ECHA
EUROPEAN CHEMICALS AGENCY

In brief

ECHA-20-B-05-EN

The use of alternatives to testing on animals for REACH

The fourth report under Article 117(3) of REACH

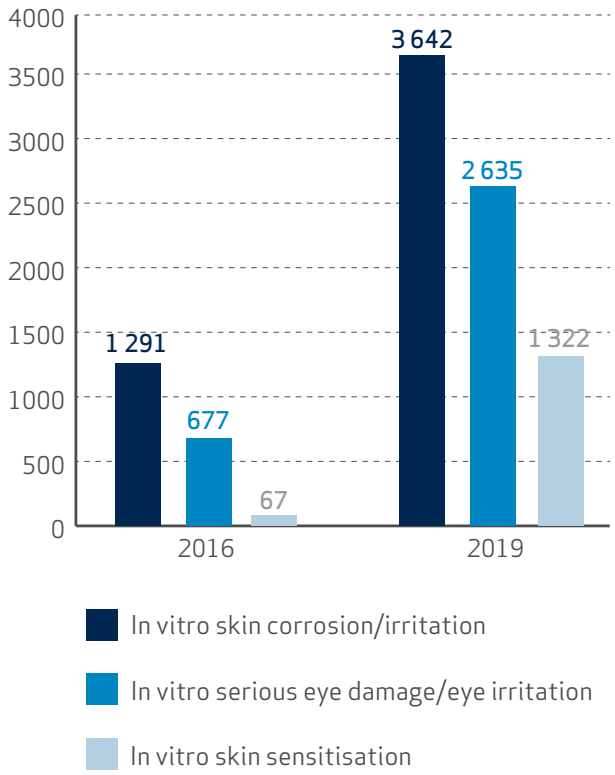
Data on more than 12 000 substances shows that registrants are sharing data, continuing to use adaptations to avoid animal testing and are using more alternatives to testing on animals.

AVOIDING TESTING ON ANIMALS THROUGH ADAPTATIONS

Registrants are using existing information and alternatives to avoid unnecessary animal testing. Experimental studies carried out according to specific test guidelines outlined in the REACH annexes were available for around 27 % of cases. Overall, registrants have used at least one adaptation to avoid animal testing for around 70 % of substances.

AMENDMENT TO REACH ANNEXES INTRODUCING ALTERNATIVE METHODS HAS CLEAR IMPACT

The amendment of the REACH annexes in 2016 and 2017 requires companies to use non-animal testing (*in vitro, in chemico*) for certain endpoints. This has had a clear impact since non-animal tests have tripled for skin corrosion/irritation, quadrupled for serious eye damage/eye irritation and increased more than 20-fold for skin sensitisation.



READ-ACROSS IS STILL THE MOST COMMONLY USED ADAPTATION

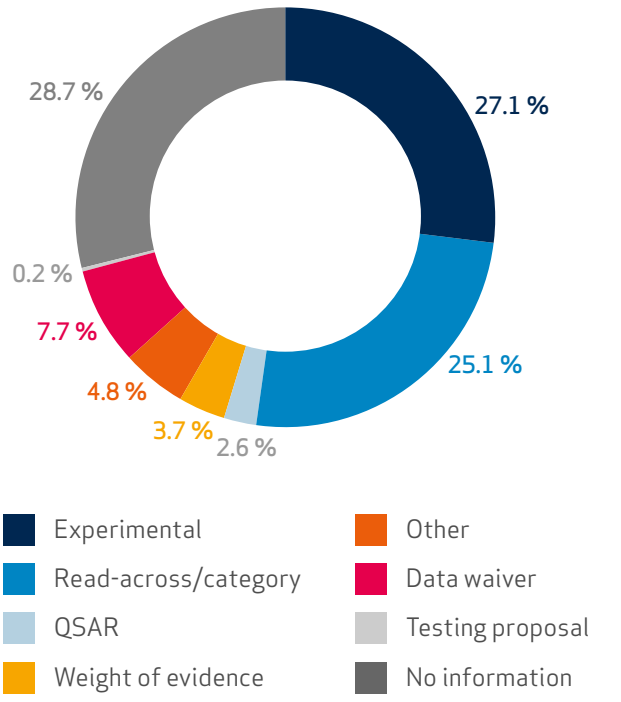
As in the 2017 report, read-across, where information on a similar substance is used to predict the properties of another, was the most commonly used alternative method – used in one of every four cases. Applying read-across correctly reduces the need for experimental testing and tests on animals.

