, N., Langley, G., Higgins, W. Estimates for Worldwide Laboratory Animal Use in 2005. ATLA 36, 327–342, 2008

<sup>33</sup> Taylor, K., Gordon, N., Langley, G., Higgins, W. Estimates for Worldwide Laboratory Animal Use in 2005. ATLA 36, 327–342, 2008



#### 6.1.5 Vertebrates in early developmental stages

Under UK law, vertebrates only become protected animals at a particular stage in their development. Prior to 2010, when the EU Directive regulating animal testing was updated, this was before half-way through gestation (mammals) or incubation (birds and reptiles), or the stage when independent feeding occurs (amphibians and fish), e.g. early chicken embryos in reproductive toxicity tests<sup>34</sup>. Michael Balls of FRAME (Fund for the Replacement of Animals in Medical Experiments) comments<sup>35</sup>: "the cut-off points used to distinguish between the early development stages of vertebrates at which the animals concerned can be used as alternatives and the stages at which they became protected, is arbitrary and unsatisfactory - it has no strong scientific basis and therefore cannot be ethically satisfactory".

Transposing the new Directive led to amendments in UK law, so that embryonic and foetal forms of mammals, birds and reptiles are now protected animals only once they have reached the last third of their gestation or incubation period<sup>36</sup>.

This conforms with the Directive<sup>37</sup> which states that there is scientific evidence showing that foetal forms of mammals "in the last third of the period of their development are at an increased risk of experiencing pain, suffering and distress, which may also affect negatively their subsequent development. Scientific evidence also shows that procedures carried out on embryonic and foetal forms at an earlier stage of development could result in pain, suffering, distress or lasting harm, should the developmental forms be allowed to live beyond the first two thirds of their development".

Eurogroup for Animals<sup>38</sup> criticised the EU Directive's regulation of birds and reptiles only from when they hatch. It considers this to be "scientifically and logically inconsistent and could lead to suffering – chicks are actively calling for around three days before hatching". Eurogroup called on Member States to regulate the use of foetal birds and reptiles from 66% of normal incubation.

#### 6.1.6 Invertebrates

Protection of animals used in experiments is generally restricted to vertebrates (at best). EU Directive 2010/63/EU, which took full effect in member states in January 2013, updated previous EU-wide animal testing laws, extended protection to cephalopods (octopuses,

<sup>34</sup> Balls, M. Replacement of animal procedures: alternatives in research, education and testing. Laboratory Animals (1994) 28, 193-211

<sup>35</sup> Balls, M. Replacement of animal procedures: alternatives in research, education and testing. Laboratory Animals (1994) 28, 193-211

<sup>36</sup> Home Office. Guidance on the Operation of the Animals (Scientific Procedures) Act 1986. 2014

<sup>37</sup> Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes

<sup>38</sup> Eurogroup for Animals. Briefing February 2011: Protection of Animals used for Scientific Purposes: Crucial animal welfare concerns in implementation of the directive.

http://eurogroupforanimals.org/files/policies/downloads/70/eurogroup\_2010\_63\_eu\_implementation.pdf



squid and cuttlefish) "as there is scientific evidence of their ability to experience pain, suffering, distress and lasting harm"<sup>39</sup>.

Prior to this, the only EU country to cover cephalopods in its legislation was the UK, which had included the common octopus (*Octopus vulgaris*) since 1993. Variances in other countries include<sup>40</sup>:

- Switzerland covers cephalopods and decapod crustaceans (e.g. shrimps, crayfishes, lobsters, and crabs)
- Norway covers squid, octopi, decapod crustaceans
- Australia covers "cephalopods such as octopus and squid"
- New Zealand legislation includes "octopus, squid, crab, lobster and crayfish"
- The Canadian Council on Animal Care's system of self-regulation, includes "cephalopods and some other higher invertebrates [that] have nervous systems as well developed as some vertebrates"

In addition to cephalopods and crustaceans, Norway also includes honey bees in its animal experimentation legislation<sup>41</sup>.

#### 6.1.7 Observational/dietary studies

In Sweden, all use of animals with a scientific purpose is defined as animal experimentation and therefore statistical data is collected on some studies which other countries do not, such as behaviour studies and feeding trials<sup>42</sup>.

In 2005, Australia reported 4.1 million observational/dietary studies on farmed animals which would not be included as animal experiments under EU definitions<sup>43</sup>.

#### 6.1.8 Fish tagging

In Canada, fish that are fitted with transmitters are included in statistics on animal testing<sup>44</sup>. Sweden keeps statistical records of fish used in assessment studies; in this category, during

Smith, J.A. et al. Cephalopod research and EU Directive 2010/63/EU: Requirements, impacts and ethical review. Journal of Experimental Marine Biology and Ecology, Volume 447, September 2013, Pages 31–45
 Smith, J.A. et al. Cephalopod research and EU Directive 2010/63/EU: Requirements, impacts and Ethical environmental of Experimental Marine Biology and Ecology, Volume 447, September 2013, Pages 31–45

<sup>39</sup> Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes

ethical review. Journal of Experimental Marine Biology and Ecology, Volume 447, September 2013, Pages 31–45
 42 European Commission. Commission Staff Working Document. Accompanying document to the Report from the Commission to the Council and the European Parliament. 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. 2013. 5/5

<sup>43</sup> Taylor, K., Gordon, N., Langley, G., Higgins, W. Estimates for Worldwide Laboratory Animal Use in 2005. ATLA 36, 327–342, 2008

<sup>44</sup> Canadian Council on Animal Care. Interpretation Bulletin no.1-1 - Animal Use Data Form. http://www.ccac.ca/Documents/Assessment/Interpretation-bulletin-AUDF.pdf. Accessed 13.4.14



2011 approximately 7,734,200 fish were caught by trawling or netting, whereas 120,500 fish were tagged<sup>45</sup>.

#### 6.1.9 Bird ringing

Legislation in the Czech Republic<sup>46</sup> classifies bird ringing (the capture of wild birds and placement of an identifying ring on one leg for conservation purposes) as an experiment and it is therefore included in statistics of animal testing. This is despite the birds being released physically unharmed. In 2011, bird ringing constituted 45.95% of the total 354,196 animals used for 'experimental and other scientific purposes' (162,768 birds).

#### 6.1.10 Experiments lasting more than one year

Long-term experiments such as carcinogenicity, chronic toxicity and two generation reproductive toxicity studies require animals to be used over the course of more than one year. However, their use may only be recorded in statistics for the first year and "countries also differ in whether and how they count the re-use, in separate experiments, of individual animals"<sup>47</sup>.

In New Zealand, records of the number of animals used in long-term experiments are reported every three years (or at the end of the year in which the project is completed, if less than three years), rather than annually<sup>48</sup>. This results in annual variability in the statistics.

# 6.1.11 USA

The USA uses the highest number of animals in labs. It does publish annual figures but these exclude most of the animal species actually used in research and testing as mice, rats, birds, fish, reptiles and amphibians are not covered by its legislation of animal labs. Taylor et al.<sup>49</sup> believe that this results in 93.2% of all animals used being missed from statistics and that the real figure of animals used in lab experiments in the USA may be closer to 17.3 million than the 1.2 million officially reported.

<sup>45</sup> European Commission. Commission Staff Working Document. Accompanying document to the Report from the Commission to the Council and the European Parliament. 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. 2013. 5/5

<sup>46</sup> European Commission. Commission Staff Working Document. Accompanying document to the Report from the Commission to the Council and the European Parliament. 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. 2013. 2/5

<sup>47</sup> Taylor, K., Gordon, N., Langley, G., Higgins, W. Estimates for Worldwide Laboratory Animal Use in 2005. ATLA 36, 327–342, 2008

<sup>48</sup> National Animal Ethics Advisory Committee. Annual Report 1 January to 31 December 2012

<sup>49</sup> Taylor, K., Gordon, N., Langley, G., Higgins, W. Estimates for Worldwide Laboratory Animal Use in 2005. ATLA 36, 327–342, 2008



For these reasons, even where data do exist, the differences in the type of data makes it extremely difficult to make comparisons.

# 7 Increases in animal use

The increase in the use of animals in labs has been recognised by de Boo and Knight<sup>50</sup> as being for two main reasons: the production and maintenance of genetically modified animals and use in chemical testing programmes.

# 7.1 GM animals

"Dramatic increases in the use of GM animals", which also requires "substantial breeding" have reversed otherwise declining numbers of animal tests in some countries. For example, in the UK, animal testing numbers had declined and stabilised until 2007 when they reached their highest peak for 15 years. GM animals were used in 8% of regulated procedures in 1995 in the UK, rocketing to 36% by 2007<sup>51</sup>.

UK animal testing figures rose by 57% (1.49 million more procedures) between 2001 and 2012. The Government<sup>52</sup> put this rise down to "increases in the use of breeding to produce GM or HM (harmful mutants – animals possessing one or more genes that have undergone mutation) animals" (+1.20 million or +155%) and fundamental biological research (+525,400 or +67%). For the first time, the number of procedures involving GM animals (1.91 million) was greater than the number performed on 'normal' animals (1.68 million). So high was this figure, that if the breeding of GM and HM animals was excluded, the total number of procedures actually decreased by 2% (-46,000) to 2.13 million procedures.

Similar increased use has been recorded in Germany and Switzerland<sup>53</sup>.

#### 7.2 Chemical testing

Programmes such as REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), a European Community Regulation on chemicals and their safe use (EC 1907/2006) which entered into force in 2007, led to massive increases in animal testing.

