

Symposium October 2009:

20th Anniversary of
ZEBET at BfR

and 50 Years of the 3Rs Principle



Expectations of animal welfare organisations in Europe

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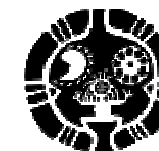


What is Eurogroup?

The voice of animal welfare to the EU

- launched in 1980
- offices in Brussels
- advocacy (lobbying and campaigning) on EU laws, national laws or high industry standards
- represents the leading European and international animal welfare organisations at EU level - 42 members - and thus speaks for millions of Europeans who are concerned about animals





Alianta pentru Protectia Animalelor
din România

Eurogroup's values and demands in the area of animal experimentation

- recognises that animals = **sentient** beings capable of feeling pain and distress
- **opposes** all experiments and procedures that cause animals (and their offspring) pain, suffering, distress or lasting harm including death
- supports and promotes the application of the **3Rs**. Replacement is the primary goal
- regulation of scientific procedures involving animals: must be subject to a **strict, transparent and publicly accountable system of regulation, control and inspection** which includes a critical review of their validity, necessity and justification, and of the application of the 3Rs.



Eurogroup's areas of concern in the area of animal experimentation

- Revision of the animal experimentation directive
- Breeding/reproduction: cloning
- Genetically modified animals used in research
- Pesticides: plant protection products and biocides
- Alternative methods – funding, development and use
- Implementation and enforcement of legislation
- Chemicals, cosmetics, pharmaceuticals, etc





Research Animals Expert's Working Group
15 July 2009

Akademie für Tierschutz (Animal Welfare Academy), Spechtstr 1, 85579 Neubiberg (Munich), Germany



The *3Rs* 1959 - 2009 – a success story

1969	United Kingdom	Foundation FRAME (Fund for the Replacement of Animals in Medical Experiments)
1976	Switzerland	FEVEE (Fonds für versuchstierfreie Forschung – Fund for Research without Animal Experiments)
1980	Germany	Establishment of the research funding programme “replacement methods for animal experiments” by the Federal Ministry of Research and Technology (now Federal Ministry of Education and Research)
1981	USA	CAAT (Centre for Alternatives to Animal Testing) at the Johns-Hopkins-University in Baltimore
1981	Germany	Research award to promote alternative methods (about 15.000.- Euro) by the Federal Ministry of Health (now Federal Ministry of Consumer Protection, Agriculture and Food)
1985	USA	International Foundation for Ethical Research
1986	Germany	Akademie für Tierschutz of the Deutscher Tierschutzbund (Animal Welfare Academy of the German Animal Welfare Federation)
1986	Germany	set (Stiftung zur Förderung der Erforschung von Ersatz- und Ergänzungsmethoden zur Einschränkung von Tierversuchen – Foundation for the Promotion of Research on Replacement and Complementary Methods to Reduce Animal Testing)
1987	Switzerland	Foundation 3R (Stiftung Forschung 3R)
1987	The Netherlands	National platform on alternatives to animal experimentation
1989	Germany	ZEBET (Zentralstelle für die Erfassung und Bewertung von Ersatz- und Ergänzungsmethoden zum Tierversuch – Centre for Documentation and Evaluation of Alternative Methods to Animal Experiments) of the Federal Ministry of Health (now Ministry of Consumer Protection, Agriculture and Food)
1990	USA	UC ALERT (UIC Centre for Animal Alternatives at the University of California)
1992	European Union	ECVAM (European Centre for the Validation of Alternative Methods) at the Joint Research Centre in Ispra, Italy
1993	Austria	MEGAT (Mittleuropäische Gesellschaft für Alternativmethoden zu Tierversuchen – Middle European Society for Alternative Methods to Animal Experiments)
1994	USA	ICCVAM (Interagency Coordinating Committee on the Validation of Alternative Methods)
1994	The Netherlands	NCA (Netherlands Centre for Alternatives to Animal Use) at the University of Utrecht
1996	Austria	zet (Zentrum für Ersatz- und Ergänzungsmethoden zu Tierversuchen – Centre for Replacement and Complementary Methods to Animal Experiments)
1999	Belgium	BPAM (Belgian Platform on Alternative Methods)
2001	Europe	Process of foundation of ECOPA (European Consensus Platform on Alternative Methods)