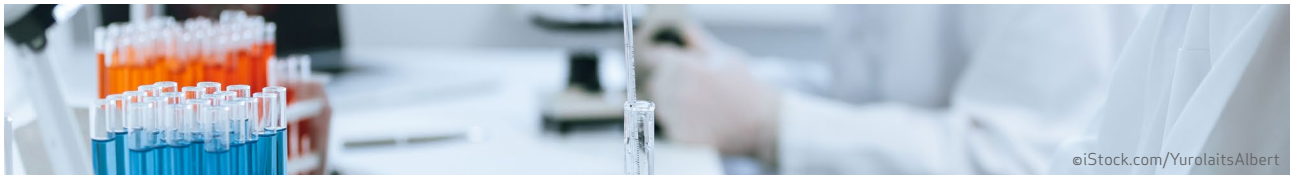
However, the use of read-across still needs to improve – for example, registrants don't always document studies correctly, substance identification is not always sufficient and there are significant deficiencies with the source studies.

OTHER ADAPTATIONS AND ALTERNATIVES USED

The other most commonly used alternatives and adaptations are:

- justifications for omitting data (data waiving, 7.7 %);
- combining information from different sources (weight of evidence, 3.7 %); and
- predicting properties from structurally similar substances using computer models (QSAR, 2.6 %).





WHICH METHODS HAVE REGISTRANTS USED?

There are relatively few differences between the approaches registrants used to fulfil the information requirements in 2019 compared to 2016.

In general, adaptations used for lower tonnage substances (registered in the 1-10 and 10-100 tonnes per year) received by the 2018 registration deadline, follow a similar pattern to those in higher tonnages.

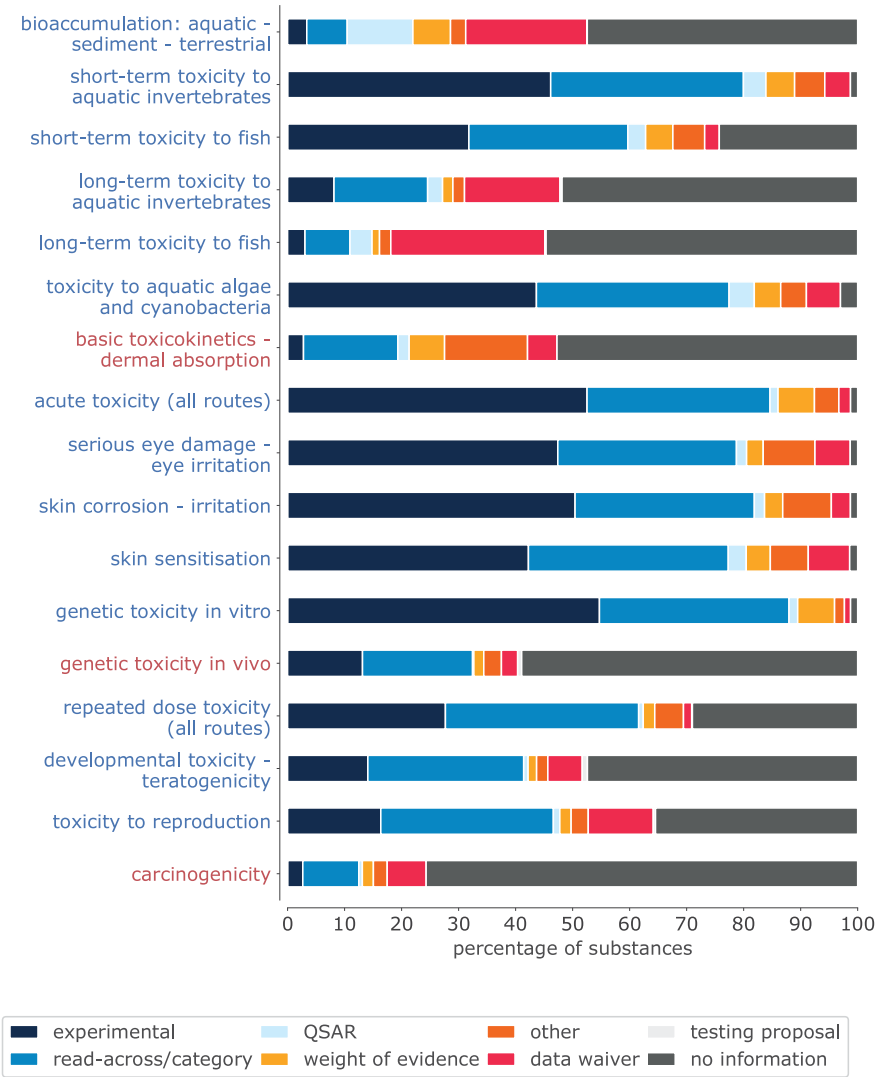
There have been significant reductions in the number of animals and costs as companies are increasingly performing **repeated dose toxicity** and **toxicity to reproduction screening** using the combined repeated dose toxicity study with the reproduction/ developmental toxicity screening test (OECD Test Guideline 422).