<sup>50</sup> de Boo, J. & Knight, A. Increasing the Implementation of Alternatives to Laboratory Animal Use. AATEX 13(3), 109-117, 2008

<sup>51</sup> de Boo, J. & Knight, A. Increasing the Implementation of Alternatives to Laboratory Animal Use. AATEX 13(3), 109-117, 2008

<sup>52</sup> Home Office. Annual Statistics of Scientific Procedures on Living Animals Great Britain 2012

<sup>53</sup> de Boo, J. & Knight, A. Increasing the Implementation of Alternatives to Laboratory Animal Use. AATEX 13(3), 109-117, 2008



REACH requires manufacturers and importers to collate information on the properties of all chemicals sold in the EU in annual quantities of more than one tonne, and to register the information, along with toxicity data, in a central database run by the European Chemicals Agency (ECHA) by 2018.

The first phase of REACH envisaged the registration of 30,000 chemical substances, but the total number of substances submitted by the 2008 deadline for registration was 143,000<sup>54</sup>.

Many of the testing methods specified by REACH use animals. Toxicity tests usually involve the poisoning of guinea pigs, rabbits, fish, birds, rats and mice<sup>55</sup>.

The use of animals in testing to meet REACH requirements is huge. The Health and Safety Executive, the UK's Competent Authority for REACH, estimates<sup>56</sup> that "for a single substance, with no pre-existing data, and no attempt to minimise animal testing, registration and subsequent fulfilment of the information gaps could require over 5,000 animals, assuming little or no avian testing."

The total numbers of animals who could be used in testing have been estimated to be as high as 54 million<sup>57</sup>.

# 8 Toxicology research

The Lush Prize aims to speed the introduction of non-animal testing, particularly in toxicity testing for consumer products and ingredients.

Toxicology is the study of the effects of chemical substances on living organisms and the ecosystem and is used to determine safe exposure levels. It is used for a vast range of products, including cosmetics, pharmaceuticals, household and agricultural products and chemicals.

Animals in laboratories are the "traditional go-to method of toxicity testing"<sup>58</sup>. Yet this is changing. AltTox.org, a website dedicated to advancing non-animal methods of toxicity testing, lists several reasons why toxicology is moving away from animal use, aside from animal welfare, including<sup>59</sup>:

56 Health and Safety Executive. REACH - Minimisation of Animal Testing. January 2010. http://www.hse.gov.uk/reach/resources/18animaltesting.pdf Accessed 15.8.12. Accessed 15.8.12

57 Hartung, T. and Rovida, C. Opinion: Chemical regulators have overreached. August 2009. Nature 460, 1080-1081. <u>http://www.nature.com/nature/journal/v460/n7259/full/4601080a.html</u>

<sup>54</sup> Menache, A. and REACH, Nastrucci , C. animal testing, and the precautionary principle. Medicolegal and Bioethics, August 2012, Volume 2012:2 Pages 13 – 29. <u>http://www.dovepress.com/reach-animal-testing-and-the-precautionary-principle-peer-reviewed-article-MB</u>. Accessed 16.8.12

<sup>55</sup> European Coalition to End Animal Experiments. REACH. <u>http://www.eceae.org/en/what-we-do/campaigns/reach</u>. Accessed 15.8.12

<sup>58</sup> Perkel, J. M. Animal-Free Toxicology: Sometimes, in Vitro is Better. Science, 2.3.14. http://www.sciencemag.org/site/products/lst\_20120302.xhtml



- Testing methods have not kept pace with scientific progress: "there has been a revolution in biology and biotechnology", with advances in cell culture, robotics, tissue engineering, bioinformatics and other methods
- Questionable reliability and relevance of current testing methods: "Whether interspecies differences are products of genetic, biochemical, or metabolic factors – or a combination – it is virtually impossible to know whether the results of testing on rodents, rabbits, or dogs will provide an accurate prediction of toxic effects in humans (i.e. questionable relevance)"
- Time and cost considerations: "Some conventional tests take months or years to conduct and analyse (e.g. 4-5 years, in the case of carcinogenicity studies), at a cost of hundreds of thousands – and sometimes millions – of dollars per substance examined (e.g. US \$2-4 million per two-species carcinogenicity study)"

In 2007, the US National Academy of Sciences<sup>60</sup> called for a major paradigm shift in toxicology that would "rely less heavily on animal studies and instead focus on in vitro methods that evaluate chemicals' effects on biological processes using cells, cell lines, or cellular components, preferably of human origin. The new approach would generate more-relevant data to evaluate risks people face, expand the number of chemicals that could be scrutinised, and reduce the time, money, and animals involved in testing."

# 9 Animal testing data in various countries

Reliable and up-to-date data on the level and type of animal experiments in individual countries is easier to obtain for some countries than others. As previously discussed, not all countries regulate animal testing and not all collate and publish statistics.

For their 2008 paper on animal use in labs worldwide, Taylor et al.<sup>61</sup> partly relied on animal protection organisations in countries where testing took place to obtain official statistics or provide estimates of the level of animal use where official statistics were considered to be incomplete. Then, to assist in providing a comparison between countries, for each country's statistics, the definitions of 'protected animal', recognised 'purpose' and 'experiment' were compared with those used in the EU, "since these constitute a significant proportion of the publicly-available statistics".

For this paper, we have relied on official statistics that were easily available through an internet search and were the known most recent data available. Although this is not a

<sup>59</sup> AltTox.org. Toxicity Testing Overview. last updated 8.9.11. <u>http://www.alttox.org/ttrc/tox-test-overview/</u>. Accessed 19.4.14

<sup>60</sup> National Academy of Sciences. Report calls for new directions, innovative approaches in testing chemicals for toxicity to humans. News Release, 12.6.07. http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=11970

<sup>61</sup> Taylor, K., Gordon, N., Langley, G., Higgins, W. Estimates for Worldwide Laboratory Animal Use in 2005. ATLA 36, 327–342, 2008



comprehensive data set and analysis, it does provide an understanding of the current level and type of animal testing in North America, Australasia and Europe. Since Taylor et al.'s 2008 paper, the EU Directive regulating animal testing has been amended, resulting in some changes to the statistics collated.

# 9.1 United States of America

The Animal Welfare Act, enacted in 1966, is the only Federal law in the United States that regulates the use of animals in research, exhibition (e.g. zoo or circus), transport and by dealers<sup>62</sup>.

However, it excludes rats, mice, birds, fish, reptiles and amphibians, as well as farmed animals who are "used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fibre"<sup>63</sup>.

Pro-vivisection groups have lobbied against attempts to widen protection for species not currently covered by the AWA, arguing that rats, mice and birds, which make up about 95% of animal use in US labs, already receive ample oversight through local institutional animal care and use committees and that regulation by the US Department of Agriculture (USDA) would lead to prohibitive increases in the cost of maintaining and using the animals<sup>64</sup>.

Statistics produced by the USDA show the number of animals used by species and by category of pain and distress. The species chart lists cats, dogs, hamsters, guinea pigs, non-human primates, pigs, rabbits, sheep, other farm animals and all other covered species, each by the State in which the experiments took place.

The 'Annual Report Animal Usage by Fiscal Year' for 2012<sup>65</sup> (the latest available) reports a total of 1,110,199 animals of the species covered being used in experiments. The state with largest animal use was California with 117,407 animals (10.58% of all experiments in the country) and Maryland with 86,163 animals (7.76%). If the number of animals represented in these figures is just 5% of all animals used in labs in the USA (estimates<sup>66</sup> generally put the figure of mice and rats used as 95-98% of all animals), the real number of animals used in 2012 would have been over 22 million.

<sup>62</sup> USDA National Agricultural Library. Animal Welfare Act. <u>https://awic.nal.usda.gov/government-and-professional-resources/federal-laws/animal-welfare-act</u>. Accessed 12.4.14

<sup>63</sup> United States Department of Agriculture. Animal Welfare Act and Animal Welfare Regulations 'Blue Book'. November 2013. <u>http://www.aphis.usda.gov/animal\_welfare/downloads/Animal%20Care%20Blue%20Book%20-%202013%20-%20FINAL.pdf</u>

<sup>64</sup> American Psychological Association. Rats, mice and birds excluded from Animal Welfare Act. Monitor on Psychology, July/August 2002, Vol 33, No. 7

<sup>65</sup> USDA Animal and Plant Health Inspection Service. Annual Report Animal Usage by Fiscal Year - 2012. http://www.aavs.org/atf/cf/%7B8989c292-ef46-4eec-94d8-43eaa9d98b7b %7D/ANNUAL\_REPORT\_ANIMALUSAGE\_FY2012.PDF. Accessed 12.4.14

<sup>66</sup> Harkness, J.E,. Turner, P.V., VandeWoude, S. and Wheler, C.L. Harkness and Wagner's Biology and Medicine of Rabbits and Rodents. Wiley-Blackwell, 2010



According to these official data, the most commonly used animals were guinea pigs (212,699 – 19.16% of all animals used) and rabbits (205,480 – 18.51%). The number of primates used was 107,125 (9.65% of all animals used), dogs 72,167 (6.50%) and cats 24,578 (2.21%). However, the most commonly used are more likely to be mice, rat and birds.