Scientifically validated methods in the fields of:

- Acute aquatic toxicity
- Acute oral toxicity
- Eye irritation
- Genotoxicity
- Monoclonal antibodies production
- Haematotoxicity
- Phototoxicity
- Pyrogenicity
- Reproductive and developmental toxicity
- Skin corrosion
- Skin irritation
- Skin sensitisation
- Vaccines: potency and safety testing

Regulatory acceptance in the fields of:

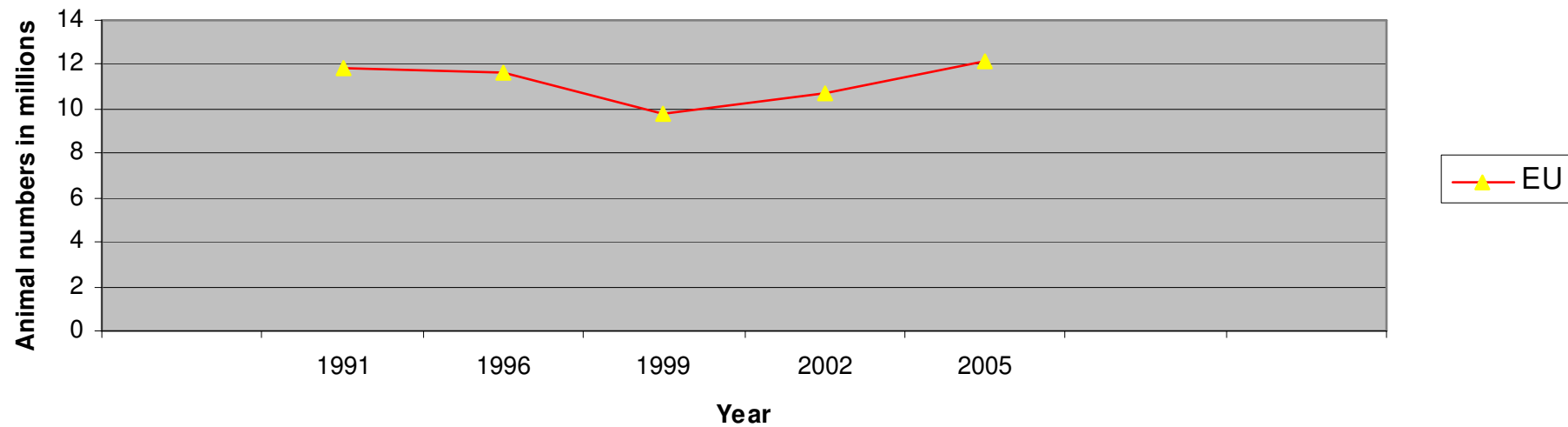
- Acute oral toxicity
- Eye irritation
- Phototoxicity
- Pyrogenicity
- Skin absorption
- Skin corrosion
- Skin irritation
- Skin sensitisation
- Vaccines: potency and safety testing



On the other hand ...



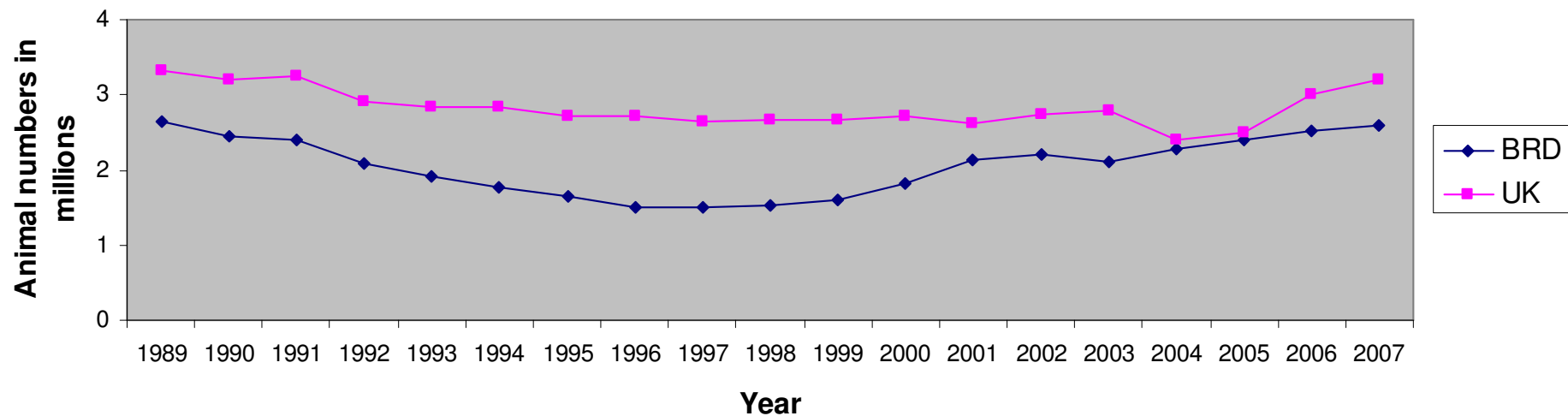
Numbers of animals used in the EU from 1991 - 2006



