New European chemicals testing policy: "REACH"

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"REACH" stands for the Registration, Evaluation and Authorisation of Chemicals. It is an EU initiative and has the objective of ensuring that chemicals are safe, both for people and the environment. It is in part intended to comply with the global commitment agreed at the World Summit on Sustainable Development in Johannesburg in 2002 to improve, by 2020, the safety of chemicals. Everyone shares this objective, of course. In 2003, the European Commission published a draft regulation setting out its proposals.[18]

REACH is particularly directed at the tens of thousands of chemicals which have been in use since before April 1981. The significance of that date is that the legislative regime changed then: chemicals used for the first time since then have had to undergo stringent safety tests. This is under Directive 67/548/EEC,[19] as substantially amended in 1992. For chemicals in use before then, the safety requirements are far more relaxed (under Regulation (EC) No 793/93[20]).

These older chemicals are called "phase-in substances" under the draft REACH regulation. This is because the new regime will only apply gradually to them. This largely depends on the total tonnage in which the chemical is produced or imported into the EU in a year, although substances classified under Directive 67/548/EEC as carcinogenic, mutagenic or toxic to reproduction ("CMR substances") have to be registered in the first phase if they meet a threshold of one tonne. The definition of "substance" begins "a chemical element and its compounds in the natural state or obtained by any manufacturing process".

Not all chemicals are covered. For example, medicines and food additives are largely excluded. There is confusion about the extent of overlap with Directive 76/768/EEC[21] concerning cosmetic products (see below).

Under the **registration** limb of REACH, each producer and importer of substances in volumes of one tonne or more per year will have to register them with the new EU Chemicals Agency, submitting information on properties, uses and safe ways of handling. They will also have to pass safety information onto manufacturers which use the substances in their production processes. Under **evaluation**, Member States will look in more detail at registration dossiers, particularly substances of concern. **Authorisation** will be necessary for CMR substances or those which accumulate in the human body or the environment. Companies will have to show that the risks are adequately controlled, or that the social and economic benefits outweigh the risks and there are no suitable alternatives (if there are the substitution principle applies).

In addition, the Commission will be able to restrict the use of certain dangerous chemicals at EU level.

The draft regulation is subject to what is known as the co-decision procedure. This means that it has to receive the agreement of both the Council of Ministers and the European Parliament. The current position is that, in November 2005, the Parliament made a number of amendments at first

[18] COM (2003) 644.
[19] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ L 196, 16.8.1967, p. 1.
[20] Council Regulation (EC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances, OJ L 84, 5.4.1993, p. 1.
[21] Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products, OJ L 262, 27.9.1976, p. 169.

reading. The Council has subsequently agreed to some of those but has also made some of its own. Agreement will probably be attained this year. If so, the new regime will come into force next year.

REACH will have very serious consequences for laboratory animals. Estimates have varied widely, but the latest suggests that over 5 million animals will be used in toxicity (poisoning) tests. This is despite the fact that there should be nothing automatic about testing on animals under the new regime – a judgement should, in principle, be made on a case-by-case basis, depending on the available data and assessment of risk. There are numerous types of test, including eye irritancy (requiring a minimum of three rabbits), skin irritancy and corrosivity, repeat dose toxicity (which can use 80 rats and/or 32 dogs over a 90-day period), chronic toxicity (160 rodents and 32 dogs over much longer periods), carcinogenicity and teratogenicity (birth defects). There is no dispute that the tests are often highly invasive.

An increasing number of scientists regard animal toxicity tests as scientifically dubious, because of the proven difficulty of extrapolating results from animals to people. *The Way Forward*, a report by the British Union for the Abolition of Vivisection (BUAV)[22] argues for a step-by-step approach, under which non-animal tests which are already available and which it regards as more reliable would be used and sufficient resources devoted to the development of others.

In a later briefing,[23] the BUAV argues, in relation to acute toxicity tests (which are particularly unpleasant):

"Existing data on acute toxicity in humans, for example from records of accidental poisoning, should take precedence over animal data and should be sought from all possible sources. Human data, and data obtained from *in vitro* [non-animal] studies, should be used to classify and label chemicals according to the Globally Harmonised System for Classification and Labelling.

