ECHA
EUROPEAN CHEMICALS AGENCY

In brief

ECHA-17-B-06-EN

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

Third report under Article 117(3) of REACH

From the database of REACH registrations submitted by companies, covering data on over 6 000 substances, it is clear that registrants are widely using alternatives to animal testing.

DATA SHARING WORKS WELL

Most registrants share data: 98 % of the substances are registered jointly. This ensures that for each substance, the test data is collected in one joint registration dossier, instead of every registrant testing the same substance individually.

ALTERNATIVES TO NEW TESTS ON ANIMALS

Registrants use existing information and alternatives to animal testing. Altogether, 6 290 substances were analysed for the report. Out of these, 89 % have at least one data endpoint where an alternative was used instead of a study on animals.

The most common alternative method was using information on similar substances (read-across), used in 63 % of the analysed substances, followed by combining information from different sources (weight of evidence, 43 %) and computer modelling (QSAR prediction, 34 %).

READ-ACROSS MOST COMMONLY USED ALTERNATIVE

Read-across has been particularly frequently used for human health data endpoints, for example, developmental and reproductive toxicity. However, its quality still needs to improve – for example, registrants often do not provide enough scientific evidence to support their read-across case.

REGISTRANTS HAVE DIFFERENT OPTIONS TO PROVIDE INFORMATION REQUESTED BY REACH

Alternative methods

- Use of information on similar substances: read-across
- Information combined together from different sources: weight of evidence
- Computer modelling: QSAR
- Studies using cells, tissues or organs: *in vitro*

Justifications for omitting studies

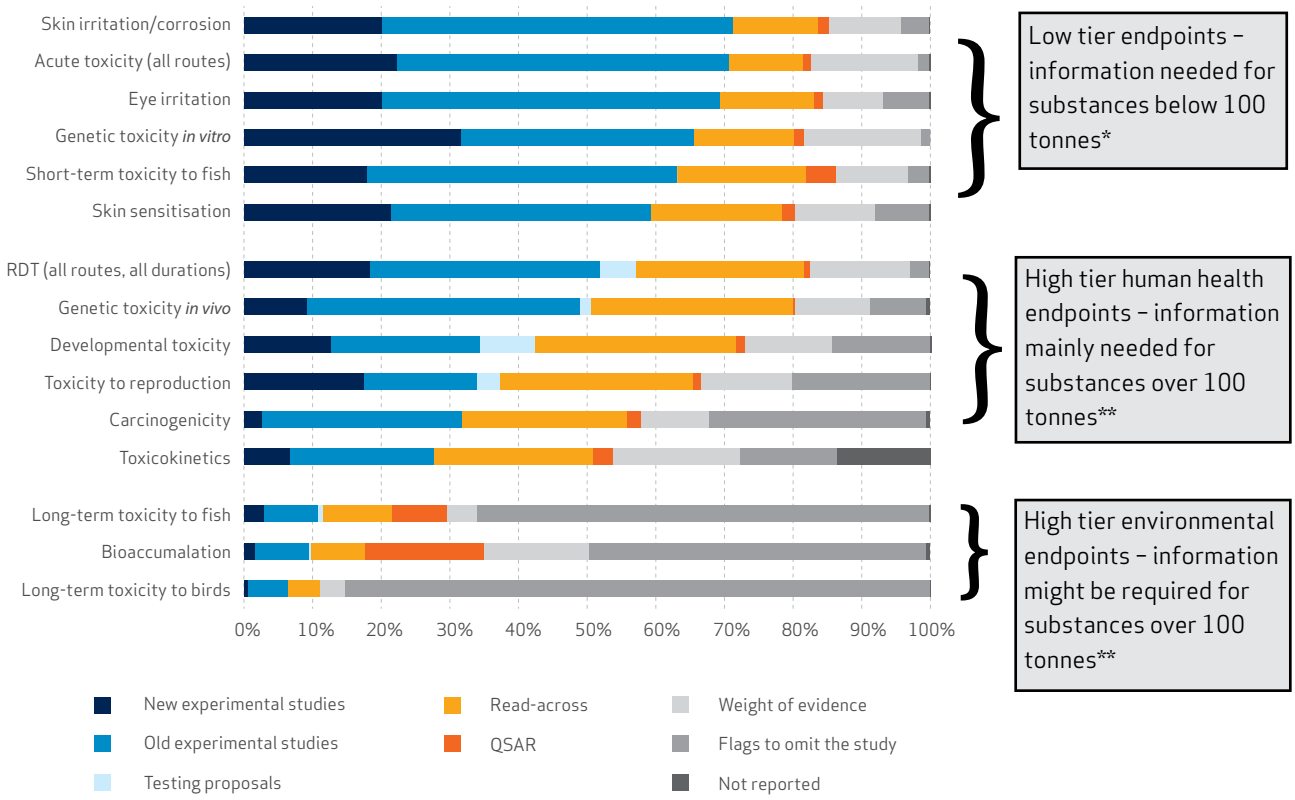
- Data waiving

Animal studies

- Results from old experimental studies
- New studies as a last resort for filling data gaps
- Testing proposals for new studies on vertebrate animals

WHAT METHODS DO REGISTRANTS USE?