On the other hand ...



Numbers of animals used in Germany and the UK from 1989 - 2007



On the other hand ...

GÜNTER VERHEUGEN

*Vice-President of the European Commission
Enterprise and Industry*

JANEZ POTOČNIK

*Member of the European Commission
Science and Research*

STAVROS DIMAS

*Member of the European Commission
Environment*

Brussels, 5 May 2008

A(08)608-D(08)466

Dear Chairman,

Vice-President Verheugen, Commissioner Potočnik and myself have followed closely the debates in your Committee with regard to the draft Commission Regulation laying down test methods pursuant to Regulation 1907/2006 (REACH). This letter represents our shared views on the issues raised at this occasion and is therefore, and because of the particular urgency of this matter, also sent on their behalf.

We share the Parliament's concern that the limited number of valid alternative tests that are available so far is disappointing, that further research and scientific progress are necessary, and that greater focus is needed to achieve more rapid results.

The debates that have taken place, together with an informal exchange of views between representatives of the Commission Services and the Parliament's Environment Committee rapporteur Mr. Sacconi on 23 April, have allowed us to better understand the particular

On the other hand ...

New scientific questions, new technologies, new products,
new legislation generate new animal experiments

- endocrine disruptors
- biotechnology
- genetic engineering
- nanotech
- TSEs (BSE etc.)
- novel food
- REACH
- Plant Protection Directive
- Biocidal Directive