Ani	ed States Department mai and Plant He	alth Inspection	Service								Page 1
Region: All State: All	Fiscal Year: 2012 Classes: All Pain Type: All										
	All Other Covered Specie	Hamsters	Cats	Dogs	Guinea Pigs	Nonhuman Primates	Other Farm Animals	Pig	Rabbits	Sheep	Total
AK	543	42	0	0	0	0	0	0	0	0	585
AL	1,169	42	257	1,336	210	223	858	1,167	986	75	6,323
AR	17	2	134	434	185	158	298	865	1.086	0	3,179
AZ	3,997	107	91	342	60	43	33	513	180	43	5,409
CA	28,679	4,412	1,965	3,139	13,606	7,567	14,803	4,563	36,350	2,323	117,407
00	2,013	1,039	386	753	2,518	0	228	584	461	617	8,599
CT	1,172	983	0	442	194	312	0	467	735	28	4,333
DC .	2,355	490	36	12	272	608	11	677	156	53	4,670
DE	28	0	0	0	20	0	482	10	12,935	38	13,513
FL	3,825	379	544	1,140	283	7,870	326	1,530	462	219	16,578
3A.	8,106	11,690	676	2,576	1,313	4,309	618	1,139	3,187	116	33,730
HI	6	0	13	51	0	0	0	101	8	0	179
A	4,501	18,549	564	1,172	1,821	23	719	4,386	2,774	605	35,114
D	192	0	46	120	36	0	124	2	49	72	641
L	6,249	2,093	1,110	3,690	2,191	704	666	1,559	2,898	605	21,765
N	3,767	1,211	767	1,498	122	187	106	914	818	194	9,584
s	1,299	93	811	1,851	1,322	203	312	362	192	64	6,509
CY	488	190	130	302	35	107	176	552	145	83	2,208
A	922	72	127	447	7	13,284	349	38	481	0	15,727
MA	9,766	7,312	58	1,482	21,585	8,478	1.704	7,123	19,058	540	77.106
MD	44.122	6.640	6	1,136	14,279	13.081	600	2,044	3.912	343	86.163

# Table 1: Number of animals used in experiments in USA, 2012<sup>67</sup>

The other available data<sup>68</sup> categories the level of pain and distress animals are subjected to. The three levels described are: No Pain, No Drugs; With Pain, With Drugs; With Pain, No Drugs. This chart shows 49% of animals were included as 'no pain, no drugs', 29.15% as 'with pain, with drugs' and 7.71% (85,240 animals) as being exposed to pain with no relief. Again, these statistics do not include rats, mice, birds, fish, reptiles and amphibians, so there is no information on the severities of pain and suffering these animals are exposed to.

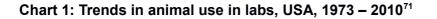
67 USDA Animal and Plant Health Inspection Service. Annual Report Animal Usage by Fiscal Year - 2012. http://www.aavs.org/atf/cf/%7B8989c292-ef46-4eec-94d8-43eaa9d98b7b %7D/ANNUAL\_REPORT\_ANIMALUSAGE\_FY2012.PDF. Accessed 12.4.14 68 Available at http://www.aavs.org/site/c.bkLTKfOSLhK6E/b.6446369/k.66FC/Animals\_Used\_in\_Research.htm#.U0qtk1VdWri. Accessed 12.4.14

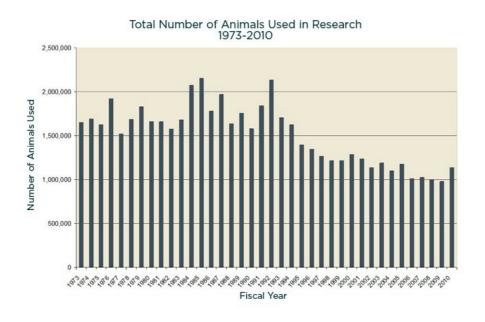


ANIMALS USED IN RESEARCH BY CATEGORY OF PAIN AND DISTRESS - 2012 Data courtesy of USDA APHIS											
	Animals Not	Yet Used	No Pain, No	o Drugs	With Pain, W	ith Drugs	With Pain, N	o Drugs	All Animals USED		-
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Total
Cats	1,966	8.00%	13,326	54.25%	9,122	37.14%	150	0.61%	22,598	92.00%	24,564
Dogs	7,765	10.76%	39,264	54.42%	24,637	34.15%	483	0.67%	64,384	89.24%	72,149
Guinea Pigs	8,487	3.99%	135,657	63.78%	43,615	20.51%	24,940	11.73%	204,212	96.01%	212,699
Hamsters	9,798	6.66%	55,683	37.85%	35,215	23.94%	46,416	31.55%	137,314	93.34%	147,112
Nonhuman Primates	42,602	39.77%	35,418	33.06%	27,831	25.98%	1,274	1.19%	64,523	60.23%	107,125
Pigs	5,196	8.42%	9,724	15.76%	44,590	72.27%	2,189	3.55%	56,503	91.58%	61,699
Rabbits	18,711	9.11%	109,565	53.32%	72,052	35.06%	5,154	2.51%	186,771	90.89%	205,482
Sheep	1,433	9.75%	4,905	33.37%	8,107	55.16%	252	1.71%	13,264	90.25%	14,697
Other covered species	60,492	23.22%	138,407	53.13%	57,226	21.97%	4,382	1.68%	200,015	76.78%	260,507
Grand Total	156,450	14.15%	541,949	49.00%	322,395	29.15%	85,240	7.71%	949,584	85.85%	1,106,034

#### Table 2: Severity of animal experiments in USA, 2012<sup>69</sup>

The US organisation, the National Anti-Vivisection Society (NAVS), has analysed<sup>70</sup> the changes in animal use in US labs and produced a number of charts, showing, for example, the trend in animal use of a period of time.





69 Available at

http://www.aavs.org/site/c.bkLTKfOSLhK6E/b.6446369/k.66FC/Animals\_Used\_in\_Research.htm#.U0qtk1VdWri. Accessed 12.4.14

<sup>70</sup> NAVS. Animals in Science. <u>http://www.navs.org/science/number-of-animals-used-in-research#.U0Wa6FVdWrg</u>. Accessed 13.4.14

<sup>71</sup> NAVS. Animals in Science. <u>http://www.navs.org/science/number-of-animals-used-in-research#.U0Wa6FVdWrg</u>. Accessed 13.4.14



# 9.2 Canada

In Canada, the federal government does not have jurisdiction to legislate over experiments involving animals as this is a provincial jurisdiction. Of the ten provinces, the only ones to legislate animal testing are: Alberta, Manitoba, Saskatchewan, Ontario, New Brunswick, Nova Scotia and Prince Edward Island<sup>72</sup>. Quebec, British Columbia and Newfoundland and Labrador do not have legislation.

The Canadian Council on Animal Care collects national data on animal experiments and produces an annual survey. Since 1996, the annual survey of animal use for scientific purposes is published using the data collected in the Animal Use Data Form (AUDF) format. Between 1975 and 1995, data was collected in a different format<sup>73</sup>.

The CCAC animal use data report for each year provides details of the species of animals used, categories of invasiveness and purpose of animal use. Data are available both within a summary report and as a downloadable Excel file.

All vertebrates and cephalopods used for research, teaching or testing, or for display purposes or eventual use in research, teaching or testing must be the subject of a written animal use protocol to be approved by the institutional animal care committee<sup>74</sup>.

Animals to be included on the AUDF include<sup>75</sup>:

- All vertebrates (including fish) used for research, teaching or testing
- Cephalopods (octopus and squid) used for research, teaching or testing
- Mammals which are tagged in studies that involve some sort of restraint and the taking of measurements or tissue samples
- Fish that are fitted with transmitters
- Animals used in lethal field sampling for research, teaching or non-routine testing purposes (not including lethal field sampling for population management and monitoring programs)
- Animals that are used outside of Canada by Canadian scientists, who have submitted an animal use protocol form for these animals to their institutional animal care committee

Animals NOT to be included on the AUDF include<sup>76</sup>:

• All animals assigned to category of invasiveness A (experiments on most invertebrates or on live isolates, e.g. the use of tissue culture)

<sup>72</sup> Canadian Council on Animal Care. CCAC training module on: guidelines, legislation and regulations. <u>http://www.ccac.ca/en\_/education/niaut/stream/cs-guidelines</u>. Accessed 13.4.14

<sup>73</sup> Canadian Council on Animal Care. Animal Use Statistics. <u>http://ccac.ca/en\_/publications/audf</u>. Accessed 13.4.14

Canadian Council on Animal Care. Interpretation Bulletin no.1-1 - Animal Use Data Form.
 <u>http://www.ccac.ca/Documents/Assessment/Interpretation-bulletin-AUDF.pdf</u>. Accessed 13.4.14
 Canadian Council on Animal Care. Interpretation Bulletin no.1-1 - Animal Use Data Form.

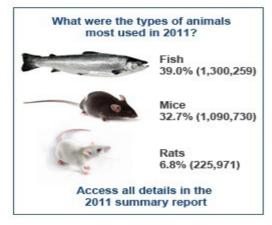
http://www.ccac.ca/Documents/Assessment/Interpretation-bulletin-AUDF.pdf. Accessed 13.4.14 76 Canadian Council on Animal Care. Interpretation Bulletin no.1-1 - Animal Use Data Form.

http://www.ccac.ca/Documents/Assessment/Interpretation-bulletin-AUDF.pdf. Accessed 13.4.14



- All invertebrates other than cephalopods
- Eggs, embryos, larvae (except for fish larvae that have reached a stage where survival can reasonably be expected)
- Fish involved in mark/recapture studies for abundance estimates, migration, and other parameters required for assessing stocks

**Picture 1: Most common species used in Canada** (image from Canadian Council on Animal Care<sup>77</sup>):



According to Canadian data<sup>78</sup>:

In 2011 3,333,689 animals were reported to the Canadian Council on Animal Care (CCAC) as used in science (research, teaching and testing) in CCAC-certified labs. The three most-used species were fish (1,300,259), mice (1,090,730) and rats (225,971).

