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Report Summary 2011

Ref.: ECHA-11-FS-06-EN
ISBN-13: 978-92-9217-599-3

The use of alternatives to testing on animals for the REACH Regulation

One of the main reasons for developing and adopting the REACH regulation was that a large number of chemical substances have been on the European market for many years, with only limited information available on their hazardous properties. It was considered that the gaps in the required information needed to be filled. This would allow industry to make better assessments of the risks posed by production and use of their substances, and to make sure there are adequate risk management measures to protect human health and the environment. To fill these gaps, new studies on chemical substances have to be conducted. Some of these are studies using experimental animals. However, there are several mechanisms in the regulation to avoid unnecessary testing on animals.

The European Chemicals Agency (ECHA) has analysed how companies provide information on the properties of their substances from the submitted registration dossiers. The analysis shows that the alternatives provided by REACH to testing on animals that REACH provides are being used and registrants so far are not carrying out unnecessary testing.

This document is a summary of the first report that the Agency is required to submit every three years to the European Commission, on how companies are using alternatives to testing on animals. Approximately 25 000 registration dossiers submitted by 28 February 2011 have been used as the main source of information for the report. The relevant information in the dossiers has been identified, extracted and analysed using specifically-developed data extraction tools. In addition, the data-sharing mechanisms – where companies making the same chemical share their data with one another - and proposals from companies to perform new tests have also been assessed.

HIGHER LEVEL OF PROTECTION

The REACH regulation aims for a high level of protection of human health and the environment from the potentially hazardous effects of chemicals. The legislation was the response to the perceived lack of information on the impact of chemicals used in daily life throughout Europe. Now, the regulation imposes a basic responsibility on companies to submit dossiers of information for each and every chemical substance that they manufacture or import at or above one tonne per year. The registrants must be able to demonstrate, using scientifically reliable data, that their chemicals can be used safely.

INFORMATION REQUIREMENTS

REACH spells out clearly the standard information required, which depends on the volume of a substance that is produced (or imported) in the EU. The volume is used as a way of measuring likely exposure, therefore the higher the tonnage produced or imported the more information that is required on the properties of the substance. Core data is required for all substances. For substances at or above 100 tonnes additional data from testing to identify long-term hazards may be required. The objective of the information requirements is to ensure a high level of protection of human health and the environment.

AVOIDING UNECCESSARY TESTING ON ANIMALS

Another principle of REACH is that the testing of chemical substances on animals should only be done as a last resort. The regulation provides a number of ways the companies registering substances can achieve this:

- sharing both new and existing data and submitting dossiers jointly with other companies;
- using alternatives to testing on animals to generate the necessary information;
- submitting testing proposals for new studies to investigate the properties for which information is not yet available for substances at or above 100 tonnes.

OPTIONS TO FULFIL THE REACH INFORMATION REQUIREMENTS

Methods to avoid the use of animals

- Use of information on similar substances (Grouping and Read-across)
- Information combined together from various sources (Weight of evidence)
- Studies using cells, tissues or organs (*in vitro*)
- Computer modelling (QSAR)

Other justifications for omitting studies

- For example, low exposure considerations

Animal studies

- Results from existing studies
- Conduct new studies as a last resort to fill data gaps in the core data essential for registration
- Testing proposals for new studies of long-term hazards for example carcinogenicity or reproductive toxicity for substances at or above 100 tonnes *

*ECHA needs to agree before a test can be done

EXPERIENCE SO FAR

This report is the first that ECHA has provided on the use of alternatives to testing on animals since REACH came into effect. It uses the registration dossiers that have been submitted between 1 June 2008 and 28 February 2011 as its main source of information. The focus of the assessment is on dossiers submitted for substances at or above 100 tonnes per year with the highest data requirements. The companies registering these substances are required to provide the core registration data, any relevant data available from earlier testing on animals

and to make testing proposals for longer-term hazards, for which data are not yet available.

DATA SHARING

One core obligation in REACH is that different companies registering the same substance share their data from studies on (vertebrate) animals. This avoids unnecessary testing on animals by allowing all companies needing data for the same substance to use the data available in one of the companies instead of each carrying out their own studies.