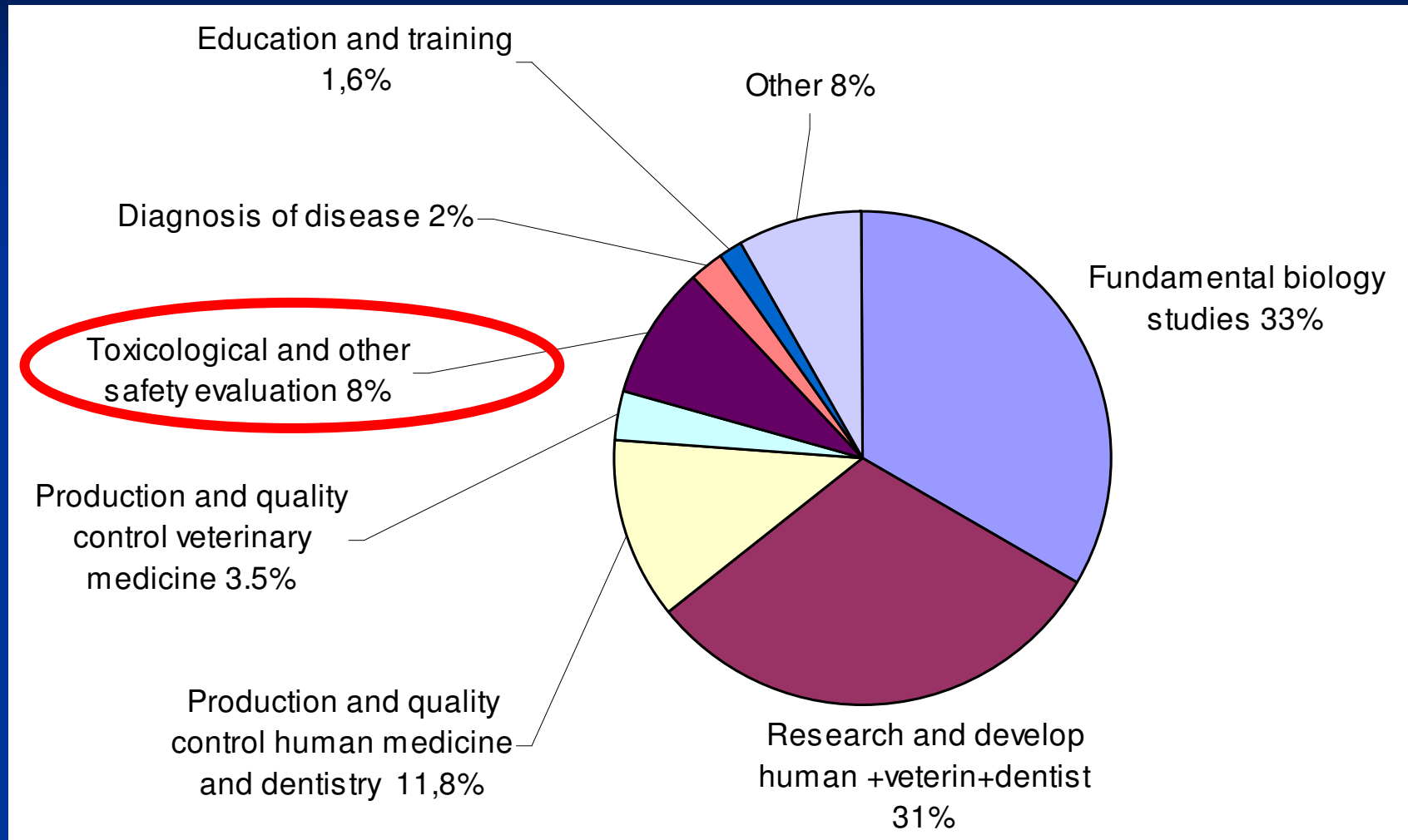
On the other hand ...

Novel in vivo test systems at OECD, e.g.

- Reproductive toxicity screen (OECD421)
- OECD426 developmental neurotoxicity test
- OECD407 enhanced 28-day subchronic toxicity test
- Uterotrophic assay (OECD validation effort)
- Hershberger assay (OECD validation effort)
- Extended one-generation study (OECD task force)
- Juvenile exposure drug testing
- OECD GD34 guidance: validation of new methods
- OECD GD43 guidance: reproductive toxicity testing strategy

On the other hand ...

Animal experimentation purposes in the European Union:



Conclusions

- last decades → many efforts for 3Rs
- animals still used as regular scientific „instruments“
- decrease in the number of animals used counteracted by new scientific opportunities for animal use (new purposes or new types of animal models)

Expectations of animal welfare organisations in Europe

- 3Rs concept needs to be enforced further and significantly expanded into areas beyond toxicology
- effective legislation to be set up for substantial reduction of the number of animal experiment

Expectations of animal welfare organisations in Europe

Regulation of animal experiments (revised Directive 86/609):

- Authorisation
- Ethical review body
- Inspections
- Transparency
- Non-human primates
-

Expectations of animal welfare organisations in Europe

EC & MS to develop coherent strategy to reach their “high priority” goal of reducing animal experiments: in research funding and legislation involving biological testing

Revision of Directive 86/609 to reflect this

Coherent strategy

- Review of all legislative requirements... e.g.: food safety
- Obligation to include animal testing in EU impact assessment system for new policies or legislation
- Coordinated approach: need for centralised management for all areas of animal testing
- EU funding for research to apply strict scrutiny
 - NO primate research
- Longer term plan on investment in alternatives

Competence Centres for Alternatives:

At EU level:

- high-level scientific strategy-setting body/committee and expert sub-groups, with Member State and stakeholder involvement
- administration and coordination provided by designated personnel within DG Environment
- provision of scientific services through ECVAM or other appropriate body

At national level:

- active participation in high-level EU scientific strategy-setting body and working groups
- establishment or expansion of national centres to coordinate Member State contributions to implementation of tasks identified by the EU strategy-setting body or its sub-groups

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Thank you for your attention
+ congrats to ZEBET!

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