

HARMFUL IF SWALLOWED

The European Commission has proposed plans for a Europe-wide programme to test thousands of 'existing' chemicals on millions of animals. It is called the EU Chemicals Policy.

'Existing' chemicals have all been on the market and in use before at least 1981. Before 1981 there was no obligation on manufacturers to test chemicals (in order to classify and label them) before putting them on the market. Consequently, the European Commission claims that little is known about the toxicity of about 75% of these existing chemicals, presenting a so-called data gap. However, a mass of data is in fact stored by chemical manufacturers on the chemicals they produce, that is never released or published. The BUAV believes therefore, that by imposing mandatory data sharing between companies and countries, many of these perceived data gaps could be filled.

The European Union's review of its chemical testing strategy provides a unique opportunity to reassess the value and weaknesses of the present approach. Currently, the environmental and human safety testing programmes are dominated by toxic tests on living animals, even though the scientific validity of many of these has never been proven and they are widely criticised. This has led to the suffering and death of millions of animals throughout Europe and, because animal tests are time-consuming and costly to perform, has also caused delays in acquiring safety data. While the goal of identifying human or environmental pollutants is laudable, the testing methods utilised must be those that offer the most reliable, scientifically credible, repeatable and humane results.

Even the European chemicals industry has criticised the plans because they would require "*enormous resourcing, both in manpower and costs and require a very high and unacceptable*

number of animals to complete the testing regimens."¹

How many animals will be used to test the chemicals?

Estimates as to how many animals will be used in this programme vary between 2 to 50 million. Whatever the final total, the new EU Chemicals Policy is set to be the largest mass animal poisoning programme in Europe's history. The tests could involve a number of different animal species, including rats, mice, guinea-pigs, rabbits, fish, birds and dogs.

The types of animal experiments involved

A huge range of animal tests has been proposed. The purpose of the testing programme is to assess the potential toxicity of chemicals. The majority of the experiments are therefore short and long term toxicity (or poisoning) studies. All forms of toxicity tests undoubtedly cause the animals a great deal of distress, suffering and pain, in some cases resulting in death. Typical symptoms include vomiting, diarrhoea, seizures, blood loss, convulsions, paralysis, ulceration, inflammation and in the cases of teratogenicity (testing for birth defects) miscarriage and developmental abnormalities on foetuses and offspring. Ultimately, the animals will either die as a result of an experiment or be killed at the end for a post-mortem examination. Exposure to toxic substances is via the following routes:

- **Oral:** - the chemical is normally either pumped directly into the animal's stomach via a force-feeding tube or it can be ingested by adding it to

the animal's food. Dosing can be performed once or repeated.

- **Inhalation:** - the animal is forced to inhale the chemical vapour either within an inhalation chamber or by being restrained with a fixed breathing mask over the mouth.
- **Injection:** - the chemical is injected intravenously (directly into the bloodstream), intramuscularly (directly into the muscle) or subcutaneously (under the skin).
- **Skin/eye:** - eye irritation involves dripping the test substance into the eyes of conscious rabbits. No pain relief is normally given. In skin irritation tests, groups of animals have their back shaved before a test substance is applied.
- **Carcinogenicity:** - animals, usually rats and mice are used in lifetime feeding studies to look for cancer causing agents.
- **Teratogenicity:** - pregnant animals are forcibly exposed to chemicals in order to study any resultant effects on the developing foetus or offspring.

Scientific failings of animal tests

Using other animals as surrogates for humans creates insurmountable complications in interpreting the results. Scientists simply cannot rely on animal test results accurately reflecting chemical effects in humans. The underlying problems are the inevitable differences between species in biochemistry, pharmacology, physiology and even anatomy.

So whilst the goal of identifying, properly labelling and even ultimately removing potentially toxic substances is a noble one, subjecting millions of animals to toxicity testing is not the best way to go about achieving that goal, either morally or scientifically.

