

Animal Testing Review Panel Report for 2005

Introduction

This is the fourth Report of the Shell Animal Testing Review Panel. (The Panel's Report for 2004 can be viewed at www.shell.com/panelreport)

The content of this Report comprises:

- Shell use of animals up to the end of 2004;
- The Panel's comments on Shell's policy and its implementation;
- The Panel's comments on Shell's engagement in the debate and formulation of public policy on animal testing

The membership and Terms of Reference of the Panel, together with the background to the establishment of the Panel, are provided at the end of this report.

Shell current use of animals

Animal usage over the period 2001-2004 reported by Shell companies is summarised in Table 1

Table 1: Number of animals used in years 2001-2004

Tests commission by	Animals used	Numbers of animals			
		2001	2002	2003	2004
Shell	Rodents	168	0	40 ^a	225
Shell	Rabbits	0	0	16	6
Shell	Fish	25,597	24,987	30,525	28,068
Industry consortia	Rodents	4,070	9,785	6,836 ^a	3,886
Industry consortia	Rabbits	0	0	0	18
Industry consortia	Fish	0	380	400	220
JVs	Rodents	524	437	60	397 ^a
JVs	Rabbits	58	49	6	43
JVs	Fish	3,600	4,670	7,236	4,208

Notes:

Industry Consortia: groups of co-producer companies (including Shell companies) that cooperate, usually within the framework of an industry trade association, to share available data and the costs of testing programmes on particular chemicals or groups of chemicals. This not only saves costs, but also reduces the numbers of animals used.

JVs: Joint Venture companies, in which Shell companies have a shareholding, but which are not under the operational control of Shell companies.

