REACH – the new EU chemicals law:
An RSPCA information paper

Introduction

In December 2006, following seven years of discussion and debate, the European Union (EU) finalised new legislation on the control of chemicals.

The aim of the new Regulation, termed REACH (for the Registration, Evaluation and Authorisation of CHemicals)[1], is to better protect people and the environment (including wildlife) against dangerous chemicals. As an EU Regulation, its wording must be directly adhered to by all Member States. **REACH will come into force in June 2007**

The RSPCA is extremely concerned that the implementation of REACH will involve the use of millions of animals in the chemical safety testing demanded by the legislation.

Since 2001, the RSPCA and Eurogroup for Animals have investigated every possible means of eliminating or avoiding the use of animals in achieving the objectives of the new strategy and have lobbied hard for amendments to the proposed legislation.

Despite some success in reducing the potential impact of REACH on animal testing, a recent assessment by the European Commission estimated that even if all the opportunities to minimise animal use (which we fought hard to get into REACH) are fully implemented, at least **8 million** animals are likely to be used in testing.

Clearly there is much more that the RSPCA and Eurogroup for Animals must press for during the actual implementation of REACH. It must be ensured, for example, that the sharing of relevant information between suppliers of the same chemical is made mandatory and is enforced in practice so that tests are not duplicated. The use of humane alternatives to animal tests must also be maximised, and new alternatives developed.

This report provides background information and then focuses on the actions that will be needed during the next few years to ensure that requirements for animal testing under REACH are minimised as far as possible.

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). *Official Journal of the European Union*, L 396/1, 30.12.2006.

Why were new laws on chemicals needed?

In the late 1990's, major concerns were expressed about the possible effects on human health and the environment of the large number of chemicals used in the EU. Over 100,000 substances which were on the market before 1981 had never been subjected to formal safety assessments. For most of these, basic information on their biological effects was lacking. Some of the most widely used chemicals had been undergoing official safety assessment, but progress was extremely slow. In 1999, the existing EU legislation on chemicals was examined and declared to be unsatisfactory by the European Commission and the Council of Ministers.

The basis for a new EU strategy for controlling the use of hazardous chemicals was first published in a European Commission White Paper in 2001. In October 2003, the Commission published its detailed proposals, called *A Regulation for the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)*. The main objectives of the new legislation were to promote the safe use of chemicals, and to improve the protection of human health and the environment from hazardous substances.

The regulation also aims to enhance the competitiveness of the European chemical industry and increase transparency with regard to information on chemicals. **Importantly, the promotion of non-animal testing is also a listed objective**.

Which substances will be tested?

The chemicals concerned are those used in industry, many of which have been in use for more than 25 years. A large number of chemical substances are used in the manufacture of consumer products. Everyday materials such as detergents, air fresheners, bleach, stain removers, polishes, paints, ink and dyes, all contain chemicals which have not been formally assessed for safety or have been assessed only by individual manufacturers. Plastic wrappers, floor and wall coverings, man-made fabrics and many other products contain chemicals that may be released during use or during waste disposal or destruction. However, pesticides, medicinal products and certain other types of substance are not covered by REACH as they fall under other legislation.

Why will animal testing be increased?

From an animal welfare point of view, the key feature of the REACH regulation is the obligation it places on chemical companies to provide information on the biological effects of their products, obtained in many cases from tests on animals. Under REACH, manufacturers or importers of chemical substances that are supplied in quantities of 1 tonne or more per year must register the substance. In order to register, they must submit information on the chemical, and the amount of information required increases with the quantity of the substance manufactured or imported.

REACH specifies the methods that should be used to obtain information. Many of these are animal tests for possible effects on human health or the environment. For instance, they are intended to detect possible harmful effects in humans ranging from skin irritation to cancer, on the health of fish in our waterways and the effects on the fertility of wild mammals and birds.

What measures will help ensure animal testing is minimised?

The RSPCA and Eurogroup for Animals identified a number of ways in which the proposals could be amended to eliminate, or at least minimise, animal testing whilst still achieving the legislation's main objectives, and we took every opportunity to lobby for their inclusion in REACH (see the 2005 RSPCA Information Paper *REACH: the new EU chemicals policy)*.

From the point of view of minimising animal testing, the final text of REACH is considerably better than the original Commission proposals. Some of the most important changes are:

- **Mandatory sharing of animal test data**: Companies registering the same chemical are obliged to share their data and, if animal testing is required by REACH, the tests will only be done by one of the registrants. Companies will face penalties if they don't comply. Duplicate animal testing should thus be prevented.

- For higher tonnage chemicals (greater than 100 tonnes per year) testing proposals must be approved by a new **European Chemicals Agency (ECHA)**, before new tests involving animals can be performed. There will be a 45-day period during which the public (including animal welfare organisations) may comment, challenge the need for the tests, or suggest alternatives.