Non-animal testing

In September 2001, the BUAV launched 'The Way Forward', a non-animal testing strategy for chemicals. This was widely circulated amongst EU Politicians, environmental groups and other relevant organisations, sparking major EU debate. Its role was to illustrate the huge range of non-animal methods available which, when part of a step-wise testing strategy, can be used to effectively regulate chemicals without animal testing. These include:

- **Skin corrosion:** corrosive chemicals can now be identified by test tube methods which have been validated and accepted at EU level. No animals should be used within the EU in such tests.
- **Eye irritation:** there are many test-tube methods for measuring eye irritation used widely within industry, but none have yet received EU regulatory approval as complete replacements for animal tests.
- **Whole body toxicity:** a combination of cell culture tests, structure-activity relationships and toxicokinetic models have the potential to replace animal tests. Non-animal methods can also be utilised to identify the most toxic chemicals.
- **Gene toxicity, cancer and birth defects:** chemicals which cause mutations or other damage to the genes can result in cancer and birth defects. There are several long-established tests for such chemicals which do not require living animals.

A number of other non-animal tests are under discussion as official OECD² guidelines. These include the SHE cell test for cancer-causing chemicals and the test-tube method for assessing skin penetration.

The way forward:

Most of the existing chemicals prioritised for additional animal testing have been used for many years without comprehensive, publicly available safety information. However, this doesn't necessarily mean that that same information does not already exist in many cases. Obligatory data sharing is therefore essential so that all previously unavailable chemicals data is revealed and the likelihood of performing experiments to establish data that already exists is much reduced.

However, safety testing on millions of animals will seriously delay the acquisition of important safety information, because many of these tests are expensive, time-consuming and of dubious scientific value. While waiting for the results of animal tests (especially for cancer and birth defects) which can take up to 5 years to complete and analyse, pollution of the soil, air, food and water by toxic chemicals

will continue unabated. This is the opposite of what the EU wishes to achieve.

A more practical, efficient and humane approach would be to screen priority chemicals through rapid, non-animal tests and then to restrict, phase out or impose a moratorium on the production and use of those which appear toxic. Further confirmatory testing, if necessary for certain kinds of toxicity, would await the finalisation of non-animal methods under a new research initiative which could be launched by the EU.

Chemicals which are classified as essentially non-toxic by non-animal methods could continue in controlled use, pending more thorough testing at a later date, if necessary. This would depend on the rapid development and validation of reliable and comprehensive non-animal tests. The European Commission should, as a matter of urgency, invest substantial funds in this process of non-animal test development and validation.

The goal of producing reliable and relevant test data on chemicals must be based on five key principles:

- Utilising existing in vitro and other non animal test methodologies
- Postponing the final testing of any substance that requires an emerging non-animal test method to be validated. To achieve this there must be a significant commitment to increase the funding available to both the development and validation of non-animal methods
- Targeting areas of research to progress new, non-animal methods
- Harmonising the international validation process so that, for example, non-animal test methods that have been validated in the United States, can be automatically and immediately accepted in the EU without having to undergo further validation
- Making obligatory the sharing of pre-existing chemicals data previously not in the public domain, both between companies and countries

This approach would also be in accord with the EU Directive 86/609/EEC, which forbids animal experiments to be conducted where an alternative method is reasonably and practicably available.

Experts in non-animal toxicology agree that such an approach will enhance human and environmental safety by offering cheaper and quicker results of equivalent or often better scientific value.

Environmental Protection

Environmentalists, consumers associations, animal protection advocates and the general public alike, would all agree that there is a need to properly identify and even phase out chemical substances that pose a potential threat as environmental pollutants and/or hazards to human health. To achieve this with any credibility at all however, the testing methods utilised must be humane those that offer the most reliable, biologically relevant and repeatable humane results.

The animal testing programme proposed by the Commission fails to meet each and every one of these criteria. There can be no doubt that animal toxicity experiments cause immense suffering and severe pain. In addition the programme's simplistic and outdated resort to laboratory based animal testing on a massive scale is fundamentally flawed scientifically.