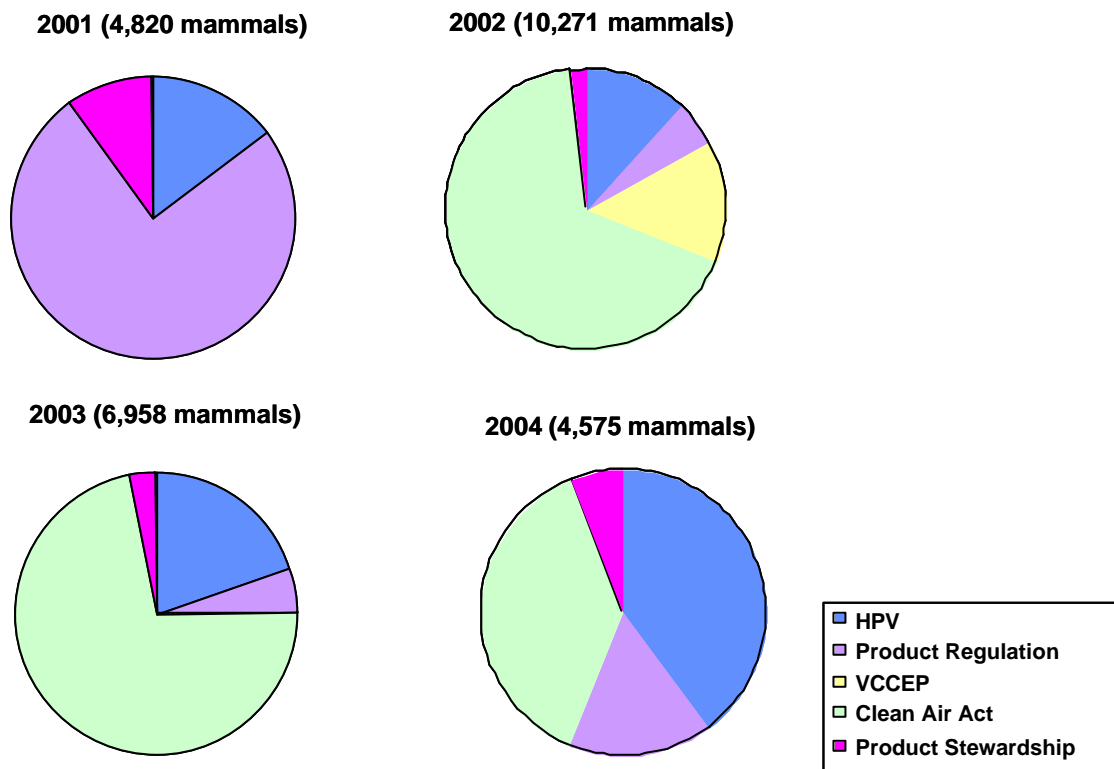
^a numbers include guinea pigs

The distribution of species used in mammalian testing is presented in Table 2.

Table 2: Mammalian species used in 2004

Species	Numbers
Rats	3,928
Mice	550
Guinea pigs	30
Rabbits	67

The purpose of the testing in mammalian species where Shell companies are involved is summarised in the following pie charts for years 2001, 2002, 2003 and 2004. For simplicity, the charts aggregate the numbers of animals used in tests commissioned by Shell companies, by industry consortia in which Shell companies participate, and by JVs.:



The purpose of fish testing and the corresponding numbers used during 2001-2004 is summarised for each of the in Table 3. The category "Operations Regulations" has been added to this Table for the 2005 figures to record the new work being undertaken by Shell companies to comply with legislation in the US for site remediation activities.

Table 3 Use of fish, 2001-2004

Purpose of test	2001	2002	2003	2004
HPV programme	-	400	532	220
Product Stewardship	700	-	60	18
Operations Regulation	-	-	-	8,840
Effluent biomonitoring	28,300	29,400	37,569	23,418
TOTALS	29,197	30,037	38,161	32,496

Notes:

Clean Air Act -the California Clean Air Act currently requires manufacturers of fuels to generate certain toxicity data based on the use of animals.

Product regulation - for example New Substance Notification, EU Existing Substances Regulation, US Toxic Substances Control Act, Canadian Product Safety regulations, all of which require the use of animals to generate product safety data.

Operations Regulation: US legislation related to site clean up and hazardous waste activities that require fish data.

HPV - the US EPA High Production Volume programme, which challenges industry to provide a standard data set, mainly based in tests using animals, for substances produced in excess of 1 million pounds per annum.

Product Stewardship -data are required to understand the health and environment hazards of a product but no specific regulatory driver is apparent

VCCEP (Voluntary Children's Chemical Evaluation Programme) - the US Children's Health programme, being run jointly between industry and the US EPA. The programme requires the generation of certain toxicity data based on the use of animals.

Effluent biomonitoring - in some countries (particularly US and Canada), it is a condition of the operating permit for certain industrial sites such as oil refineries and chemical plants that the toxicity of effluent waters is tested on a range of aquatic organisms, including fish

In its review of animal use in 2004, the Panel noted that the pattern of use, and the purposes for which it was undertaken, remain fairly constant. The majority of testing is a specific response to regulatory requirements or to programmes set up by industry with regulatory endorsement of the US EPA; the proportion of testing for Product Stewardship continues to be small.

The total numbers of animals used was smaller in 2004 than in the previous two years and, as in previous years, the majority of these were fish, mostly used for effluent biomonitoring.

The Panel's work inherently depends on having timely, accurate and rigorous data on animal use, and whilst it has been generally content with reporting to date, it asked Shell to expedite the annual returns, and also asked for detailed information from Shell on how the numbers are recorded and compiled. The Panel welcomed Shell's efforts to produce returns in a timely fashion, and also welcomed the full report describing the process and management of the returns procedure. It will receive further information in the course of 2006 on the application of the Shell standard on animal testing in Joint Ventures

The Panel reviewed the individual tests conducted and sought further information and clarification in relation to three:

- (i) the nature of the testing of a Gas to Liquids material
- (ii) the need to test bitumen fumes
- (iii) the reason for tests involving fish in Nigeria.