61% of these animals (2,032,837) were used for studies of a fundamental nature/basic research. Education/training purposes accounted for 4.7% of total animal use.

7.8 % (258,883 animals) were used in 'studies for regulatory testing of products for the protection of humans, animals, or the environment'. Examples include safety testing and regulatory toxicology<sup>79</sup>.

In the highest Category of Invasiveness, CI E (procedures which cause severe pain near, at, or above the pain tolerance threshold of anaesthetised conscious animals), 128,873 animals were used, representing 3.9% of total reported animal use. The remaining animals were

<sup>77</sup> Canadian Council on Animal Care. Animal Use Data for 2011. <u>http://ccac.ca/en\_/publications/audf/stats-aud/data-2011. Accessed 13.4.14</u>

<sup>78</sup> Canadian Council on Animal Care. Animal Use Data for 2011. <u>http://ccac.ca/en\_/publications/audf/stats-aud/data-2011</u>. Accessed 13.4.14

<sup>79</sup> Canadian Council on Animal Care. Instructions for the Completion of the CCAC Animal Use Data Form. http://www.ccac.ca/Documents/Assessment/AUDF\_Instructions.pdf. Accessed 18.4.14



fairly evenly split between the other categories: little or no comfort or stress; minor stress or pain of short duration; moderate to severe distress or discomfort. The three most used species of animals in CI E were fish, mice and guinea pigs.

The number of animals subjected to categories CI D and CI E, i.e. moderate to severe pain, was 1,237,050 - 37.1% of all animals.

The CCAC data<sup>80</sup> have two major limitations:

- Not all animal labs in Canada submit data. Participation is only mandatory for labs that receive research funding from the Canadian national funding agencies (Canadian Institutes for Health Research and the Natural Sciences and Engineering Research Council). Although some other labs still submit annual data, not all do. The number of labs using animals that do not submit data to the CCAC is not known.
- 2. The data do not show whether an individual animal has been used in more than one experiment. "If an animal had been used two or more times in a calendar year (re-use), then only the most invasive use of that animal was reported by CCAC. This means that numbers presented for animal use per CI and animal use per PAU [type of experiment] have been under-reported."

# 9.3 Australia

In Australia, the Code for the Care and Use of Animals for Scientific Purposes governs how animals used in research must be treated<sup>81</sup>. The Code is enforced at state and territory level, mostly through animal welfare acts. It requires all research involving animals be approved by an Animal Ethics Committee<sup>82</sup>.

Under this Code<sup>83</sup>, an animal is classed as: "any live non-human vertebrate (that is, fish, amphibians, reptiles, birds and mammals encompassing domestic animals, purpose-bred animals, livestock, wildlife) and cephalopods". For any animal species not covered by the Code, individual institutions are responsible for determining when their use requires approval from an AEC, "taking into account emerging evidence of sentience and ability to experience pain and distress. Animals at early stages in their development – that is, in their embryonic, foetal and larval forms – can experience pain and distress, but this occurs at different stages of development in different species. Thus decisions as to their welfare should, where possible, be based on evidence of their neurobiological development. As a guide, when

<sup>80</sup> Canadian Council on Animal Care. 2011 Animal Use Statistics.

http://www.ccac.ca/Documents/Publications/Statistics/CCAC\_Animal\_Use\_Statistics\_2011.pdf. Accessed 13.4.14 81 Animal Liberation. Vivisection. <u>http://www.animal-lib.org.au/campaigns/animals-for-science/vivisection</u>. Accessed 14.4.14

<sup>82</sup> Animal Ethics Infolink. Animal ethics committees. <u>http://www.animalethics.org.au/animal-ethics-</u> committees. Accessed 14.4.14

<sup>83</sup> National Health and Medical Research Council. Australian code for the care and use of animals for scientific purposes. 8th Edition 2013



embryos, foetuses and larval forms have progressed beyond half the gestation or incubation period of the relevant species, or they become capable of independent feeding, the potential for them to experience pain and distress should be taken into account".

Statistics are submitted on a state or territory level. In New South Wales, for example, all accredited labs must complete an Annual Return on Animal Use, a requirement of the Animal Research Act 1985. The form requires information on numbers and species of animals used, the purpose of the research and the type of procedure carried out and is published in the Animal Research Review Panel Annual Report<sup>84</sup>.

Humane Research Australia collects annual data from each state/territory and publishes this on its website<sup>85</sup>. However, data are not provided for all states. 2011 statistics<sup>86</sup> are provided for three states, totalling 4,930,466 animals. Using 2009 figures for the other five states/territories, HRA estimates that almost 7 million animals would have been used in 2011. There does not appear to be comparative data over a period of time showing whether there have been any fluctuations in the number of animals used or of the species involved.

The available 2011 figures show that of 4,930,466 animals used, 1,139,136 (23.10%) were domestic fowl and 928,217 (18.83%) were mice. Listed in the statistics were also 'exotic zoo animals'. Of 4,930,022 animals listed in data on types of experiment (a discrepancy with the overall figure of animals used), over 2 million (41.24%) were described as being subjected to 'minor conscious intervention', half a million (10.32%) as 'major physiological challenge' and 24,702 as 'death as an end point' (e.g. lethal dosing experiments).

# 9.4 New Zealand

Animal testing in NZ is governed by the Animal Welfare Act 1999<sup>87</sup>, which requires the person or organisation involved to hold an "approved code of ethical conduct". Where research or testing is deemed "necessary in the national interest", the Minister for Primary Industries may authorise it without the approval of an AECA<sup>88</sup>, although this appears not to happen.

The Animal Welfare Act is currently undergoing review, including some sections relating to animal testing.

Under the Animal Welfare (Records and Statistics) Regulations 1999, code holders are required to keep records and provide an annual return to the Ministry of Primary Industries.

<sup>84</sup> Animal Ethics Infolink. Annual statistics report. <u>http://www.animalethics.org.au/animal-ethics-</u> <u>committees/annual-statistics-report</u>. Accessed 14.4.14

<sup>85 &</sup>lt;u>http://www.humaneresearch.org.au/statistics/</u>

<sup>86</sup> Humane Research Australia. Statistics: Animal use in research & teaching, Australia. http://www.humaneresearch.org.au/statistics/. Accessed 15.4.14

<sup>87</sup> Ministry for Primary Industries. The Animal Welfare Act - A Framework for the 21st Century. http://www.biosecurity.govt.nz/legislation/animal-welfare-act/index.htm. Accessed 15.4.14

<sup>88</sup> National Animal Ethics Advisory Committee. Annual Report 1 January to 31 December 2012



All animal experimentation (research, teaching and testing – RTT) in the country is overseen by NAEAC, the National Animal Ethics Advisory Committee, a small body within the Ministry for Primary Industries. According to SAFE (Save Animals From Exploitation)<sup>89</sup>, "NAEAC relies on the Ministry for support, meets part time, has minimal funding, is not independent, and does not have proper staffing or appropriate membership. The real power resides with various Animal Ethics Committees (AECs), which approve the actual individual testing projects. Incredibly, these AECs are set up and run by the very companies that wish to conduct tests on animals. Once permitted, only a very small percentage of projects are actually monitored by the AECs."

Statistics are published in NAEAC's Annual Report<sup>90</sup>.

Figures for 2012<sup>91</sup> show:

- A total of 301,964 animals used in research, testing and teaching were reported in 2012
- Recognising that agriculture is a primary industry in NZ, farmed animals made up 55.9% of the total number of animals used. Cattle made up 41.3% of the total number (124,582 individuals) and sheep 12.8% (38,544). 54.3% of all animals used in testing were supplied by farms
- 18.5% (55,870) of all animals used were mice
- Fish replaced birds as the fourth most common species in 2012, making up 9.3% of the total numbers (27,949 fish)

The biggest increases reported were for cattle (+ 17,981; 16.9% rise); fish (+ 12,418; 80%); possums (+ 3,941; 242%); reptiles (+ 3685; 221.5%); amphibia (+ 1415; 233.5 percent); marine mammals (+ 491; 168.2%); horses (+ 99; 15%).

Long term animal experiments:

Although the number of animal experiments reported in the 2012 figures was a reduction of 7.6% over the previous year, the rolling 3-year average was marginally up. The NAEAC Report<sup>92</sup> notes: "Records of the number of animals used in long-term projects are not reported annually to MPI but every three years or at the end of the year in which the project is completed (if less than three years). [...] Much of the annual variability in the statistics can be attributed to the three-yearly cycle of reporting of long-term projects. [...] In both 2009 and 2010, the numbers fell, and the increase in 2011 was predicted on the likelihood that a number of long-term studies would be reported. That increase has been followed by the 2012 fall. Although the 2012 numbers were lower than in the previous year, the three-year rolling average, a truer reflection of overall use, rose slightly."

