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Press Release:

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New study inaccurate on the number of test animals for REACH

A new study has overestimated the impact of EU legislation on animal testing by six times. The real figures are more likely to be the ones assessed and published when the new chemicals legislation (REACH) was prepared and negotiated.

What are the facts?

It was estimated during the negotiation of the REACH legislation that 9 million laboratory animals would be involved in the tests required and that the costs for conducting the tests would amount to 1.3 billion €. The study now published by Costanza Rovida and Thomas Hartung suggests that the testing required would involve 54 million vertebrate animals and that the costs would amount to 9.5 billion €.

The European Chemicals Agency has reviewed the study and concludes that the original estimates on the number of animals still hold. The new study overestimates three things:

- The likely number of substances that will be registered under REACH and requiring a full data set is overestimated – by almost two fold - mainly because the assumptions are not justified and seem to be incorrect.
- The likely number of tests and laboratory animals required is overestimated and is approximately six times higher than the likely reality. The overestimation is mainly because the availability of existing information and the possibilities for adapting the information requirements are not taken in to account, and further because the rules for requesting testing in a second species are not interpreted correctly;
- The likely costs for conducting the tests are overestimated by approximately the same factor.

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Geert Dancet, Executive Director of ECHA said *“REACH is all about protecting human health and the environment. The challenge is to have scientifically sound information on the potential hazards of substances whilst at the same time minimising unnecessary animal testing. One of the fundamental aims of REACH is to promote alternative methods for assessing hazards of substances and to see animal testing as a last resort. All parties involved should take this very seriously, and so do we here in ECHA. Clearly, the exact numbers will only be known once all the registrations are submitted and testing proposals are received, but, based on the information that we have and our discussions with industry, the numbers provided in this study are thankfully very wide of the mark.”*

Detailed notes to editors

REACH

One of the main reasons for developing and adopting the REACH Regulation was that a large number of substances have been manufactured and placed on the market in Europe for many years, sometimes in very high amounts, and yet there is very little information on the hazards that they pose to human health and the environment. There is a need to fill these information gaps to ensure that industry is able to assess hazards and risks, and to identify and implement the necessary risk management measures in order to protect humans and the environment. It has been known and accepted since the drafting of REACH that the need to fill the data gaps would result in an increased use of laboratory animals for the next 10 years until that goal has been reached. Nevertheless, in order to minimise the number of unnecessary animal tests, the REACH Regulation provides a number of possibilities to adapt the testing requirements and use existing data and alternative assessment approaches instead. Experience with for instance the OECD High Production Volume Chemicals Programme has clearly demonstrated that when substances of similar structure and toxicity profiles are assessed as a group (category) substantial savings in the number of tests can be achieved.

Background

At the time when the REACH Regulation was negotiated and adopted (2003-2006), the European Commission conducted a number of analyses of the possible impact on business. These analyses included estimates of the number of substances to be registered, the likely number of tests to be conducted and the number of animals required for that, and the likely costs of such testing.

The number of substances to be registered at the first registration deadline in 2010 was estimated to be approximately 8,700 substances. However, only about 3,500 of these substances had to fulfil the full information requirements pertaining to substances manufactured or imported in large amounts (≥ 1000 tonnes/year). The remaining substances were either “intermediates” for which much lower information requirements apply, or substances in lower amounts, but classified as either Carcinogenic, Mutagenic or Toxic to Reproduction (CMR), or in the most severe environmental hazard class (“R50/53”).

Similarly, the number of substances to be registered at the second registration deadline in 2013 was estimated to approximately 7,500. Again only about 2,500 of these substances had to fulfil the information requirements for substances manufactured or imported in tonnages from 100 to 1000 tonnes per year.

Various estimates of the number of tests and consequently the number of laboratory animals required were made. The Commission initially estimated the number of laboratory animals

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required to 2.6 million (van der Jagt et al. 2004) but this did not include the number of offspring produced during reproductive toxicity testing. Subsequent estimates taking into account the offspring produced during testing gave estimates of approximately 9 million laboratory animals (cf. Höfer et al. 2004).

In the Commission's Extended Impact Assessment from October 2003, the costs of conducting the testing were estimated to 1.3 billion € assuming extensive use of alternative testing and non-testing methods for obtaining the necessary information and that exposure based waiving would be possible.