Options that registrants use to cover REACH information requirements for different data endpoints



For low tier endpoints (covering mainly acute and local effects), registrants mainly use experimental studies, many of them carried out before REACH. New experimental studies were carried out for about 20 % of the substances. Around 34 % of substances are covered by alternatives, such as read-across, QSAR, weight of evidence and data waiving.

Less experimental data is available for high tier human health endpoints. About 12 % of the substances are registered with new experimental studies, while old experimental studies amount to 28 % on average. Read-across is used for 27 % of the substances, followed by weight of evidence (12 %).

For high tier environmental endpoints, very little experimental data is available. On average, 9 % of substances were registered with experimental studies, out of which only 1.6 % are new experimental studies. Data waiving is used most frequently (67 % of substances), followed by QSARs (9 %) and read-across (8 %).

Taking all of the endpoints and substances analysed that might require tests on vertebrate animals, registrants used data from new vertebrate animal studies in 11 % of the cases.

QUALITY DEFICIENCIES

There are quality deficiencies in the alternative methods used, especially with read-across. These include, for example, poor documentation, insufficient substance identification, deficiencies in the source studies and supporting data, and shortcomings in the toxicological hypothesis.

Therefore, additional data is still needed to enable the safe use of chemicals.

*substances that are manufactured or imported in quantities of less than 100 tonnes a year
**substances that are manufactured or imported in quantities of 100 tonnes a year or more

WORK TO PROMOTE ALTERNATIVE METHODS

ECHA uses the report's findings to promote alternative methods through its guidance, web pages, webinars and events.

For substances that are produced or imported in quantities of less than 100 tonnes a year, there are appropriate *in vitro* methods and a lot of experimental data already available. As the toxicological properties required for these substances are less complex, alternatives like read-across and QSARs can be applied more easily. ECHA encourages registrants to make the best use of these methods.

For substances produced or imported in quantities of more than 100 tonnes a year, ECHA will focus on observed shortcomings, for example, to improve read-across. It has published the read-across assessment framework, which allows registrants to improve their read-across justifications.

ECHA supports the development of the OECD QSAR Toolbox. It is a software that can be used to support read-across.

The development of scientific new approach methodologies will bring new high throughput assessment methods, which can support current alternative approaches, and might provide more human relevant information.

ECHA continues to explore how to make better use of the registration data to contribute to the development of alternative methods. This includes developing the OECD set of tools that form the knowledgebase for the toxicological effects of substances and for a non-toxic environment.

ECHA also gives regulatory input to scientific projects and activities and contributes to the development and promotion of alternative methods through the OECD.

FURTHER INFORMATION

"The use of alternatives to testing on animals for the REACH Regulation" report is available under:

» https://echa.europa.eu/about-us/the-way-we-work/plans-and-reports

How to avoid unnecessary testing on animals

» https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals

Information on animal testing

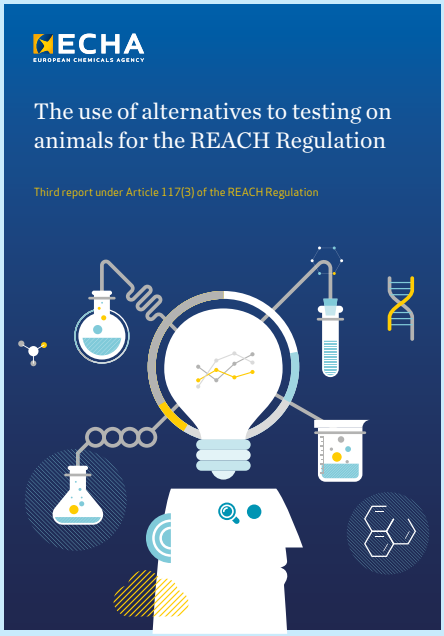
» https://echa.europa.eu/chemicals-in-our-life/animal-testing-under-reach

Practical guide: How to use alternatives to animal testing

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

OECD and EU test guidelines

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



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