In screening large numbers of chemicals to prioritise those in need of further testing, chemicals without existing acute toxicity information should first be assessed for potential to use read-across techniques from structurally related analogues. (Q)SAR models and *in vitro* cytotoxicity tests (currently under validation) would be applied for the identification of highly toxic substances.

A fuller assessment of acute toxicity, if needed in some cases, would be based on the addition of absorption/penetration assays *in vitro* and *in silico*, test-tube measurements of plasma protein-binding and likely target organ distribution (via blood/tissue partitioning *in vitro*); plus *in vitro* metabolism studies. This information would be brought together by means of toxicokinetic modelling."

The BUAV also argues that the mass of existing animal data held by companies should be made available.

A number of amendments to the draft regulation have been proposed, particularly by the Parliament, to lessen the impact on animals. In some respects, it and the Council agree. For example, they agree that there should be less demanding information requirements (and therefore, in practice, fewer animal tests) for substances produced in the 1-10 tonne band.

An important amendment introduced by the Parliament (and agreed to by the Council) requires there to be only one registration per chemical, with data-sharing. This was at the instigation of the UK Presidency and Hungary. Phase-in substances will have to be pre-registered between 12 and 18 months after REACH comes into effect. This is designed to minimise duplicate animal testing, which occurs when a company does not know that another company has already carried out particular animal tests, or cannot access the data. Although there are still

[22] 2003.
[23] *Acute toxicity testing in REACH*, 2005.

some ambiguities, the two sets of data-sharing amendments, though they differ in some respects, bring the Commission's rhetoric about the mandatory sharing of animal test data closer to reality.

In short, companies will not be able to register substances unless they share data (with cost-sharing arrangements). The Council amendments do not, however, extend to non-animal test data, as do the Parliament's. This is an important omission, because the existence of non-animal data can obviate the need for animal tests, a principle accepted by the draft regulation as a whole.

Data-sharing apart, the Parliament's amendments are generally better for animal protection than the Council's. For example, the Parliament proposed that, if the European Centre for the Validation of Alternative Methods (ECVAM) (an EU agency), says that a non-animal method is valid, a procedure to replace the equivalent animal method in the technical annexes to the draft regulation should be initiated within 14 days.

Similarly, a Parliament amendment requires proposals to carry out animal tests to be open for comment by interested parties and evaluated by experts on non-animal methods (including ECVAM) before being given the go-ahead. Finally, the Parliament proposed that part of the registration fee should be allocated to the development of non-animal test methods.

In each case, proposals which seem eminently reasonable have not found favour with the Council. There is a sense that a prime concern for the Council is to protect the competitiveness of the EU chemicals industry – the largest in the world.

In addition, the Parliament and Council have come up with very different proposals with respect to the relationship between REACH and Directive 76/768/EEC. Under the latter, tests on animals for cosmetics carried out in the EU will be prohibited by 2009 at the latest. The complication is that chemicals used in cosmetics are often also used in other products. In *French Republic* v *European Parliament and Council of the European Union*,[24] in which France sought to strike down the animal protection parts of a 2003 amendment to Directive 76/768/EEC,[25] Advocate-General Geelhoed said:

"… it seems clear that the ban on animal tests applies equally to tests performed for the purposes of complying with other legislation, in so far as substances that have been the subject of such tests may not be used as or in cosmetic products. This interpretation seems necessary for the *effet utile* of the Directive and is consistent with the intention expressed in the preparatory documents leading up to its adoption."

At present, neither the Parliament's nor the Council's amendments make the obverse clear – that ingredients intended to be used in cosmetics are outside the scope of REACH.

The primary position of animal protection organisations is that it is ethically wrong to cause suffering to animals to test chemicals. They also point to the scientific drawbacks of the animal tests and the greater reliability and potential of non-animal methods. However, since some use of animals under REACH is inevitable, they believe there is an imperative to reduce it as much as possible, by focussing on good-quality science, full use of different types of data and the promotion of alternatives.

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[24] Case C-244/03, not yet published in the European Court Reports.

[25] Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products, OJ L 66, 11.3.2003, p. 36.