New publications casting doubt on the earlier estimates

Two new publications are now questioning the estimates of both testing costs and the number of laboratory animals required for fulfilling the information requirements under REACH. These publications are:

- C. Rovida & T. Hartung: Re-evaluation of animal numbers and costs for in vivo tests to accomplish REACH legislation requirements for chemicals – a report by the Transatlantic Think Tank for Toxicology. ALTEX 26, 1/09.
- T. Hartung & C. Rovida: Chemical regulators have overreached. Opinion in Nature, vol. 460, 27 August 2009.

ECHA's analysis

Possible number of substances to be registered under REACH

The articles conclude that the most likely numbers of substances to be registered under REACH are as follows:

- ≥ 1000 tonnes/year: 6,286 – 47,858 substances
- $\geq 100 - 1000$ tonnes/year: 5,721 – 53,048 substances

The basis for the lower estimates is the work done by the Joint Research Centre of the European Commission on the number of "phase-in" (older) substances in the two tonnage bands indicated and requiring full data sets (Pedersen et al. 2003). These estimates were then adjusted upwards by Hartung and Rovida with 97% due to growth of the European chemical industry and 18% due to new EU Member States since the beginning of the 1990s. However, there is no justification provided for the postulated proportional link between the number of substances and economic growth. Neither is there any justification provided for the postulated proportional link between the number of substances and the number of EU Member States. In ECHA's view such links are either non-existent or at best, negligible. Instead, there are probably much stronger causal links between economic growth and the manufactured and imported tonnage. However, for substances manufactured or imported in amounts ≥ 1000 tonnes/year, this does not have an impact on the testing requirements and the number of testing animals needed for conducting the tests. For substances in the 100 to 1000 tonnes/year range, there is the possibility that amounts could increase and therefore they might move to the higher tonnage level and consequently require further testing.

The basis for the higher estimate is the number of pre-registrations received by ECHA in the period of 1 June to 1 December 2008. All so-called existing substances contained in EINECS (i.e. ~100,000 substances that were on the market between 1971 and 1981) were pre-registered with indications of registration deadlines in either 2010 (≥ 1000 tonnes/year substances) or 2013 ($\geq 100 - 1000$ tonnes/year). The authors realise themselves that it is unlikely that all existing substances would be manufactured or imported in amounts ≥ 100 tonnes/year and none of them in smaller amounts. ECHA can only support this conclusion.

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ECHA has estimated that the most likely number of substances to be registered by 1 December 2010 is slightly over 9,000 (which is close to the number originally estimated by the European Commission of 8,730). This number includes also intermediates, CMR substances between 1 and 1000 tonnes, and substances classified with R50/53 between 100 and 1000 tonnes. ECHA has not yet conducted a similar analysis of pre-registrations of substances under 1000 tonnes/year, but it is likely that similar conclusions on the number of later registrations will be reached.

There are many reasons for the very high number of pre-registrations: some companies (notably distributors) have pre-registered the complete EINECS inventory, many companies have pre-registered more substances than necessary most probably to secure their business, some have pre-registered more substances than necessary in response to late legal interpretation on certain categories of substances such as re-imported substances, recovered substances, etc. ("double" pre-registrations), others have pre-registered alloys instead of pre-registering the individual metal constituents, etc.

Thus, we can conclude that the most likely number of substances that will be registered will be slightly higher than originally estimated by the European Commission. From this it follows that the number of substances requiring the full data sets would also be slightly higher than originally estimated, but that it is substantially lower than calculated by the two authors. Nevertheless, in the end we will only know the correct number when the first registration deadline of 1 December 2010 has passed.

Number of tests and laboratory animals required

It is of course evident that using an overestimated number of substances to be registered under REACH leads to an overestimate of the number of tests and laboratory animals required.

The tests that evidently require the highest number of laboratory animals are the tests related to reproductive toxicity, particularly the developmental toxicity study and the two-generation reproductive toxicity study.

First of all, the two authors seem to suggest that industry is almost starting from scratch, i.e. that hardly any data is available at all, therefore leading to new testing for 95-100% of the substances. This is of course not correct as already described by the Joint Research Centre of the Commission in its estimate of the number of tests required. It was estimated that test data are already available (based on information in IUCLID submitted from industry), that some use of QSARs and read-across is possible, and that some of the tests can be waived either because the substance is already classified or because the estimated exposure is so low that no testing is required.