Over-reliance upon animal testing has proved fallible in numerous cases in the past, and a narrow and simplistic scope for research has proved inadequate in addressing environmental health risks. It is vital, therefore, that in the pursuit of our shared goal to protect ourselves and our planet for the future, we do not repeat the mistakes of the past.

Significant differences between species in terms of biology, anatomy, physiology and biochemistry, mean that extrapolating animal data to have relevance in the human context is highly uncertain. We simply cannot rely on animal experiments to produce reliable, repeatable and scientifically credible results. One example of this would be that all rodents are physiologically unable to vomit toxins from the body. By contrast, via spastic contractions in the stomach and intestine (vomiting), humans *can* eliminate noxious agents from the body. This means that rodents will necessarily endure a proportionally greater amount of exposure to and

absorption of any given toxin, making comparison to the human scenario highly questionable.

In addition, laboratory animals are typically kept in highly controlled, segregated, sterile environments, in which temperature, humidity & lighting are artificially controlled, wall surfaces disinfected and food and bedding sterilised. Despite this obviously abnormal existence, these animals are used as substitutes for humans who, toxicologists admit, do not live in controlled environments, are genetically diverse, may move widely from area to area and from job setting to job setting, making it impossible to determine which of many exposures may cause a particular illness.

Further, the very conditions in which laboratory animals are kept, and the round of painful and debilitating experiments to which they are routinely subjected, are capable, in themselves, of affecting every organ and/or biochemical system in the body including immunologic function. Noise, restraint, isolation, pain, psychological distress, overcrowding, regrouping, separation from mothers, sleeplessness, hypersexuality, surgery and anaesthesia can all increase mortality, contact sensitivity, tumour susceptibility and metastatic spread, as well as decrease viral resistance and immune response.

Devising and implementing an appropriate testing strategy for the EU Chemicals Policy is an opportunity for all interested parties to work together – environmental protectionists, animal advocates, consumers associations, industry, regulatory agencies. The goal of the programme, to identify potentially hazardous substances, is in all our interests. But crucially, so too is using the best possible strategy for obtaining that information. It simply isn't good enough, both ethically or scientifically, to rely on animal testing methods simply because we have always used them in the past. In the face of often cheaper, quicker, relevant, accurate and humane alternatives to using animals, we have to meet the challenge of looking beyond animal testing. If not, after years of testing and millions of animals' lives taken, we will have data, but will it be data worth having?

Get Active

The BUAV's Harmful If Swallowed campaign opposes all animal testing for the EU Chemicals Policy and proposes instead a non-animal testing strategy.

- The EU Commission recently completed an Internet consultation exercise on the proposed EU Chemicals Policy and revealed some hope that our work had – to a small degree in these early stages – begun to pay off. During the two-month consultation process (May – July 2003) the BUAV, along with hundreds of our supporters, made a substantial and detailed submission to the consultation.
- Finally on 29th October, the European Commission published its final draft legislation for a new EU chemicals policy. The good news is that, thanks to dedicated BUAV lobbying, animal testing requirements have been reduced, and a number of new non-animal tests have been included. However, the policy – which promised to address major concerns about hazardous chemicals in everyday use – still relies heavily on cruel and misleading animal tests that will not produce meaningful environmental and health benefits and will cause the death of millions of animals.
- Now, the EU Chemicals Policy enters the co-decision procedure. Co-decision requires the European Parliament and Council of Ministers to state their positions, debate and amend the proposals and then to agree the final text of the regulation before it can become law. This procedure will take a minimum of two years and possibly three. Check out our website at www.buav.org for Latest News updates on this lengthy procedure.
- MEPs will be debating the draft regulation over the coming months. Please write to your MEP to let them know that you are supporting the BUAV's campaign and to ask them the following three crucial questions:
 1. During first reading of the proposed chemicals regulation, what will you do to ensure that all

existing test data is brought forward by chemical companies?

2. How will you ensure that there is maximum use of non-animal tests when the proposed chemicals regulation is implemented?
3. What action have you taken, or do you intend to take, to ensure that the speedy development and validation of non-animal toxicity testing is prioritised by the European Commission?

