ECHA
EUROPEAN CHEMICALS AGENCY

FACTS & FIGURES

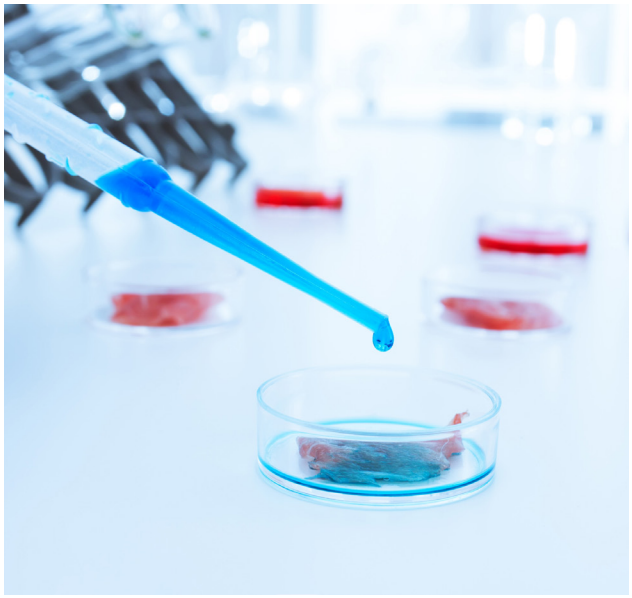
ECHA-14-A-08-EN

The use of alternatives to testing on animals for REACH

Second report under Article 117(3) of the REACH Regulation

Registrants use a number of alternative testing methods to generate information on the hazards of chemicals, as required by the REACH Regulation. Over 38 000 registration dossiers in ECHA's data base have been used as the main source of information for this report.

To avoid unnecessary animal testing, industry has shared data on substances as well as increasingly used alternatives, such as build categories and predict substance properties by "read-across". Progress has also been made in the use of *in vitro* methods.



The aim of the REACH Regulation is to ensure a high level of protection of human health and the environment. Companies registering chemicals must therefore demonstrate that their substances can be used safely. REACH defines the information requirements, which mainly depend on the volume of the substance produced or imported and the intrinsic hazardousness of substance. Testing on animals should only be undertaken as a last resort – when there is no other scientifically reliable way to examine the impact of chemicals on humans or the environment.

The report shows that registrants make use of alternative testing methods and strategies. Building categories and predicting substance properties by read-across is the most widely used method. This means filling a data gap for a substance by using information from similar substances. Combining information together from different sources (weight of evidence) is the second most common method, followed by computer modelling (qualitative/quantitative structural-activity relationship, (Q)SAR).

OPTIONS TO FULFIL THE REACH INFORMATION REQUIREMENTS

Alternative methods

Use of information on similar substances: grouping and read-across

Information combined together from different sources (weight of evidence)

Computer modelling ((Q)SAR)

Studies using cells, tissues or organs (*in vitro*)

Animal studies

Results from existing studies

New studies only as a last resort

Proposals to do animal tests require approval from ECHA

Justifications for omitting studies

For example, low exposure considerations

DATA SHARING IN USE

REACH stipulates that companies share testing data with other companies registering the same substance. The aim is to avoid duplication of tests and thereby reduce to testing needs on vertebrate animals. Most registrants comply with this obligation and also submit data jointly. By the second registration deadline in 2013, ECHA received 8 317 new registrations that were part of joint submissions. These joint submissions, along with 713 new individual registrations, covered 2 998 substances produced at or above 100 tonnes per year.

READ-ACROSS - MOST COMMONLY CHOSEN ALTERNATIVE APPROACH

Building of categories and predicting substance properties by read-across was the most common alternative method chosen by registrants. In 75 % of the analysed dossiers, it was used for at least one endpoint. In particular, read-across was used for higher tier endpoints, where alternative test methods or strategies approved for regulatory use are not yet available (for example, sub-chronic toxicity, pre-natal developmental toxicity or toxicity to reproduction).

IN VITRO METHODS ADVANCING

Registrants have applied *in vitro* methods to provide information on skin and eye irritation, and skin corrosion. Since 2011, the number of such tests used by registrants has grown from 442 to 1 410.

Almost 20 % of the analysed dossiers contained *in vitro* studies, either alone or combined with other information.