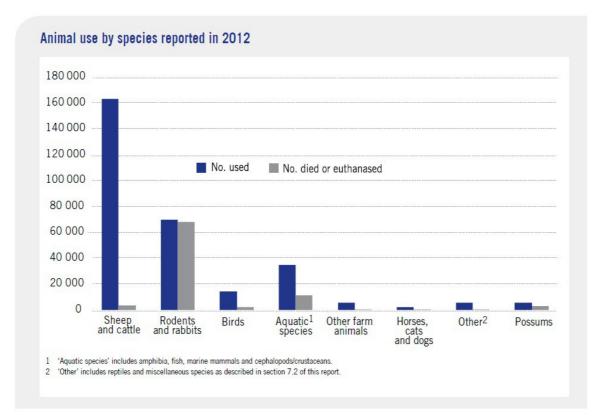
<sup>89</sup> SAFE. Time for progress for animals used in experiments. <u>http://animalwelfare.org.nz/</u>. Accessed 15.4.14

<sup>90 &</sup>lt;u>http://www.biosecurity.govt.nz/regs/animal-welfare/naeac/annual-reports</u>

<sup>91</sup> National Animal Ethics Advisory Committee. Annual Report 1 January to 31 December 2012

<sup>92</sup> National Animal Ethics Advisory Committee. Annual Report 1 January to 31 December 2012





#### Chart 2: Animal use by species, New Zealand, 201293

The NZ statistical report provides basic information on the types of experiments animals are used in as shown in the table below.

The 'testing' category is described as: "Animals used for public health testing or to ensure the safety, efficacy or quality of products to meet regulatory requirements for human or animal products, either in New Zealand or internationally." 7.6% of all animals used are placed in the 'testing' category, which equates to 22,949 animals.

Development of alternatives: "Work aimed at developing methods to replace or reduce the use of live animals in research, testing and teaching." 0.5% (1,510 animals) were used for this category.

<sup>93</sup> National Animal Ethics Advisory Committee. Annual Report 1 January to 31 December 2012



#### Table 3: Category of experiments, New Zealand, 2011 and 2012<sup>94</sup>

Purpose of manipulation	% of animal	s used
	2012	2011
Veterinary research	34.2	19.9
Basic biological research	23.5	15.6
Animal husbandry	12.4	24.2
Medical research	9.4	8.7
Testing	7.6	10.3
Teaching	6.3	15.3
Environmental management	2.1	2.2
Production of biological agents	1.9	1.9
Species conservation	1.9	1.1
Development of alternatives	0.5	0.2
Other	0.4	0.5

Severity of experiments:

A total of 16,767 animals (5.6% of the total) experienced experiments of "high impact" or "very high impact". The species that experienced a 'very high' impact were rodents, fish, 'pest' species, pigs' and cephalopod/crustacea.

88,995 animals (29.47%) died or were euthanased during, or after, experiments in 2012.

<sup>94</sup> National Animal Ethics Advisory Committee. Annual Report 1 January to 31 December 2012



2012 summary	Total reported	No/virtually no impact	Little impact	Moderate impact	High impact	Very high impact
Rodents and rabbits	70 002	3 193	24 264	29 717	3 225	9 603
Sheep and cattle	163 126	65 027	94 972	2 994	133	0
Aquatic species <sup>1</sup>	34 909	13 870	18 678	2 146	150	63
Other domestic species	8 127	2 045	5 880	196	3	3
Birds	14 638	8 220	3 468	1 145	1 805	0
Possums	5 570	562	279	3 847	615	267
Other <sup>2</sup>	5 592	93	3 528	1 073	868	32
Grade totals	301 964	93 010	151 069	41 118	6 799	9 968
Grade percentages		30.8%	50.0%	13.6%	2.3%	3.3%

#### Table 4: Severity of experiments on animals, New Zealand, 2012<sup>95</sup>

Aquatic species' includes amphibians, fish, marine mammals and cephalopods/crustaceans.
 'Other' includes reptiles and miscellaneous species as described in section 8.2.

High impact experiments are described as being of "moderate impact and long duration or high impact and short duration" and very high impact as "high impact and long duration".

#### Re-use of animals

In 2012, 10.1% of animals (30,498) were used more than once for RTT. This the highest proportion of re-use since 2000. Domestic animals (including farmed animals) made up 71.1% of the animals who were reused, with 30.9% of reptiles and 21.6% of fish also being re-used<sup>96</sup>.

National Animal Ethics Advisory Committee. Annual Report 1 January to 31 December 2012
 National Animal Ethics Advisory Committee. Annual Report 1 January to 31 December 2012



#### Table 5: Number of animals used and percentage died, New Zealand, 2008 - 2012<sup>97</sup>

Animal Usage Report: Five-year summary of the number of animals used and the percentage that died or were euthanased (by species)

	20	12	20	11	20	10	20	09	20	08
	No. used	% died or euthanased	No. used	% died or euthanased	No. used	% died or euthanased	No. used	% died or euthanased	No. used	% died or euthanased
Amphibia	2021	64	606	13	811	7	2378	14	264	5
Birds	14 638	15	40 937	35	7492	33	49 023	78	31 053	23
Cats	695	<1	978	10	554	1	1132	12	804	4
Cattle	124 582	<1	106 601	<1	42 341	2	24 763	3	69 564	1
Cephalopods/ crustaceans	4154	27	5118	86	<mark>3107</mark>	7	N/A	N/A	N/A	N/A
Deer	3927	8	16 779	<1	9 094	1	5967	3	2951	6
Dogs	915	2	1048	12	814	7	690	7	792	5
Fish	27 949	32	15 531	64	15 611	15	23 736	46	41 057	44
Goats	1568	<1	1983	<1	1161	5	3231	6	1374	1
Guinea pigs	2090	96	2394	97	2316	96	4061	99	3075	98
Horses/ donkeys	758	<1	659	3	840	2	709	1	525	1
Marin <del>o</del> mammals	783	0	292	0	212	0	651	0	1535	0
Mice	55 870	99	74 133	98	84 620	94	90 982	91	87 154	98
Pigs	264	58	809	54	513	69	995	24	417	58
Possums	5570	54	1629	84	1223	76	4797	63	1644	80
Rabbits	1519	95	1921	94	1846	95	2018	97	2049	96
Rats	10 523	92	10 674	93	11 166	96	17 333	82	13 960	95
Reptiles	5349	<1	1664	1	1686	14	7422	1	2327	1
Sheep	38 544	7	<mark>4</mark> 2 571	6	55 859	5	45 991	9	78 093	4
Misc. species	245	28	443	10	883	31	11 232	13	2882	13
Total no. used	301 964		326 770		242 149		297 111		341 520	
Yearly %		29%		37%		43%		55%		40%

NZ has a small population and few anti-vivisection organisations. Both SAFE (www.safe.org.nz) and the NZ Anti-Vivisection Society (www.nzavs.org.nz) provide limited analysis of national statistics.

<sup>97</sup> National Animal Ethics Advisory Committee. Annual Report 1 January to 31 December 2012



#### 9.5 Europe

For the 28 Member States of the European Union, Directive 2010/63/EU (which revised the earlier Directive 86/609/EEC) on the protection of animals used for scientific purposes, regulates the use of animals in experiments. The Directive is transposed into national law by each country.

Article 54 of the Directive<sup>98</sup> requires that "Member States shall collect and make publicly available, on an annual basis, statistical information on the use of animals in procedures, including information on the actual severity of the procedures and on the origin and species of non-human primates used in procedures". These are the only figures collated on a multi-national basis.

Europe-wide data was first published in 1994 then again in 1999, covering data collected in 1991 and 1996 respectively. These reports "allowed only a limited amount of statistical analysis due to the absence of a consistent system of reporting the data on the use of experimental animals"<sup>99</sup>. In 1997 an agreement was made to submit data for future reports under a format of eight harmonized tables; this was published for the first time in 2007, containing data collected in the 10 Member States which joined the EU in 2004. Other reports were then produced in 2010 (for data from 2008 in 27 Member States) and in 2013 (for data from 2011 in 27 Member States)<sup>100</sup>.

In 2012, a Decision was made to establish a common format for submitting the required information by each Member State, "for the data to be meaningful, accurate and comparable" and to ensure consistency in the implementation of the Directive<sup>101</sup>. The first data under the new statistical reporting format will be collected from 1 January 2014<sup>102</sup>.

The latest available European data was published in 2013 and refers to experiments that took place in 2011 (other than one Member State, France, which was reporting for 2010). 27 countries were members of the EU at this time. These data reveal that 11.5 million animals (11,481,521) were subjected to experiments in the EU during 2011. A detailed table of the numbers of animals used in each country is attached as Appendix 1.

<sup>98</sup> Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes

<sup>99</sup> European Commission. Commission Staff Working Document. Accompanying document to the Report from the Commission to the Council and the European Parliament. 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. 2013. Part 1/5

<sup>100</sup> European Commission. Commission Staff Working Document. Accompanying document to the Report from the Commission to the Council and the European Parliament. 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. 2013

Consolidated Commission Implementing Decision 2012/707/EU as corrected by Decision 2014/11/EU
 European Commission. Legislation for the protection of animals used for scientific purposes.
 http://ec.europa.eu/environment/chemicals/lab animals/legislation en.htm. Accessed 16.4.14



(EU data excludes numbers of genetically-modified animals used solely to maintain established breeding colonies, but the UK records them for its own national report. An additional 2 million animals is missing from the EU-published data – see section on UK later in this report).

EU statistics listed here are taken from Part 1/5 of the 2013 European Commission Staff Working Document<sup>103</sup>.