Find out the name of your MEP at www.europarl.org.uk/uk_meps/MembersMain.htm and send letters to (your MEP), The European Parliament, Rue Wiertz, Brussels 1047, Belgium. We will be monitoring the voting activity of MEPs so please send any responses you receive to Emily McIvor our Political Co-ordinator so we can check promises against action!

- In February 2004 we published our latest detailed report 'Chemicals Safety & Animal Testing: A Regulatory Smokescreen?' Aimed primarily at politicians and environmental organisations this document explains why animal testing is not the answer in tackling the safety issues of thousands of chemicals. You can order this report and our earlier report 'The Way Forward' by sending a cheque for £3 each report (made payable to BUAV) or you can access both reports as pdfs on our website www.buav.org by clicking on the relevant Latest News item.
- Sign our 'EU Funding for Non-Animal Toxicity Testing' petition. Contact the BUAV for petitions or sign on-line by visiting www.buav.org and click on the Sign Our Petitions box on the home page. Hard copy petitions must be returned before April 2004.
- Whilst many environmental organisations have vastly improved their stance on animal testing, none of the major organisations will oppose all chemicals animal testing. If you are a member of an environmental group such as Friends of the Earth, Greenpeace or the World Wide Fund for Nature (WWF), please do write to them about your concerns about animal toxicity testing and ask for their policy on Chemicals

and animal testing. Send any responses to us at the BUAV.

- Write to Alun Michael MP, responsible for the UK chemicals policy, at the Department for Environment, Food & Rural Affairs (DEFRA), Nobel House, 17 Smith Square, London SW1P 3JR and politely let him know that you are supporting the BUAV's proposal for a non-animal testing strategy.
- Contact the BUAV for **campaign posters and leaflets**.

BUAV's Campaign countdown

- Spring 2000: BUAV uncovers the EU Commission's plans for a massive new European chemical testing programme. No mention is made of the inevitable animal testing until the BUAV intervenes.
- June 2000: BUAV attends meeting of EU 'competent authorities' and demands that animal protection is given major consideration
- June 2000: BUAV launches the Harmful If Swallowed campaign & leads the fight to oppose Europe's largest ever animal poisoning programme
- July 2000: BUAV launches the campaign with an exclusive article in The Observer newspaper
- October 2000: BUAV follows up with more revelations in The Observer and calls for non-animal testing instead of killing millions of animals
- December 2000: the European Coalition to End Animal Experiments takes up the BUAV's campaign call
- January 2001: BUAV and PETA join forces to produce a joint petition
- February 2001: the EU Commission's White Paper Strategy for a future Chemicals Policy is published – the BUAV condemns the massive animal testing that will result.
- March 2001: BUAV formally submits its objections to the White Paper to the Department of the Environment and starts pursuing membership of the UK Chemical Stakeholders Forum to represent laboratory animals
- April 2001: Institute of Environment & Health (IEH) draft report for the UK government estimates that up to 50 million animals could die for the new EU programme. BUAV provided input for the report.
- April 2001: BUAV attends Stakeholder conference in Brussels on chemicals testing
- May 2001: The BUAV is formally accepted as a permanent member of the UK Chemical Stakeholders Forum
- June 2001: The IEH report is published and the BUAV generates instant media interest in the shocking estimates.