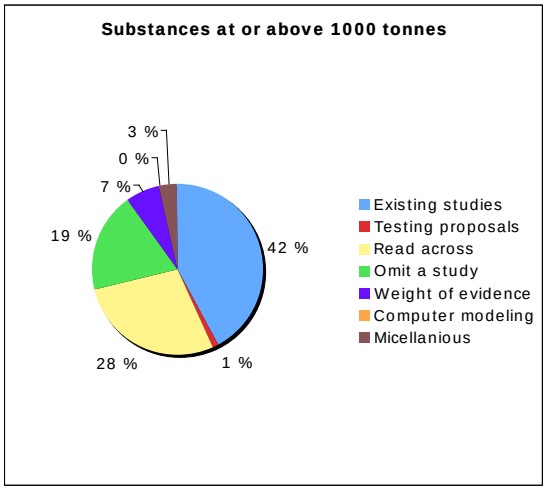
The results of the current analysis demonstrate that the data sharing mechanisms are working and that registrants used them extensively to fulfil their information requirements. Only a limited number of companies appeared to have used the opportunities for submitting data separately.

Another indication of the activity by industry regarding data sharing is when potential registrants make an inquiry to ECHA to find out if their substance has already been registered with a view to using the existing studies. The Agency has processed almost 1 500 inquiries made by potential registrants, and of these, about 50% have led to registration.

ALTERNATIVES TO NEW ANIMAL TESTING

Registrants made full use of the options available in REACH to use alternatives to carry out new tests on vertebrate animals.

- Registrants mainly used existing animal **studies** that had already been **conducted before REACH**.
- Predicting the properties of substances by **read-across** (comparing one substance with another similar one where test data are already available) was the second most common means of fulfilling the information requirements.



REPEATED DOSE TOXICITY – OPTIONS USED TO FULFIL REACH INFORMATION REQUIREMENTS.

NEW TESTS

The report also provides the number of studies conducted for the purpose of REACH. These include both animal studies and *in vitro* studies that do not use animals but instead cells, tissues or organs to predict the hazardous properties of substances. The current analysis shows that in total 1 491 new *in vitro* studies and 1 849 new animal studies have been conducted since REACH entered into force. The majority of the new animal studies were to provide core data that is mandatory to submit a complete registration dossier. However, 107 studies on animals with a report date of 2009 or after appeared to have been conducted in the absence of testing proposals: The reason for this can be analysed during the evaluation process.

Type of experimental study	Total number*
New experimental studies using cells, tissues or organs	1 491
New experimental studies on animals	1 849
All new experimental studies	3 340

*excludes category dossiers covering many similar substances and dossiers covering only intermediates which have greatly reduced information requirements

TESTING PROPOSALS

Registrants submitted testing proposals for additional data on vertebrate animals to fulfil their obligation for information on long-term hazards. The Agency needs to agree before such a new study can be conducted. In total so far, 574 registration dossiers included testing proposals;

- amounting to 1 175 individual tests;
- of which 711 were proposals for vertebrate animal studies.

PROPOSALS TO TEST ON VERTEBRATE ANIMALS

Test	Number of proposals
Repeated dose toxicity (oral)	121
Repeated dose toxicity (dermal)	6
Repeated dose toxicity (inhalation)	27
Genetic toxicity (*in vivo*)	25
Carcinogenicity	3
Toxicity to reproduction	231
Developmental toxicity	239
Bioaccumulation: aquatic / sediment	17
Long-term toxicity to fish	38
Long-term toxicity to birds	4
Total	711

The Agency received fewer testing proposals than had been anticipated based on previous estimates from the European Commission or from interested scientists. The reason for this appears to be that registrants have used other available options to fulfil the information requirements before resorting to making a testing proposal for new studies. The most common alternatives to testing used by registrants to fill data gaps were the **grouping** and **read-across** approaches; in other words, companies proposed to conduct one study to cover more than one substance or to use existing data from related substances.

EVALUATION OF DOSSIERS

Although the evaluation of dossiers is at an early stage, it can be said that the justifications that registrants have provided, for the use of alternatives methods to fulfil information requirements, often fall short of what the legislation requires. As the registration data has to be of sufficient quality for classification and labelling, and for risk assessment it is inevitable that when the dossiers are checked for compliance the Agency will need to ask for some new animal tests to ensure that the information necessary for ensuring the safe use of chemicals is available, unless registrants can improve their scientific justifications.

The Agency will continue using the experience of the evaluation process to help registrants to produce better quality dossiers. This will include awareness raising on alternatives to testing on animals and the promotion of best practice on their use.

LINKS

This report summary is available in EU 22 languages.

The full report on the Use of Alternative to Test on Animals in REACH: 2008 to 2011 can be downloaded here. The report is available only in English. It was published on 30 June 2011.

REACH Regulation EC No 1907/2006 Article 117(3)

- Article 117(3)

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