Secondly, the two authors also assume that for 80% of the substances, testing in a second animal species is required. While the exact quantification of this figure is very difficult, this is also an overestimation. The REACH Regulation clearly specifies that for substances ≥ 100 tonnes/year a decision on the need to perform a study at this tonnage level (or the next on a second species) should be based on the outcome of the first test in one species and all other relevant available data.

The possible interpretation of these specifications was discussed among experts during the development of ECHA's guidance on Information Requirements and Chemical Safety Assessment (R.7.6.6, volume 4). For the developmental toxicity study, the guidance states that if the outcome of the first developmental toxicity study is positive, this may be enough for classification and risk assessment and a study in a second species will not be required. When the first study is negative, a study in a second species will normally be required at ≥ 1000 tonnes/year, unless the Weight of Evidence assessment or specific data, e.g. toxicokinetic data, provide scientific justification not to conduct the study in a second species. Thus, only when all available and relevant information has been assessed and it is

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concluded that sufficient information is not available, then a study in a second species should be proposed. In that case, the company will make a testing proposal to ECHA, and ECHA then publishes the proposal online to allow any scientifically valid information and studies to be submitted, before finally deciding on the need to conduct the test.

For the two-generation reproductive toxicity study, the guidance states that the two-generation study is very rarely conducted in a species other than the rat, and it is envisaged that a second species study could not be justified (Volume 4, p. 368). Thus, for this test it is even less likely that testing in a second species will take place for many substances.

In conclusion, the number of tests and laboratory animals required is overestimated by the two authors because of their overestimate of the number of substances likely to be registered and their misunderstanding of the information requirements and the possibilities for adapting the standard information requirements that have been built into the REACH Regulation. The previous estimates of the likely number of new tests required to fulfil the data requirements under REACH remains broadly correct and the number of laboratory animals required is around 9 million.

The costs of testing

The likely average costs of individual tests which have been collected and analysed by the authors are accurate. However, because the number of tests required has been overestimated, the total testing costs are also overestimated.

References

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Press Release:

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Helsinki, 15 September 2009

CLARIFICATION WILL AVOID UNNECESSARY ANIMAL TESTS

Unnecessary animal tests will be avoided and costs to industry reduced as a result of a new clarification of the information requirements for manufacturers and importers of chemical substances under the REACH regulation.

The clarification is specific. It applies to companies manufacturing or importing substances at quantities greater than or equal to 100 tonnes (and 1000 tonnes) per year who need to provide information in their registration dossiers on the repeated dose toxicity or reproductive toxicity of their substance.

Put simply, companies who need to provide information based on long term toxicity studies¹, do not need to also submit the results of screening or short term studies² in order for their submission to be considered “complete” by the European Chemicals Agency. Companies are encouraged to consult the Agency’s fact sheet for the complete clarification to enable them to decide which information they need to provide for their dossiers to pass the technical completeness check. The clarification is one further contribution for companies to consider as part of an integrated approach to obtaining the information necessary to determine the hazards and risks that their substances may present for human health and the environment.

When a dossier has passed the completeness check, a registration number is provided to the company who can then continue to manufacture, import and market the substance.

ECHA emphasises that the information requirements constitute the minimum information required for a technical dossier to pass the completeness check for the two particular hazard endpoints - repeated dose toxicity and reproductive toxicity - and that additional information may be necessary to comply with the REACH legislation and to ensure safe use.

Registrants who decide to submit testing proposals for the longer term studies without having completed the shorter ones **must** take account of that by including in the Chemical Safety Report and in the exposure scenario the interim risk management measures that they put in place and those they recommend to downstream users in order to manage the risks yet to be

¹ A 90 day repeated dose toxicity study or a pre-natal developmental toxicity study

² A 28 day repeated dose toxicity study or a screening for reproductive/developmental toxicity study

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explored. The responsibility for the safe use of the chemical lies with the manufacturers, importers and downstream users.

More information

Link to Factsheet: http://echa.europa.eu/doc/reach/reach_factsheet_testing.pdf

Questions concerning information requirements and the technical completeness of the dossiers can be submitted to ECHA via the helpdesk web form which is available at www.echa.europa.eu.

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