France	2,200,152
Germany	2,073,702
United Kingdom*	2,050,458
Spain	900,127
Italy	781,815
Belgium	665,079
Netherlands	514,617
Czech Republic	354,196
Denmark	282,840
Poland	282,160
Hungary	276,179
Sweden	271,041
Ireland	264,990
Austria	191,288
Finland	136,043
Romania	60,156
Portugal	46,556
Estonia	41,035
Greece	28,001
Bulgaria	17,259
Slovakia	15,717
Slovenia	11,874
Latvia	10,329
Lithuania	4,067
Cyprus	1,328
Luxembourg	502
Malta	10

#### Table 6: EU countries and their use of animals, in descending order<sup>104</sup>

<sup>103</sup> European Commission. Commission Staff Working Document. Accompanying document to the Report from the Commission to the Council and the European Parliament. 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. 2013. Part 1/5

<sup>104</sup> Based on data contained in European Commission. Commission Staff Working Document. Accompanying document to the Report from the Commission to the Council and the European Parliament. 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. 2013. Part 1/5



\*EU data excludes numbers of genetically-modified animals used solely to maintain established breeding colonies, but the UK records them for its own national report. An additional 2 million animals is missing from the EU-published data above.

France, Germany and UK each used over 2 million animals (55% of all animals used in the EU). On the other end of the scale, Luxembourg used 502 and Malta 10 animals.

Species used:

Mice make up the majority of animals used in experiments in the EU (60.96% - 6,999,312 individuals). Rodents together with rabbits represent 80% of the total number of animals used. The second most used group is represented by cold-blooded animals namely reptiles, amphibians and fish at 12.4%.

Birds are the next highest animal group used at 5.9%.

# Artio+Perissodactyla 1,28% Birds 5,88% Cold-blooded animals 12,47% Rabbits 3,12% Other Rodents 0,47% Guinea-Pigs 1,49% Rats 13,96%

Percentages of animals used by classes in the Member States

#### Chart 3: Percentages of animals used in EU, 2011<sup>105</sup>

More than 60% of animals were used in categories of experiments classed as research and development in the fields of human medicine, veterinary medicine, dentistry and in biological

<sup>105</sup> European Commission. Commission Staff Working Document. Accompanying document to the Report from the Commission to the Council and the European Parliament. 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. 2013. Part 1/5



studies of fundamental nature. Production and quality control of products and devices in human medicine, veterinary medicine and dentistry used 14% of the total number of animals. Toxicological and other safety evaluation represents 8.75% of the total number of animals used.

Changes in animal use:

In 2011, the number of animals used for research and development for human medicine, dentistry and veterinary medicine had dropped from the 2008 figures, from 22.8% to 18.8% (a decrease of 575,518 animals). The percentage of animals used for fundamental biological research increased sharply from 38% to 46% (715,519 animals). Both fundamental biological research and research and development in human and veterinary medicine are the areas using by far the highest number of animals in the EU.

# Toxicology:

The number of animals used for toxicological and other safety evaluation amounts to 8.75% of the total (1,004,873 animals) in the EU report. This percentage has remained fairly stable since 2002.

Further substantial increases since 2008 have been observed for mice (+521,000) and fish (+324,000), used in larger numbers for fundamental biological studies. In the case of mice used in 'biological studies of fundamental nature', Member States indicated that it was due to an increase in developmental assays and research using transgenic (genetically-modified) mice as specific models for e.g. ocular research, bone metabolism and fertility.

Toxicological or other safety evaluations are split according to the type of sector for which they are intended. 0.35% of animals were used for toxicological evaluation of three groups of products/substances, i.e. additives in food for human consumption, cosmetics and household products. 8.07% were used for toxicological tests for products intended for industry and for agriculture, little different to the 2008 figures. However, here was a net increase in the number of animals used for potential contaminants of the environment, from around 65,000 to approximately 92,000<sup>106</sup>.

The largest percentage (47.5%) of use of animals in toxicological and other safety evaluation is due to acute and sub-acute toxicity tests. Nearly 15% of animals were used for testing carcinogenicity, mutagenicity and toxicity to reproduction. The second largest percentage of 22% is to cover other toxicological and safety evaluation<sup>107</sup>.

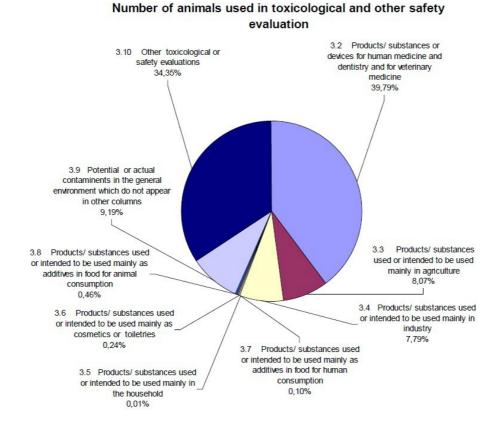
<sup>106</sup> Seventh Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union. 2013

<sup>107</sup> 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. 2013



There has been a continuous increase over the last four reports in the proportion of animals used for acute and sub-acute tests, from 36%, 42%, 45% to 47.5% respectively. This represents an increase of more than 8,400 animals since the last report. In 2011 the number of the animals used for reproductive toxicity testing increased from 9% in 2008 to 11.35% - an increase of almost 19,000 animals<sup>108</sup>.

The number of animals used in testing cosmetics and toiletries fell from 1,960 to 90 animals. This is despite an EU ban on animal testing for cosmetics and cosmetic ingredients coming into place in 2009<sup>109</sup>.



#### Chart 4: Number of animals used in toxicological and other safety testing, EU, 2011<sup>110</sup>

<sup>108</sup> 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. 2013

<sup>109</sup> European Commission. Commission Staff Working Document. Accompanying document to the Report from the Commission to the Council and the European Parliament. 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. 2013. Part 1/5

<sup>110</sup> European Commission. Commission Staff Working Document. Accompanying document to the Report from the Commission to the Council and the European Parliament. 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. 2013. Part 1/5



The EU reports show a decrease of 4.3% (519,501 animals) in the number of animal experiments carried out between 2008 and 2011. This was "cautiously welcomed" by the European Coalition to End Animal Experiments. However, they noted that they believed "this is likely to be more of a reflection of the economic climate as none of the member countries have a committed strategy for reduction in place"<sup>111</sup>.

Eurogroup for Animals also commented<sup>112</sup>: "The overall use now stands at just below 11.5 million animals, a decrease of half a million since the last set of statistics for 2008. Even though this decrease is welcomed, there is still no substantial evidence that this will be the new trend as there remains no comprehensive approach across the EU to decrease the use of animals for research and testing."

# 9.10 Individual European countries

Parts 2-5 of the 2013 European Commission Staff Working Document<sup>113</sup>, which forms part of the Seventh Report on animal testing statistics, contains the data from individual Member States.

As previously noted, France, Germany and the UK used 55% of the total number of animals used throughout the EU in 2011. Analysis of the statistics by the European Coalition to End Animal Experiments<sup>114</sup> reveals:

Species use which increased (compared to 2008):

- Other carnivores (foxes, badgers, seals, otters and polecats): +75% (+4,982 animals)
- Fish: +29% (+1,397,462 animals)
- Horses, donkeys and ponies: +12% (+6,686 animals)
- Rabbits: +8% (+358,213 animals)

According to the 2013 Commission Staff Working Documents, the countries in which numbers of animals used in testing increased include:

• Denmark: 4.2% increase - in 2011, 282,840 animals were used for experimental purposes in Denmark, 11,372 more than in 2010<sup>115</sup>.

<sup>111</sup> ECEAE. The European Coalition to End Animal Experiments reacts with disappointment to today's EU statistics on animal experimentation. News Release, 12.12.13. <u>http://www.eceae.org/hr/category/latest-news/346/the-eceae-reacts-with-disappointment-to-todays-eu-statistics-on-animal-experimentation</u>

<sup>112</sup> Eurogroup for Animals. Latest Statistics for Animals Used for Scientific Procedures in EU Now Out. News, 13.2.13. <u>http://eurogroupforanimals.org/news/latest-statistics-for-animals-used-for-scientic-procedures-in-eu-now-out</u>

<sup>113</sup> European Commission. Commission Staff Working Document. Accompanying document to the Report from the Commission to the Council and the European Parliament. 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. 2013. <u>http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2013:0497:FIN:EN:PDF</u>

<sup>114</sup> ECEAE. The European Coalition to End Animal Experiments reacts with disappointment to today's EU statistics on animal experimentation. News Release, 12.12.13. <u>http://www.eceae.org/hr/category/latest-news/346/the-eceae-reacts-with-disappointment-to-todays-eu-statistics-on-animal-experimentation</u>



- Ireland: A total of 264,990 animals were used. This represents an increase of 135% compared to the 112,835 animals used in 2008<sup>116</sup>.
- Netherlands: In 2011 the total number of animals used was 514,617. This is 3.2% (16,314) more than the number of animals used in 2010 (498,303)<sup>117</sup>.
- Austria: 2.1% increase in animal use. The statistics for 2011 shows that in total 191,288 animals were used in procedures in Austria<sup>118</sup>.

By contrast, there was a 53% reduction in animal use in Bulgaria in 2011<sup>119</sup>.

#### 9.11 United Kingdom

UK Government statistics<sup>120</sup> show that 4.11 million 'scientific procedures' involving animals started in 2012, an increase of 317,200 (+8%) compared with 2011.