Decisions on compliance checks and testing proposals in the last three years are likely to account for a moderate increase seen in the availability of ***in vivo*** **pre-natal developmental toxicity** and **(sub) chronic repeated dose** studies.

NEWLY RECEIVED DOSSIERS

1-10 tonnes per year:
For newly received registrations in the 1-10 tonne per year band, there have been fewer experimental studies and less read-across, but more weight of evidence, QSAR and data waiving. These dossiers have the lowest data requirements, and registrants have used alternative approaches even more so than in other tonnage bands.

The low tonnage dossiers submitted before 2016 contain more additional information on top of the standard information requirements than those submitted in 2019.



10-100 tonnes per year:
Newly received registrations for substances in the 10-100 tonne per year bracket also follow a similar pattern as those in higher tonnage bands. **Acute toxicity** is an exception as there have been fewer experimental studies, but more weight of evidence, QSAR and data waiving.

The percentage of **short-term toxicity to fish** studies has decreased since 2016, which shows adaptations for this standard information requirement have been used effectively. However, **long-term aquatic experimental** studies have seen a minor increase.

COMPLIANCE ISSUES

There are still too many incompliant registration dossiers that need to be updated, either voluntarily or after ECHA has requested for this in a compliance check decision. The compliance of standalone **QSAR predictions** was also checked with a substantial number of them being inadequate.

Registrants should take the opportunity to strengthen their alternative approaches by using the resources available through ECHA's guidance, practical guides, webinars and other advice from the Agency's publications, especially the progress made in evaluation.

CHEMICALS KNOWLEDGEBASE

ECHA's registration database gives a unique starting point from which to build up a chemicals knowledgebase that could be used to further develop alternative approaches to animal testing in the future.

Such a knowledgebase would be an integral resource that could be used to support the goals of the European Green Deal and Digital Agenda, and reinforce initiatives under the chemicals strategy for sustainability, including moves towards making the EU a toxic-free environment and the circular economy.

PROMOTING ALTERNATIVE METHODS

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

With the chemicals knowledgebase as one of the resources, ECHA will use the report's findings to continue to promote non-animal testing methods by developing and maintaining tools, guidance and web content to support registrants.

It will continue to follow and contribute to the developments at the OECD and to grasp opportunities to adopt alternative approaches into the regulatory arena when they are viable. To stimulate the use of non-animal test methods, ECHA continues to actively support the development of the OECD QSAR Toolbox, a software tool increasingly used in computational toxicology and chemical hazard assessment.

ECHA is also exploring ways to exploit new approach methodologies (NAMs) with the aim of reinforcing their applicability in a regulatory context. In this regard, it is leading and collaborating in various projects involving new approaches on an international level.

These approaches are crucial as they allow better informed decisions to be made for the protection of human health and the environment, while minimising the need for studies on animals.

FURTHER INFORMATION

The use of alternatives to testing on animals for the REACH Regulation report is available at:
» https://echa.europa.eu/about-us/the-way-we-work/plans-and-reports?panel=animal-testing-reports#animal-testing-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-guideline

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