

REACH The Consequences for Animal Welfare

Overview

REACH, is the European Union Regulation for the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). The new legislation will replace 40 different pieces of legislation. Its objectives are to promote the safe use of chemicals and improve the protection of human health and the environment from hazardous chemicals. It also aims to maintain and enhance the competitiveness of the European chemical industry and **promote alternative test methods**. Under REACH, chemical substances that are manufactured or imported in quantities of 1 tonne or more per year must be registered (around 30,000 substances).

The REACH Regulation was formally adopted on the 18 December 2006 by the Council (Environment) following the vote, on the agreed compromise, by the European Parliament on the 13 December 2006. The Regulation will enter into force on 1 June 2007. It requires the registration over a period of 11 years of the 30 000 chemical substances which are in use today. The most dangerous among them will be progressively phased out and replaced by safer substances. The management will be the responsibility of the new European Chemicals Agency (ECHA) in Helsinki.

Animal Testing

The REACH Regulation will dramatically increase the number of animals used in testing in the EU. Most of this testing will occur during the first 11 years of REACH. It does however include a number of provisions intended to lessen its impact on animal use.

Animal testing is expected to decrease from original estimates due to mandatory sharing of animal test data. Companies testing the same chemicals are obliged to share their data to ensure there is no duplication of animal testing. Available studies will be shared and safety testing will only be carried out once where no data is available. Companies will face penalties if they don't comply.

Furthermore, to decrease the duplication of animal testing, the testing proposals of high tonnage chemicals must be approved by the Agency, and after 45 days during which the public may comment, before new tests involving animals can be performed.

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

The Agency is obliged to submit a report to the Commission every 3 years on the implementation of non-animal test methods, with the first report scheduled for 1 June 2011. Additionally, the Commission must publish a report every 5 years on the funding of Alternative test methods, and this report is scheduled for the 1 June 2012.

With the increased focus on alternatives due to the disturbing fact of the high numbers of animals to be used under REACH, there have been many additional efforts to promote alternatives to animal testing methods:

Briefing on: REACH

Firstly, the European Centre for the Validation of Alternative Methods (ECVAM) is busily developing and validating non-animal testing methods and testing strategies that limit animal use; and the Commission along with several industry sectors have come together to form a partnership (EPAA) to focus on the development, funding, use, implementation and validation of alternatives.

The Cosmetics Directive (76/768/EEC), 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, remains intact. However, it is possible some ingredients may still be tested under REACH.

Specific References in the Regulation to animal testing

Recital (1)	Promotion of the development of Alternative Methods for the assessment of hazards of substances
Recital (13)	Cosmetics
Recital (33)	Joint submission and sharing of information to reduce testing on vertebrate animals
Recital (37)	Tests to comply with requirements of protection of laboratory animals (86/609/EEC) and GLP (Good laboratory Practice)
Recital (40)	Commission, Member States, industry and other stakeholders should continue to contribute to promotion of alternative test methods (International and National). Framework Programmes and Animal Welfare Action Plan important
Recital (47)	In accordance with Directive 86/609/EEC , it is necessary to replace, reduce, and refine testing on vertebrates
Recital (49)	Sharing of information, in particular to reduce animal testing
Recital (50)	Sharing of information, in particular to reduce animal testing
Recital (64)	To prevent unnecessary testing , interested parties have 45 days to comment on testing proposals
Article 2 (4b)	REACH regulation shall apply without prejudice to Directive 76/768/EEC (cosmetics) as regards testing involving vertebrate animals within the scope of that Directive
Article 2 (6 b)	Title IV shall not apply to Cosmetic products in their finished state (76/768/EEC)
Article 13 (1)	Generation of info by means other than vertebrate animal tests (eg. Alternatives)
Article 13 (2)	Alternative methods to be reviewed and improved. Stakeholder consultation. Amendment of Regulation to include test methods
Article 14 (5b)	Chemical safety reports : Cosmetic Products
Article 25 (1)	Testing on vertebrate animals undertaken only as a last resort
Article 26 (1c)	Duty to inquire prior to registration about studies involving vertebrate animals
Article 26 (3)	Studies involving vertebrate animals shall not be repeated
Article 27 (1a)	Sharing information : request information involving tests on vertebrate animals.
Article 30 (1)	Before testing it is important to inquire if a relevant study is available
Article 30 (3)	Studies involving animal test must be shared
Article 38 (2f)	Downstream User must report information on proposal for additional vertebrate animal testing
Article 40 (2)	To prevent unnecessary testing , interested parties have 45 days to comment on testing proposals which are published on Agency website
Article 56 (5a)	Authorisation does not apply to uses in Cosmetic products
Article 67 (2)	Cosmetic products
Article 117(3)	Agency to submit report to Commission every 3 years on implementation of non-animal test methods . (First report 1 June 2011)
Article 117 (4b)	Commission to publish a report every 5 years on funding for Alternative test methods. First report 1 June 2012)
Article 138 (3)	Review on Alternative methods . Related to Art 117 (4b).
Article 138 (9)	Commission to review testing requirements in Annex of reproductivity testing of substances of 10 tonnes or more by June 2019.
Annex I 4.1	Alternative test methods and ECVAM
Annex VI – Step 1 and Step 4	Animal testing only as a last resort