The rise was mainly due to an increase of 363,100 (+22%) in the breeding of genetically modified (GM) animals and harmful mutants (HM - possessing one or more genes that have undergone mutation), mainly mice, to 1.98 million procedures, nearly half (48%) of the total number of procedures performed.

There were 4.03 million animals used for the first time in procedures started in 2012, an increase of 322,700 (+9%), reflecting the increase in the numbers of procedures started.

<sup>115</sup> European Commission. Commission Staff Working Document. Accompanying document to the Report from the Commission to the Council and the European Parliament. 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. 2013. 2/5

<sup>116</sup> European Commission. Commission Staff Working Document. Accompanying document to the Report from the Commission to the Council and the European Parliament. 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. 2013. 3/5

<sup>117</sup> European Commission. Commission Staff Working Document. Accompanying document to the Report from the Commission to the Council and the European Parliament. 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. 2013. 4/5

<sup>118</sup> European Commission. Commission Staff Working Document. Accompanying document to the Report from the Commission to the Council and the European Parliament. 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. 2013. 5/5

<sup>119</sup> European Commission. Commission Staff Working Document. Accompanying document to the Report from the Commission to the Council and the European Parliament. 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. 2013. 2/5

<sup>120</sup> Home Office. Annual Statistics of Scientific Procedures on Living Animals Great Britain 2012



This figure conflicts with that published in the EU report<sup>121</sup>, which states that the UK used 2,050,458 animals in 2011. The UK's own national report<sup>122</sup> for 2011 put the figure as just over 3.79 million. This is because the UK includes numbers of genetically-modified and harmful mutant animals used solely to maintain established breeding colonies, but the EU does not. This accounts for another 1.7 million animals.

#### Chart 5: Trends in animal use in labs, UK, 1945 - 2012<sup>123</sup>

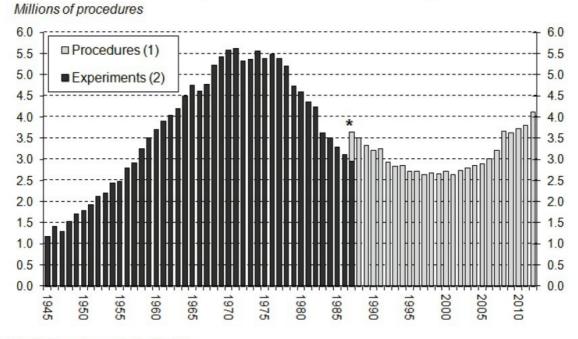


Figure 1: Experiments or procedures commenced each year, 1945–2012

(1) Scientific Procedures under the 1986 Act

(2) Experiments under the 1876 Act

\* The 1987 total includes experiments under the 1876 Act as well as procedures under the 1986 Act.

Species used in 2012:

- Mice were the most commonly used species accounting for around three-quarters of procedures (74%)
- Fish (12%), rats (7%) and birds (4%) were the next most frequently used species. Domestic fowl accounted for 89% of all procedures using birds

<sup>121</sup> European Commission. Commission Staff Working Document. Accompanying document to the Report from the Commission to the Council and the European Parliament. 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. 2013. Part 5/5

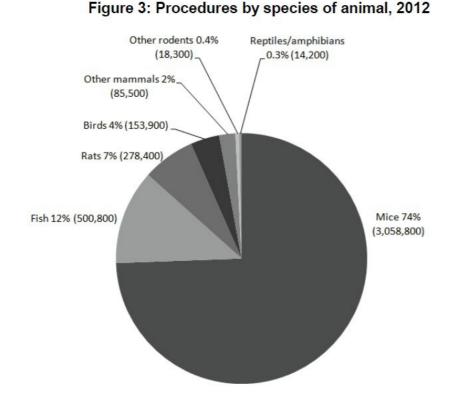
<sup>122</sup> Home Office. Annual Statistics of Scientific Procedures on Living Animals Great Britain 2011

<sup>123</sup> Home Office. Annual Statistics of Scientific Procedures on Living Animals Great Britain 2012



- Other mammals accounted for 2% of all procedures, of which dogs, cats and nonhuman primates combined were used in 0.2% of all procedures, with a combined total of 8,100
- Other rodents and reptiles/amphibians accounted for 0.4% and 0.3% of procedures respectively

There were increases in 2012 in the numbers of procedures for the following species: mice (+379,058 or +14%); sheep (+5,157 or +14%); goats (+1,462 or +746%), up from 196; guinea pigs (+1,203 or +10%); and non-human primates (+545 or +22%). There were falls for the following species: fish (-63,073 or -11%); amphibians (-2,218 or -14%); rabbits (-1,595 or -10%); and pigs (-961 or -22%).



# Chart 6: Percentages of animals used, UK, 2012<sup>124</sup>

Toxicology experiments:

In 2012, 377,000 procedures were undertaken for toxicological or other safety/efficacy purposes, 9% of the total 4.11 million procedures. This represents a decrease of 22,100 (-6%) compared with 2011, which continues the overall trend of a fall in toxicological procedures in recent years. The decrease in 2012 was mainly attributable to a decline in the use of fish (-41,600 or -55%) but there was also a rise in the use of mice (+16,400 or +10%).

<sup>124</sup> Home Office. Annual Statistics of Scientific Procedures on Living Animals Great Britain 2012



In 2012, 281,700 (75%) of toxicological procedures were for pharmaceutical safety/efficacy evaluation, with 223,100 involving mice or rats (79% of all pharmaceutical safety/efficacy evaluation procedures) and 2,100 (less than 1%) involving non-human primates.

Mice were the main species used with 184,000 procedures (49% of the toxicological total). Rats and fish were the next most common species, accounting for 111,500 (30%) and 34,700 (9%) of toxicological procedures respectively. Other species used were birds (17,700 or 5% of the toxicology total), rabbits (10,000 or 3%), other animals (9,600 or 3%) and all other rodents (9,400 or 2%).

6% of procedures (23,900) did not conform to any legislative requirements.

Severity of experiments: According to the Home Office<sup>125</sup>, the transposition of the European Directive in 1 January 2013 "means that the actual severity experienced by animals in research and testing will be reported for the first time. The assessment of actual severity will include consideration of the lifetime experience of the animals, also expressed as 'cumulative severity'. This includes examining housing and husbandry, transport and length of time under procedure as well as the severity of the experiments themselves".

Comparing the number of animal experiments against figures for the number of lab inspectors, which continued to decline, the BUAV was able to show<sup>126</sup> that each inspector was responsible for supervising over 200,000 experiments a year.

<sup>125</sup> Home Office. Report of the Animal Procedures Committee for 2011. 2013

<sup>126</sup> BUAV. BUAV denounces Government's broken promises as animal experiment toll rises to over 4m; primate use soars by 22%. <u>http://www.buav.org/article/1303/buav-denounces-governments-broken-promises-as-animal-experiment-toll-rises-to-over-4m-primate-use-soars-by-22</u>. News Release, 16.7.13



#### **10** Overview of key statistical findings

In the few countries where we have collated current data within this report, we can make the following observations:

#### 10.1 Numbers of animals used

# Table 7: Number of animals used in experiments in countries covered in this report,2011/2012

Country	Year	Number of animals	Notes
USA	2012	1,110,199	Not including mice, rats, birds, amphibians, reptiles. True number estimated to be over 22 million
Canada	2012	3,333,689	Not all animal labs in Canada submit data
Australia	2011	Estimated 7 million	Data not available for all states
New Zealand	2012	301,964	
UK	2012	4.11 million	

Europe: Data on animal testing in Europe is available for 2011 (although data for France is for 2010). 27 countries were members of the EU at this time. Total number of animals used: 11,481,521

# Table 8: Top five EU Member States used in experiments in countries covered in this report, 2011

Country	Number of animals
France	2,200,152
Germany	2,073,702
United Kingdom	2,050,458
Spain	900,127
Italy	781,815

(NB: For Table 8 we have used the statistics from the EU report which excludes the number of genetically-modified animals used for breeding. Therefore UK statistics are different by 1.7 million compared to other tables in this section)



#### 10.2 Most commonly used animals

# Table 9: Most commonly used species in animal testing in countries covered in thisreport, 2011/2012

Country	Year	Species	Number of animals	Percentage of all animals used
USA*	2012	Guinea pigs	212,699	19.16%
		Rabbits	205,480	18.51%
Canada**	2012	Fish	1,300,259	39.00%
		Mice	1,090,730	32.72%
		Rats	225,971	6.78%
Australia***	2011	Domestic fowl	1,139,136	23.10%
		Mice	928,217	18.83%
New Zealand	2012	Cattle	124,582	41.3%
		Sheep	38,544	12.8%
		Mice	55,870	18.5%
UK	2012	Mice	3,058,800	74%
		Fish	500,800	12%
		Rats	278,400	7%

\* Figures do not include mice, rats, birds, amphibians, reptiles.

\*\* Not all animal labs in Canada submit data

\*\*\*Based on data from three states (4,930,466 animals)

#### 10.3 Severity of experiments

The level of pain caused to animals during experiments is not always recorded in statistical reports and, where it is, is not always described in the same way. The table below looks at the highest level of pain detailed in the available reports.