- The **Cosmetics** Directive (76/768/EEC) remains intact, especially in relation to the 7th Amendment which bans the use of animals in safety testing for most cosmetics ingredients or products from either 2009 or 2013. However, it is possible some ingredients may still be tested under REACH if they are not used exclusively in cosmetics.

- **Alternatives to animal testing** are strongly promoted throughout the REACH text. For example, Article 1 states that one of the objectives of REACH is the 'promotion of alternative methods for assessment of hazards of substances'. It is also stressed throughout the text that animal testing must only be undertaken as a last resort.

- The new European Chemicals Agency is obliged to submit a report to the European Commission every 3 years on the **implementation of non-animal test methods**, with the first report due on June 1, 2011. Additionally, the Commission must publish a report every 5 years on the funding of alternative test methods - the initial report is due on the June 1, 2012.

How many animals will be used?

If the original proposals for REACH of 2001 had been adopted unchanged, tens of millions of animals would have suffered and died in the tests demanded for assessing the safety of chemicals. In 2001, the number of animals who might be used was estimated to be about 12 million. However, this estimate did not include the large number of fetal and newborn rats and rabbits who would be destroyed in the course of tests on reproduction and fetal development. It also took no account of the very real possibility that tests on each chemical might be done more than once, if several suppliers of the same chemical failed to co-operate in registering their products. The real potential for animal use was therefore very large indeed, and probably several times the estimate.

In 2006, the European Commission undertook a detailed study of the number of animals who might be used, based on the final text of the REACH Regulation. This concluded that if non-animal tests were not employed at all, 23 million animals would be used, including the offspring in reproductive and developmental studies. This would be reduced to 8 to 13 million if all currently available non-animal methods were fully utilised.

Obviously it is essential that all the available opportunities to avoid animal testing are taken by the companies registering their products, that data sharing is rigorously enforced, and that the authorities issue and promote detailed guidance on how to minimise animal use during testing. It is also vital that concerted efforts are made to develop new non-animal test methods and bring them into use within the 11 years allowed for REACH registration.

Can the use of alternative methods be increased?

The activities of animal welfare organisations such as RSPCA and Eurogroup have drawn attention to the high numbers of animals who may be used in implementing REACH, and there have been some encouraging signs that our demands for humane alternative methods have brought results. For example, the European Centre for the Validation of Alternative Methods (ECVAM)[2] is currently developing and validating many non-animal testing methods and testing strategies that could limit animal use in REACH. The Commission has also established a partnership (the European Partnership for Alternative Approaches to Animal Testing[3]) with companies from several industry sectors to focus on the development, funding, use, implementation and validation of alternatives. Furthermore, funds have been made available from the EU Research Framework Programme[4] for research into new alternative methods.

Some of these initiatives may take years to come to fruition, so it is vital that existing alternative approaches are used as far as possible. For example, chemicals of similar structure may be tested as a group rather than individually, and much more use could be made of computer predictions based on chemical structure. Tests based on the use of cultured cells can be used in many cases to identify very hazardous chemicals and reduce the need for animal tests. **It is extremely important that the use of these approaches is explored thoroughly and that companies are directed to use them by the authorities.**

What can be done to minimise animal testing for REACH?

Clearly, much more needs to be done to ensure that animal use in REACH testing is minimised. The RSPCA and Eurogroup for Animals will be working hard to ensure that alternative methods are given prominence in testing guidelines to be published by the European Commission, that non-animal testing strategies are accepted by regulatory authorities, and that data sharing is rigorously enforced.

The management of REACH will be the responsibility of a new European Chemicals Agency in Helsinki. Exactly how this Agency will function is not yet clear, but it must have input from animal welfare organisations. The Agency, the European Commission, or the Member States authorities must ensure that:

- Data sharing and avoidance of duplication of testing is rigorously enforced
- No animal test is allowed if the information demanded by REACH is not strictly necessary for the safety assessment of a particular chemical, or if necessary information can be obtained in any other way
- When proposals for animal testing are evaluated, the comments made by stakeholders and alternatives experts are fully taken into account before decisions are made on the acceptability of the testing
- Technical guidance is written, and updated regularly, to ensure that animal use and animal suffering are minimised
- New alternative methods or testing strategies are developed and validated rapidly, and that they are incorporated without delay into technical guidance and the REACH regulations.

[2] ECVAM is overseen by the European Commission and its main duties are: to co-ordinate the validation of alternative test methods at the European Union level; to act as a focal point for the exchange of information on the development of alternative test methods; to set up, maintain and manage a database on alternative procedures; to promote dialogue between legislators, industries, biomedical scientists, consumer organisations and animal welfare groups, with a view to the development, validation and international recognition of alternative test methods.

[3] See: http://ec.europa.eu/enterprise/epaa/index_en.htm

[4] which is the main instrument for the funding of science and technology research in the EU