Briefing: Challenging REACH Decisions

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EU Regulation 1907/2006 (REACH) introduced a new and ambitious scheme for the regulation of chemicals in the EU. It aims to protect human health and the environment, whilst maintaining the competitiveness of the EU chemicals industry and innovation and facilitating the internal market. It covers both existing and new chemicals ('substances') and seeks to fill information gaps in company safety portfolios. It does not extend to substances used in certain types of products, such as medicines and pesticides. The legislation is very complicated.

To the chagrin of consumer and environmental lobbies, very few substances will be banned, although there will be restrictions on the use of some high-risk substances. REACH is about managing risks on an informed basis. Responsibility for safety rests with companies.

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The problem for laboratory animals is that they are one of the primary vehicles for generating the required information, especially for substances produced at high volumes. Estimates vary but it is certain that REACH will lead to millions of additional animal tests. The tests meet various forms of toxicity (poisoning) 'endpoints' and are often highly invasive. Many believe they represent crude science.

Despite the overall context for animal welfare, some of the legislative rhetoric sounds reasonably promising. Animal tests are to be a 'last resort'. The Three Rs principle – under which animals cannot be used if there is a replacement method, numbers should be reduced as far as possible and suffering kept to a minimum (refinement) – is stressed. That applies to the test methods regulation which the European Commission must keep updated as much as to decisions under REACH itself. Companies must share data to avoid duplicative tests. REACH gives precedence to the animal test bans in the cosmetics directive. There is a degree of new transparency. Third parties can provide information relevant to proposals for animal tests at the higher tonnages.

As with so much animal protection legislation, the reality, sadly, falls some way short of good intention. Animal welfarists believe that both the Commission and the European Chemicals Agency (ECHA) have shown themselves to be toxicologically deeply conservative, with a preference for bureaucratic convenience over protecting animals. ECHA, the primary regulator, has published voluminous guidance, mostly in step with the legislative principles, but the experience of the BUAV and the European coalition it leads, ECEAE, is that it increasingly opts for animal tests as the default position, sometimes in the face of clear words in REACH.

One of their complaints is that ECHA now argues that, if a company registering a substance proposes particular animal tests, it cannot stop the company from carrying them out, even though ECHA believes they are not necessary and would therefore breach REACH (and the animal experiments directive). This is clearly wrong. CEFIC, the umbrella body for the European chemicals industry, has accused the agency of scientific inconsistency and going beyond common toxicology practice.

What is to be done? Lobbying continues, including legal argument.

Concerns are highlighted through the media. Ultimately, of course, alleged unlawfulness needs to be challenged through legal means. At European level, this can be very difficult. The rules for standing for the General Court and the Court of Justice – the recently renamed European Union Courts – are extremely restrictive, far more restrictive than the English approach, for example. Environmental groups are given a degree of access through the Aarhus Convention, but other NGOs find it all but impossible to establish standing. This is because they are not 'directly and individually concerned' by decisions, as the courts have interpreted that phrase in the relevant treaty rule. The problem is particularly acute for animal protection NGOs because, unlike some NGOs advocating for groups of people, their intended beneficiaries have no standing themselves.

The Lisbon treaty has relaxed the rule to some degree but it remains to be seen what difference this makes in practice. It is likely that in most cases the only method of challenge will remain via domestic courts, with the hope that they will make a reference to the Court of Justice. This adds to expense and delay, and there is no guarantee of a reference – there might, for example, be a domestic solution which leaves the EU-wide question unresolved.

It is easier, fortunately, to intervene in cases – though that of course depends on someone else bringing a case. The ECHA Board of Appeal, in the face of fierce opposition from ECHA itself, has given ECEAE permission to intervene in the first substantive appeal against an ECHA regulatory decision. The Board of Appeal recognised that animal protection is a key objective under REACH and that ECEAE, as an accredited ECHA stakeholder, could add value to the appeal.

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The case involves a refrigerant for car air-conditioning systems. The company, Honeywell, fulfilled all the standard REACH requirements, including a battery of animal tests. In one of these, a developmental toxicity test, a number of pregnant rabbits died at certain dosages (though the foetuses were unaffected). ECHA, understandably, was concerned. It could have insisted that the company's risk management measures reflected the concern and focused on the classification and labelling of the substance (under separate legislation). And it could have earmarked the substance for special evaluation by member states, perhaps leading to restricted use. It chose instead to exercise the discretion, unusually given to it by REACH for this sort of test, to order a further test.

There is nothing wrong with that in principle. However, the test it ordered is virtually unprecedented in toxicology (which leads to obvious interpretative problems), and almost certainly falls outside international testing guidelines. The test would involve forcing 120 rabbits to inhale the substance for several hours a day, for five or seven days a week, for 90 days, while held in a small chamber. Rabbits are known to experience high levels of stress in the lab, which apart from adding to their suffering could confound the result.

ECEAE argues that the appropriate approach (assuming any further studies) is, first, to find out why the pregnant animals died (strangely, Honeywell had not carried out an autopsy); second, to use a recognised in vitro test to determine whether the rabbit is the appropriate test species for the substance – in other words, whether there was correlation between rabbits and humans; and then, if it is, to use an established mathematical formula to extrapolate from that test to humans. No further animal test is needed, ECEAE contends. It complains that the decision is scientifically flawed and disproportionate, in EU law terms.

The appeal raises important points of principle, with implications far beyond this particular substance. For example, ECHA has sought to sideline the last resort principle, and it says that, in its decisions, it has no obligation to order a stepwise approach, under which the need for each further test is evaluated depending on the results of preceding tests. Instead ECHA has ordered Honeywell to carry out the rabbit test regardless of what preliminary further investigation shows.

In light of the complicated background and the principles at stake, ECEAE has suggested an oral hearing. In the meantime, it has been granted permission to intervene in another appeal, brought by Dow Chemicals, where the issue is whether ECHA has applied appropriately a technique called read-across. Under read-across, tests on a substance, including animal tests, can be avoided where there is enough evidence about toxicity from structurally similar substances. And there are other important recent ECHA decisions which ECEAE believes are unlawful and where it may well apply to intervene if an appeal is brought.