#### Table 10: Severity of experiments in countries covered in this report, 2011/2012

Country	Year	Level of pain	Number of animals	Percentage of all animals used
USA	2012	With Pain, No Drugs	85,240	7.71%
Canada	2012	CI E (procedures which cause severe pain near, at, or above the pain tolerance threshold of anaesthetised	128,873	3.9%



		conscious animals		
Australia*	2011	Major physiological challenge	half a million	10.32%
New Zealand	2012	high impact and very high impact	16,767	5.6%
		died or euthanased	88,995	29.47%

\*Based on data from three states (4,930,022 animals)

#### 10.4 Toxicology

#### Table 11: Number of animals used in toxicology experiments, 2011/2012

Country	studies		Number of animals	Percentage of all animals used
Canada	2012	Studies for regulatory testing of products for the protection of humans, animals, or the environment	258,883	7.8 %
New Zealand	2012	Public health testing or to ensure the safety, efficacy or quality of products	22,949	7.6%
UK	2012	Toxicological or other safety/efficacy purposes	377,000	9%
European Union	2011	Toxicological and other safety evaluation	1,004,873	8.75%

Although it is difficult to draw conclusions from a small set of data, Table 11 shows that in these regions, toxicology experiments make up around 8% of all animal tests. If this was extrapolated to a global figure, based on Taylor et al.'s estimate of 115.3 million animals used worldwide, approximately nine million animals may be used in toxicology experiments.



# 11 Conclusions

This paper shows that there are great differences in the way in which individual countries approach the regulation of animal testing. Some have no legislation, some provide for self-regulation, others have formal regulation and enforcement. In the European Union, a Directive on animal experimentation is transposed into national law by all Member States.

Equally, collection and analysis of data varies considerably, from none at all to the EU situation where data are collated on a multi-national basis and attempts have been made to formalise the collection of comparative data.

A clear example of the way in which data is not uniformly presented is the UK. As an EU Member State it has to submit its animal testing data for inclusion in an EU-wide statistical report. However, the EU excludes numbers of genetically-modified and harmful mutant animals used solely to maintain established breeding colonies, whereas the UK includes them. So, the EU report states that the UK used 2,050,458 animals in 2011, yet the UK's own national report for the same year put the figure as 3.79 million, a discrepancy of 1.7 million animals.

The species that are covered by national law also differs. In the USA, approximately 95% of all animals used in labs are not even covered by law or statistical collection as mice, rats, birds, reptiles and amphibians are not included in the Animal Welfare Act. As few invertebrates are included any legislation around the world, it is impossible to estimate the numbers used.

Exclusions on data collection also differ to varying extents in relation to a number of other factors, such as: animals killed to supply tissues; genetically-modified animals used to maintain established breeding colonies; animals killed as 'surplus to requirements'; use of cephalopods and crustaceans.

For these reasons, even where data do exist, the differences in the type of data make it extremely difficult to make a comparative analysis. Changes in the way in which data is collated and published (as has happened in the EU) also cause difficulties in tracking fluctuations over long periods. In its recent alteration to data collection in Member States, the EU could have done more to ensure an accurate data set was requested, such as information on animals killed for tissues and organs.



It is clearly no easy task to accurately determine the extent of animal experiments on a global scale. Taylor et al., in their 2008 paper<sup>127</sup>, came the closest to understanding the worldwide scale of animal testing with their estimate of 115.3 million animals in 179 countries, a huge figure but one which they concluded "is still likely to be an underestimate".

As was mentioned in the introduction, it is important to know the scale of animal testing (both nationally and globally) if we are to have a proper and transparent discussion about the scientific and ethical issues surrounding animal experiments and assess the impacts of regulation and the uptake of non-animal testing methods.

In addition, a 2003 workshop on animal experiments stated<sup>128</sup>: "There is also a concern that in order to avoid making costly changes, institutions may choose to 'export' their animal research to countries that have more questionable standards of laboratory animal care, thus generating genuine animal welfare concerns". Yet, with lack of regulation comes lack of statistical collection and analysis, making such theories difficult to confirm.

An end to the use of all animals in experiments and a focus instead on real science, not based on unreliable methods and incorrect species, would benefit all animals, both human and non-human. Ensuring that all countries that continue to experiment on animals publish accurate data would go a long way to aiding the important discussions of the level of animal testing, its purposes and the extent to which animals suffer. The level of toxicology testing involving animals, of particular relevance to the Lush Prize, could also then be determined.

Those data need to be complete and not exclude, as most presently do, animals killed as 'surplus' or for tissues and organs; genetically modified animals used solely to maintain established breeding colonies, etc.

<sup>127</sup> Taylor, K., Gordon, N., Langley, G., Higgins, W. Estimates for Worldwide Laboratory Animal Use in 2005. ATLA 36, 327–342, 2008

<sup>128</sup> Preface: The Development of Science-based Guidelines for Laboratory Animal Care: Proceedings of the November 2003 International Workshop International Workshop on the Development of Science-based Guidelines for Laboratory Animal Care Program Committee, National Research Council

# Appendix 1:

Species	AT	BE	BG	CY	CZ	DK	ET	FI	FR	DE	EL	HU	IE	п	LV	LT	LU	MT	NL	PL	PT	RO	SP	SK	SI	SE	UK	Totals
La.Mice	153153	406883	3819	1328	72855	141991	26048	73503	1326274	1451045	24354	143755	248958	515946	6300	2131	470	0	237784	95115	24399	44575	634912	8747	11133	185913	1155920	699931
I.b.Rats	9026	89547	2569	0	30829	67159	2556	18586	252589	312740	2266	70873	10476	155136	4020	1297	32	0	98881	38171	11290	5161	126406	5327	393	35202	252437	160296
I.c. Guinea- Pigs	3797	24300	3700	D	3304	4672	72	11	35543	24258	39	9228	545	13784	0	177	0	0	5493	8943	4	6607	13749	645	48	1151	11514	17158
I.d. Hamsters	125	2435	516	0	119	178	120	201	8210	4187		88	0	517	0	0	0	0	3632	278	6	263	1492	0	0	881	2003	2525
1.e .Other Rodents	64	421			1316	115	0	2682	224	4111		0	2	1946				0	979	11710	74		80	17	0	1483	3243	2846
I.f. Rabbits	15633	54001	822	0	7677	3602	3	357	125913	87303	701	7567	715	8392	0	274	0	0	6293	2198	102	2195	21302	299	234	710	11920	35821
I.g.Cats	14	630	8	0	181	0	0	454	569	585	19	34	120	0	0	0	0	0	174	480		0	229	10	0	34	172	37
I.h.Dogs	75	490	0	0	1386	470	0	2805	3032	2474	4	675	473	408	9	0	0	0	692	229	20	0	1252	0	0	530	2872	1789
I.i Ferrets	12	192	0	0	193	129	0	0	351	96	8 - B	0	0	0	0	0	0	0	852	0		0	87	0	0	76	552	254
1.j. Other Carnivores	0	0			45	197	0	656	0	262		0		0				0	430	2149			245		0	256	742	498
I.k. Horses, donkeys and cross- preds	128	54			595	67	40	23	373	1140		9	238	34				0	2371	766		14	345		7	107	374	668
I.I.Pigs	1553	2622	110		2263	8694	325	681	7364	15090	390	1278	286	2486		19		0	14686	1147	474	2	11046	84	13	2277	4370	7728
1.m Goats	60	86			106	74	0	40	710	394		0	39	34				0	284	396	99		455		0	13	117	290
1.n. Sheep	683	542	320		1147	191	0	684	5491	3287	8	160	348	243				0	2600	379	29	131	2790	14	4	285	9556	288
1.o.Cattle	1582	810			783	513	6750	63	2362	4300		5	1700	27				0	2383	3489		3	1464	0	0	370	4310	3091
1.p. Prosimians	0	0	0	0	0	0	0	0	83	0		0	0	0	0	0	0	0	0	0		0	0	0	0	0	0	8
1.q. NW Monkeys	0	0	0	0	0	0	O	0	163	191		0	0	79	0	0	0	0	22	0		O	1	0	O	0	244	70
1.r. OW Monkeys	0	20	0	0	30	0	0	O	1564	1579		7	0	371	0	0	0	0	184	0		0	342	0	0	0	1215	531
1.s Apes	0	D	D	0	0	0	0	0	0	٥		0	0	0	0	0	0	0	D	0		0	0	0	0	0	0	
1.t.Other Mammals	0	64			2838	32	20	17	2	1154		0	480	184				10	41	594			56		٥	1625	771	788
1.u.Quail	0	651	0	0	230	0	0	0	122	2821		235	0	4	0	0	0	0	68	1247		9	105	88	0	0	34	561
.v.Other pirds	1940	16493	1080		170261	3245	701	4426	71821	31271		36304	503	29305		20		0	99354	13615	433	1196	21341	486	0	2804	162852	66943
.w.Reptiles	0	459			1258	237	0	15	74	1011	1	0		239				0	133	15		8	0	8	0	0	383	383
Lx Amphibians	176	2113	4285		3989	115	0	73	3279	4453	220	725	21	894		149		0	1247	964	25		1097		0	1216	4542	2958
I.y.Fish	3267	60266	30	11118	52771	51159	4400	30766	354039	119949	· · · · · · · · · · · · · · · · · · ·	5236	88	51786				0	36034	100275	9601		61330	ä	42	36108	420315	1397462
.z.TOTAL	191288	665079	17259	1328	354196	282840	41035	136043	2200152	2073702	28001	276179	264990	781815	10329	4067	502	10	514617	282160	46556	60156	900127	15717	11874	271041	2050458	1148152

# Table 1.1: Total number of animals used for experimental purposes in the EU Member States

Data of 2011 (\*)

(\*) France is reporting for 2010