It was satisfied with the explanations it received from Shell.

Since the numbers of animals used are determined largely by regulatory attitudes, which differ between the US and Europe, the Panel attaches particular importance to Shell's work with regulators, mostly through industry groups, to promote sound yet proportionate regulation. In particular, it welcomes work with the European Commission to develop more appropriate approaches to hazard assessment for the new Chemicals Policy (REACH). These approaches should significantly reduce the numbers of animals that would otherwise be required in the REACH programme.

The same drivers for testing are expected to apply to 2005.

Policy and its implementation

At the suggestion of the Panel, Shell companies continue to seek information from laboratories on how they evaluate animal distress. The responses indicate a number of significant differences between laboratories, particularly regarding the criteria that have to be met before euthanasia of the animal is permitted, the levels of authority required to authorise euthanasia, and the timeliness of any intervention to alleviate distress. The Panel has drafted a guide on good practice in this area that Shell companies can use in discussions with the laboratories they engage.

Shell seeks to assess and improve the practice of the laboratories it uses, and the Panel has welcomed and sought to support this work. It has, in particular, attempted to work with Shell to devise a document that would set out good practice in relation to the identification of animal distress, humane endpoints and euthanasia. This document could be used to monitor and encourage good practice. The Panel welcomed Shell's continued assistance and commitment to this work, and hopes to conclude its work to date by providing specific guidance to Shell on these issues in 2006.

Shell's engagement in the development of alternative methodology and the debate and formulation of public policy on animal testing

General Policy

Shell companies continue to promote a reduction in the use of animals in testing, by:

- Promoting knowledge-based chemical assessments, using read-across and computational modelling for Structure Activity Relationships where appropriate
- Guiding the direction of research programmes,
- Facilitating industry and government funding for such programmes
- Influencing industry and regulatory thinking.

Engagement

Shell companies are active in a number of groups with the long-term aim of developing humane and alternative means of evaluating the health impact of oil and chemical products:

- The Advisory Board of CAAT (Johns Hopkins Center for Alternatives to Animal Testing), providing oversight and direction to the research programmes that CAAT sponsors.
- Cefic's (European Chemical Industry Council) Long Range Research Initiative (LRI) through which industry efforts are coordinated in support of the 3Rs including the input to the recent industry-Commission Partnership announced in 2005;
- The Toxicology committee of FRAME (Fund for the Replacement of Animals in Medical Experiments) based in the UK
- The Scientific Committee of ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals) which runs in taskforces and workshops related to animal testing

Shell has been involved in a collaborative project between ECETOC and ECVAM (the Commission's European Centre for the Validation of Alternative Methods) to reduce numbers of fish used in acute toxicity studies. Shell companies continue to sponsor research at Liverpool University (UK) to investigate the application of new genomic technology to ecotoxicity testing.

Shell Chemicals Limited has actively participated in the European Commission REACH Implementation Project to prepare guidance on legislative approaches to hazard assessment that could reduce animal testing. In addition, Shell has agreed to participate in a collaborative project initiated through the UK government (DEFRA) to develop computational tools to reduce the amount of testing under REACH

In the context of animal use in Europe, Shell companies are not a major user. It does, however, possess considerable influence and the Panel continues to welcome Shell's support for the development and application of 3Rs through its support for a variety of activities and initiatives. Particular importance is attached to the encouragement of proportionate and appropriate regulation in this area. Shell's important engagement with the European Commission in relation to the REACH programme is to be commended. Given the proportion of fish in the numbers of animals used by Shell companies, the Panel also recognises the value and significance of the work in the field of alternatives to the use of fish

Conclusion

The Panel has continued to examine critically Shell's current and projected use of animals in testing. It has welcomed Shell's:

- readiness to supply information as requested and its commitment to ensuring accurate reporting of relevant data.
- awareness of animal welfare issues and support of good practice in laboratories to minimise potential distress.
- initiatives in seeking regulation which will minimise the use of animals