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- June 2001: BUAV and the European Coalition publish and submit a policy document on the chemicals white paper to the European Commission
- June 2001: Council of Ministers form an opinion on the white paper. Intense lobbying by the BUAV's lobbyist in Brussels.
- July 2001: BUAV exclusive in Sunday Express revealing that the majority of EU toxic animal testing is likely to take place in the UK
- August 2001: EU Environment Committee report on the chemicals white paper first debated. BUAV input throughout July.
- September 2001: BUAV launches "The Way Forward", our non-animal testing strategy for chemicals, which starts a major debate in Europe about non-animal testing. The Way Forward is sent to every relevant UK government department, Members of the European Parliament and EU Environment Commissioner, Margot Wallström.
- September 2001: EU Environment Committee report on the chemicals white paper second debate.
- October 2001: BUAV front page story with The Guardian about the massive number of animals set to die.
- November 2001: BUAV front page story with Independent on Sunday about the animal death toll.
- November 2001: BUAV amendments on non-animal toxicity research inserted into the 6th Framework Programme.
- November 2001: European Parliament first reading on the white paper proposals. Following months of lobbying MEPs by the BUAV, BUAV amendments are inserted.
- November 2001: BUAV initiate meetings with environmental groups about chemical testing policy
- December 2001: BUAV Chief Executive holds meeting with Environment Minister Michael Meacher MP to discuss the UK's position on chemicals testing
- December 2001: BUAV presents oral evidence to the House of Lords Select Committee on chemicals testing
- January 2002: BUAV's scientific advisor meets with ECVAM to discuss non-animal chemical test methods
- March 2002: BUAV lobbying calls for a 120 day public comment period on all test guidelines and BUAV supporters send "public right to know" lobby postcard
- March 2002: House of Lords Select Committee Report on chemicals testing is published, endorsing most of the BUAV's major campaign points and urging the UK to take more decisive action on alternatives.
- April 2002: BUAV as Chair of European Coalition and Coalition member ADDA hold press conference in Barcelona on chemicals testing
- April 2002: BUAV and the European Coalition to End Animal Experiments hand-in millions of petition signatures to the Environment Commission on World Lab Animal Day
- May 2002: BUAV attends OECD meeting in Paris on Existing Chemicals
- June 2002: BUAV attends OECD meeting in Japan on international toxicity testing
- July 2002: BUAV meeting with industry representatives to discuss chemical testing
- July 2002: BUAV attends DG Research conference to highlight questions about funding of alternatives
- July 2002: Inspired by the BUAV's non-animal strategy, the European Centre for the Validation of Alternative Methods (ECVAM) is now drafting its own document on alternative techniques to test chemicals.
- August 2002: BUAV presentation on chemicals campaign at the World Congress on Alternatives.
- September 2002: BUAV presentation on transparency and data sharing at European Environment Bureau (EEB) Conference, Copenhagen
- October 2002: BUAV and the European Coalition launch new EU-wide petition calling for targeted funding for non-animal toxicity tests
- October 2002: BUAV present oral evidence at the Royal Commission on Environmental Pollution, regarding toxicity testing on animals
- November 2002: BUAV joins the Danish Society for the Protection of Laboratory Animals to meet the Danish Environment Minister, to discuss chemicals testing.
- December 2002: BUAV attends UK Chemical Stakeholders Forum meeting
- January 2003: BUAV presents paper on non-animal toxicity testing at meeting of environmental groups hosted by EEB.
- March 2003: Joint policy statement agreed with environmental groups on data sharing and ending duplicate animal testing.
- May 2003: The Commission published its draft consultation document (and launched its internet consultation phase).
- July 2003: Deadline for end of internet consultation phase – the BUAV and hundreds of BUAV supporters send in detailed submissions to the Commission.
- September 2003: BUAV starts research for major new report on chemical case studies & animal testing
- October 2003: BUAV represents lab animals at OECD Paris meeting
- October 2003: EU Commission publishes final draft legislation for EU Chemicals Policy.
- November 2003: BUAV attends meeting with DEFRA Minister Alun Michael MP to discuss EU chemicals
- November 2003: BUAV attends meeting of EU Consensus Platform on Alternatives
- January 2004: BUAV meets EU Environment Committee to debate the draft chemicals regulation.
- February 2004: BUAV publishes "Chemical Safety and Animal Testing: A Regulatory Smokescreen?", our non-animal testing strategy for chemicals.

The draft legislation will now go through what is called the “co-decision procedure” whereby the issue is debated between the EU Parliament and the Council of Ministers.

¹ CEFIC briefing, 3 June 2000

² OECD - International toxicity testing guidelines are established by the Organisation for Economic Cooperation and Development (OECD).

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Updated March 2004