



EUROPEAN COALITION TO **END ANIMAL EXPERIMENTS**

WHITE PAPER

Strategy for a future Chemicals Policy ECEAE position paper



Introduction

The European Commission has proposed a new Europe-wide chemicals testing strategy. This rolling programme aims to test thousands of 'existing chemicals' on millions of laboratory animals. 'Existing chemicals' are chemicals that have been on the market and in use before 1981. The new testing strategy will also influence how new chemicals are tested in the future.

The ECEAE supports the aim of properly identifying and controlling chemicals that may be potentially hazardous to human health or wildlife and environmental protection. However, the ECEAE opposes animal testing as part of the current chemicals testing strategy proposed by the European Commission.

Chemicals data

- 1** The ECEAE does not support the assumption that a huge 'knowledge gap' exists for 'existing chemicals' – until data is shared, the extent of any perceived 'knowledge gap' cannot be calculated.
- 2** The ECEAE believes that a significant amount of hazard data does already exist for many of these chemicals, both in publicly accessible databases, from epidemiological studies, forensic institutes and toxicity information centres, and in the privately held databases of individual chemical companies.
- 3** The ECEAE supports an obligatory 'amnesty period' for chemical companies to share previously withheld information on chemicals. Such an 'amnesty' in the USA in 1999 produced over 10,000 data submissions that would have otherwise been assumed non-existent.
- 4** The ECEAE believes that the above points are in accordance with Council Directive 86/609/EEC which demands that member states must mutually acknowledge each others' test data; Council Directive 92/32/EEC Article 15 on the renotification of the same substance and avoidance of duplicating testing on vertebrate animals, and Council Directive 793/93/EEC Article 16 on the confidentiality of data. The two latter Directives are amendments under Council Directive 67/548/EEC on the Approximation of Laws, Regulations and Administrative Provisions Relating to the Classification and Labelling of Dangerous Substances. The need to avoid duplicate animal testing, and the importance to achieving this objective of companies and countries sharing information, is stressed in these and other key pieces of EU legislation. The problem is that currently the practice does not reflect the legislative principle. If it did, a huge amount of animal testing would be automatically avoided. The European Commission must ensure that these provisions are strictly implemented in future.

Environmental, human health and wildlife protection

- 1** The ECEAE agrees that there is a need to properly identify chemicals and other substances that may potentially pose a serious threat as environmental pollutants and/or hazards to human and wildlife health.
- 2** The ECEAE agrees with the ‘right to know’ which chemicals are present in products, and what the potential risks are of these chemicals, in accordance with the Copenhagen Chemicals Charter, October 2000.
- 3** The ECEAE supports the “precautionary principle”, action to reduce exposure without waiting for ‘absolute proof’ of harm. The ECEAE therefore supports a phase-out of persistent, bio-accumulative or hazardous chemicals in accordance with the Copenhagen Chemicals Charter, October 2000, in order to reduce or eliminate exposures to such chemicals. Many chemicals could be phased out immediately, based on data available today demonstrating a strong likelihood to bio-accumulate, persist in the environment, or be carcinogenic or mutagenic.
- 4** The principle of substitution (whereby industry is compelled always to use the safest substance where alternatives to dangerous substances exist) must be rigorously applied without animal testing.
- 5** The ECEAE supports a commitment to stop all releases to the environment of hazardous substances by 2020, in accordance with the Copenhagen Chemicals Charter, October 2000.
- 6** There is an urgent need to develop a modern, reliable chemical testing strategy, which effectively protects consumers and the environment. The ECEAE believes that the present system of outdated, non-validated animal-based test methods, instead of being a solution, is in fact part of the problem, and their continued use could unwittingly permit the continued use and release of toxic substances into the environment.]

Animal testing: ethical and scientific considerations

- 1** The ECEAE believes that, for the new chemicals testing programme to achieve its goals with credibility, the testing methods utilised must be those that offer the most reliable, biologically relevant, repeatable and humanely acquired results. The ECEAE does not believe that animal testing is ethically or scientifically the best method to acquire such results.

- 2** The level of laboratory animal suffering and death as a consequence of the proposed chemicals testing strategy is likely to be immense.
- 2** The ECEAE does not believe that to deliberately cause animals suffering and death in the laboratory can ever be morally justifiable.

- 1** There is a considerable body of scientific evidence documenting the failure of animal-based toxicity studies, in particular, to accurately predict human reactions to chemicals. Significant species differences in anatomy, physiology, biochemistry and metabolism make extrapolation of results from animal tests to humans, at best, highly questionable.

- 2** 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, over-crowding, bedding materials, 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.