History of how the Animal Testing Review Panel came to be established

Shell's rationale for establishing the Panel:

Oil and chemical companies face an increasing dilemma in responding to potentially conflicting societal demands to demonstrate the safety of their products, whilst at the same time reducing the use of animals in testing. Regulatory drivers are likely to result in an increasing requirement for the use of animals in product safety testing in the next few years. Against a background of increased external debate, Shell reviewed its established animal testing policy and practices during 2001. Shell concluded there was a need to formalise its practices in the form of a Shell Group Standard, to put in place a more structured and demonstrable management process to support this Standard, and more effectively to communicate the Shell position both internally and externally. The rationale for establishing the Review Panel was to provide an externally credible independent scrutiny of Shell's activities in this area.

Shell invited Professor Michael Banner, (at that time, Professor of Moral and Social Theology, King's College London) to chair the Panel. Professor Banner proposed to Shell that the following people be invited to join the Panel:

Professor Paul Flecknell (Director, Comparative Biology Centre, University of Newcastle);

Dr Andrew Rowan (Executive Vice President, Operations, Humane Society of the US);

Professor Willem Seinen (Institute for Risk Assessment Sciences, University of Utrecht).

All invitations were accepted, and the Panel has met twice a year since 2002.

Modus operandi and terms of reference of the Panel (reconfirmed by the Panel in April 2003)

Individual Panel members are invited to serve on the Panel for a period of three years, with the possibility of being invited to serve for a second period of three years. The Panel will recommend candidates who could be invited by Shell to join the Panel, either as replacements for current members when their term is completed, or to supplement the current Panel membership.

The terms of reference of the Panel are:

To review and comment on the implementation of the Group's Animal Testing Standard (www.shell.com/animaltesting) and the supporting management processes by:

- Reviewing and commenting on the animal testing programme conducted by Shell companies during the previous calendar year;
- Reviewing and commenting on the processes designed to ensure compliance with the Group Standard;
- Reviewing and commenting on the role of Shell in the debate and formulation of public policy on animal testing;
- Producing a short report in the first quarter of each year which will be made public;
- Identifying 'good practice' standards towards which Shell companies should aspire.

Biographical summaries of Panel members

Professor Michael Banner

(Director of the ESRC Genomics Policy and Research Forum and Professor of Public Policy in the Life Sciences School of Clinical and Molecular Medicine, University of Edinburgh)

Michael Banner has taught philosophy and theology in the Universities of Oxford, Cambridge and London. Amongst other commitments, he has served as member of the UK Royal Commission on Environmental Pollution and has just completed an eight year term as chair the UK Home Office's Animal Procedures Committee.

Professor Paul Flecknell

(Director, Comparative Biology Centre, University of Newcastle)

Paul Flecknell is a veterinary surgeon with specialist training in laboratory animal science. He has special interests in laboratory animal welfare. He has been a member of the UK Home Office Animal Procedures Committee, and has played an active role in promoting animal welfare through involvement with a range of other organizations. He is currently vice chairman of the board of the UK National Centre for the 3Rs.

Dr Andrew Rowan

(Executive Vice President, Operations, Humane Society of the United States)

Andrew Rowan has been an advocate for alternatives (the Three Rs) since 1976 when he joined FRAME as their Scientific Administrator. He has written numerous scientific articles on the Three Rs and sat on government and industry advisory panels. He was Chair of the Fourth International Congress on Alternatives, held in August of 2002.

Professor Willem Seinen

(Institute for Risk Assessment Sciences, University of Utrecht)

Willem Seinen has a chair in toxicology at the Utrecht University and coordinates research programmes on both human and environmental exposure assessment and toxicology. He has been president of the Netherlands Society of Toxicology and member of numerous governmental and non-governmental advisory boards on health and environmental effects of chemicals.