Registrants used approaches based on alternative methods for skin sensitisation, even though these are still in the early stages of development.

THIRD PARTIES CONSULTED

ECHA publishes all proposals to test on vertebrate animals on its website. After a testing proposal has been published, third parties have 45 days to submit scientifically-valid information, addressing the relevant substance and hazard endpoint.

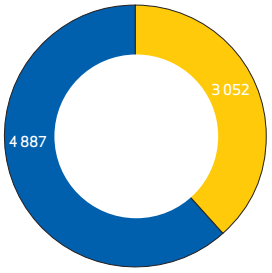
At the end of 2013, the Agency had held over 500 public consultations on testing proposals, covering nearly 1 000 such tests. ECHA received around 650 comments, mostly from animal welfare organisations and industry groups. It sent this input to the registrants for their consideration in the decision making.

Most comments addressed the use of alternative approaches. In a number of cases, registrants used the information to fulfil the information requirement and removed their testing proposals.

Testing on vertebrate animals is only allowed as a last resort under REACH. ECHA's objective is to promote non-animal testing methods and other alternatives.

NUMBER OF NEW TESTS

By 1 October 2013, ECHA's database contained information on 7 939 new experimental studies for those endpoints which may involve testing on vertebrate animals. Out of these, 3 052 are *in vitro* tests, using cells, tissues or organs, and 4 887 are experiments on animals. Registrants have provided most of these new studies to fulfil their obligations to provide information required by REACH Annexes VII and VIII. This data is mandatory to submit a complete registration dossier.



New experimental studies since 2009

- *In vitro* tests
- Tests on animals

TESTING PROPOSALS

Registrants need to submit proposals for new higher tier tests that are required to fulfil information requirements which apply to substances manufactured or produced at or above 100 tonnes per year. ECHA evaluates the proposals and needs to agree, in consultation with the Member States, before any tests can be conducted.

For the 2013 deadline, registrants submitted 701 proposal to test on vertebrate animals. ECHA will have evaluated them all by 1 June 2016. Most proposals concern developmental toxicity and repeated dose toxicity studies.

Tests for substances produced at or above 100 tonnes	Number of proposals
Developmental toxicity	308
Repeated dose toxicity (oral)	222
Toxicity to reproduction	72
Genetic toxicity	41
Repeated dose toxicity (dermal)	25
Long-term toxicity to fish	23
Bioaccumulation: aquatic / sediment	7
Repeated dose toxicity (inhalation)	1
Total	701

METHODOLOGY USED

Every three years, ECHA reports to the European Commission on how alternative methods have been used to generate information on intrinsic properties of chemical substances and for risk assessment. Over 38 000 registration dossiers have been used as the main source of information for this report. This includes dossiers submitted for the 2010 and 2013 deadlines, mainly covering substances imported or manufactured at more than 100 tonnes per year and these are the focus of in-depth analyses conducted for this report.

The relevant information in the dossiers has been identified, extracted and analysed using specifically developed data extraction tools. The quality of the scientific information in registration dossiers was not analysed.

SUPPORT TO REGISTRANTS

ECHA promotes the use of alternative methods through publications, its website, guidance, campaigns and events. The findings of this report will be used to support registrants preparing for the 2018 deadline.

The promotion of the correct use of read-across and the development of the OECD QSAR toolbox project are among the Agency's priorities. ECHA also disseminates the information from registration dossiers and its decisions on testing proposals and compliance checks on its website. This information will assist registrants to identify data that may be useful, for example, for potential read-across. ECHA also publishes annual evaluation progress reports including observations and recommendations to registrants from their dossier and substance evaluations.

LINKS

Information on animal testing

» http://echa.europa.eu/chemicals-in-our-life/animal-testing-under-reach

OECD and EU test guidelines

» http://echa.europa.eu/support/oecd-eu-test-guidelines

Practical guides

Practical Guide 1: How to report in vitro data
Practical Guide 5: How to report (Q)SARs
Practical Guide 6: How to report read-across and categories
Practical Guide 10: How to avoid unnecessary testing on animals

» http://echa.europa.eu/practical-guides

The use of alternatives to testing on animals for REACH - Second report under Article 117(3) of the REACH Regulation:
http://echa.europa.eu/publications

Summary leaflet available in 23 EU languages

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