Chemicals testing – a new approach

- 1** The current EU chemical testing review provides a unique and exciting opportunity for the European Commission to reassess the value and weaknesses of the present chemical testing approach. By working with animal protection and environmental organisations, the European Centre for the Validation of Alternative Methods (ECVAM) and other ‘alternatives’ experts, industry and regulatory bodies, the European Commission has the opportunity to develop a comprehensive new strategy for the modernisation and improvement of chemical testing Europe-wide.
- 2** Instead of relying on the much criticised and highly uncertain testing methods of the past, the Commission should launch a new, co-ordinated research and regulatory initiative based on a more accurate, efficient, cost-effective and humane approach that will not only save animals’ lives, but will also benefit environmental protection, human safety and consumer confidence. Such a targeted initiative by the EU to modernise its chemical testing strategy would demonstrate a clear commitment to developing the most reliable, ethical and accurate test methods.
- 3** This approach would also be in accord with EU Directive 86/609/EEC, which forbids animal experiments to be conducted where an alternative method is reasonably and practicably available and also the European Council Convention of 23 March 1998, 1999/575/EC.

Non-animal alternatives

- 1** The ECEAE believes that the future of safe, accurate and reliable chemicals testing lies in the utilisation of non-animal test methodologies. Tests utilising human cells and tissues represent the best models for human toxicity in particular. The development of such tests is progressing quickly, with new methodologies expected soon.
- 2** The ECEAE welcomes the inclusion of animal welfare as one of the political objectives of the European Commission's proposed strategy for a future chemicals policy. However, there is a real danger that without a strictly enforced timetable relating to the introduction of alternatives non-animal tests, the strategy would bring about vastly increased levels of animal testing and fail in its objectives of encouraging the development of alternative tests.
- 3** In spite of considerable efforts to develop replacement alternatives to traditional animal based tests, there are a number of significant barriers to such alternative methods being accepted. The ECEAE believes strongly that these barriers must be removed, so that more accurate and humane test methods can replace animal based experiments.
- 4** Throughout the White Paper, lack of attention is paid to non-animal alternatives. To ensure that the most biologically relevant, accurate and repeatable test methodologies are utilised for the EU chemicals testing programme, the European Commission must actively prioritise potentially promising non-animal tests and encourage and support their validation and acceptance.
- 5** The White Paper's proposals for some additional 'alternatives' funding is too vague. The Commission should make a major, explicit and fast-track commitment to significantly increase the budget for ECVAM and to ensure that it can play a vital role in validating many non-animal tests which are close to final development, within the next few years. This should include specific funding proposals and be linked to a strictly enforced timetable as part of the chemicals strategy, to reflect the importance of switching to non-animal test methods.
- 6** Most of the animal tests still used today have never been scientifically validated to prove their accuracy, relevance and repeatability. By contrast, before acceptance, non-animal alternatives are subjected to extremely lengthy validation studies that can take as long as ten years or more. During validation, the non-

animal alternative tests are validated against the data generated from the equivalent non-validated animal based tests they are intended to replace. This timetable can be improved and reduced if the political will exists to make this a reality. To do so, the European Commission, together with ECVAM and other alternatives experts, must carefully review the existing validation and acceptance process to improve techniques for evaluating non-animal alternatives; dramatically reduce the time taken to validate and accept tests and to harmonise international validation and acceptance systems, particularly between ECVAM and ICCVAM.

- 7** There are also a huge number of non-animal alternative test methods that are both commercially available and indeed widely used by industry, and yet not officially 'validated'. The European Commission must also prioritise these non-animal test methods when considering what non-animal tests are potentially available for use as part of the chemicals testing strategy.

The European Coalition's 7 Step Action Plan for a new EU Chemicals Strategy

- Action 1** make public (for a significant period before testing starts) lists of all chemicals nominated for testing at each stage of the chemicals testing strategy. For example, to be published on a website, in order to allow for public comment, as was one in the US with the HPV Program.
- Action 2** impose mandatory data-sharing between companies and countries of existing chemicals information and global co-ordination of chemical testing programmes to make use of the maximum amount of existing chemicals data and avoid duplicate testing. Sources of existing data would include epidemiological studies and accidental human and environmental exposure data held by pathology and forensic institutes, poisons centres, institutes of occupational health etc. The European Chemicals Bureau, in its extended role, should co-ordinate the assessment and collection of existing data, and sharing of new data.
- Action 3** target areas of research to progress new, non-animal test methods and prioritise the validation of emerging new in vitro methodologies. A targeted timetable for validation of non-animal tests should be written into the chemicals strategy and strictly enforced. To achieve this there must be a significant commitment to increase the funding available to both the development and validation of alternative methods, for example, through ECVAM.
- Action 4** further harmonise the international validation and acceptance process to maximise the use of validated alternative methods and avoid repeat validation studies.
- Action 5** evaluate all available data (according to Action 2.) of each chemical and immediately restrict, phase out or impose a moratorium on the production and use of those chemicals that appear most hazardous. Evaluation should include their application/exposition, physical and chemical properties, their capacity for bioaccumulation and environmental persistence. The best way to protect humans, wildlife and the environment, is to actively reduce their exposure to potentially hazardous chemicals that persist and accumulate in the environment.

Action 6 where further information on a chemical is required, a battery of in vitro tests should be performed in accordance with a Stepwise strategy, such as cytotoxicity, genotoxicity and QSAR etc, and according to the results, respective measures should be taken.

Action 7 where a risk assessment / safety evaluation is not possible for certain chemicals after performing all available in vitro tests, any further testing should be postponed to await the final validation of new alternative methods under the Commission's new, co-ordinated initiative.