Making use of publicly available studies within the REACH Regulation: An overview of submitted terrestrial toxicity data

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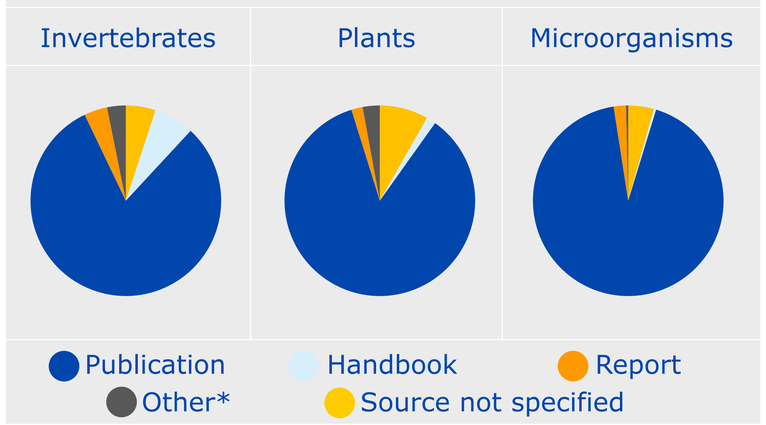
The aim of the REACH Regulation is to ensure a high level of protection of human health and the environment. Testing on animals to fulfil REACH information requirements should only be undertaken as a last resort – when there is no other scientifically reliable way to examine the impact of chemicals. Registrants use a number of alternative methods to generate information on the hazards of chemicals, such as predicting substance properties by read-across, combining information together from different sources (weight of evidence), or by using different modelling approaches.

Additionally, registrants can fulfil REACH requirements by submitting information already available from different sources (scientific journals, handbooks, published reports). This poster provides an overview of this type of information based on the registration dossiers submitted to ECHA from 1 June 2008 to 1 August 2015, covering the first two registration deadlines.

The majority of publicly available studies submitted within the REACH framework consists of publications from scientific journals



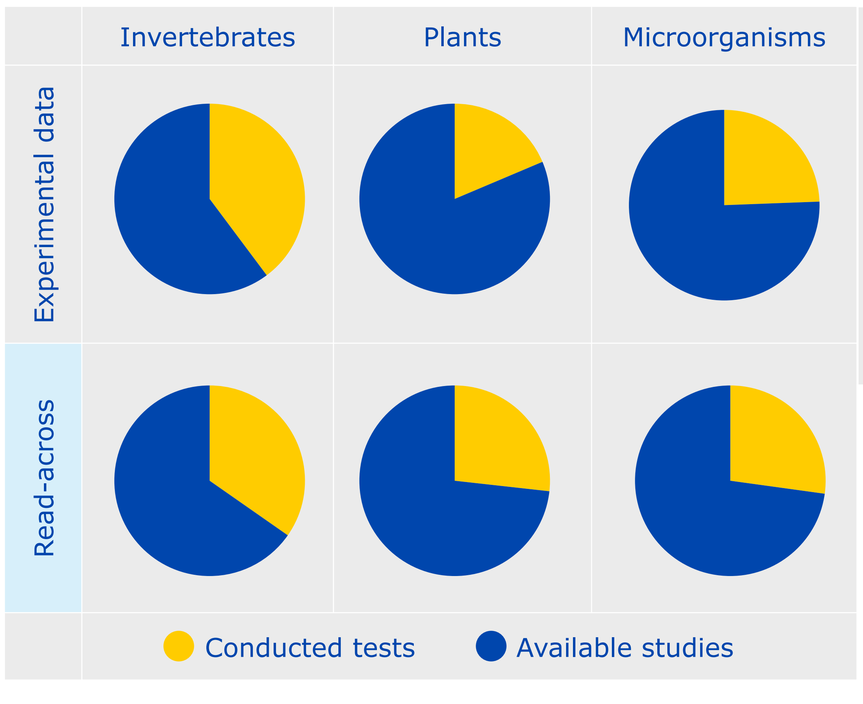
Number of unique references for the most frequently reported journals in the REACH database. One publication may be submitted multiple times – for different substances, dossiers, or endpoint study records.

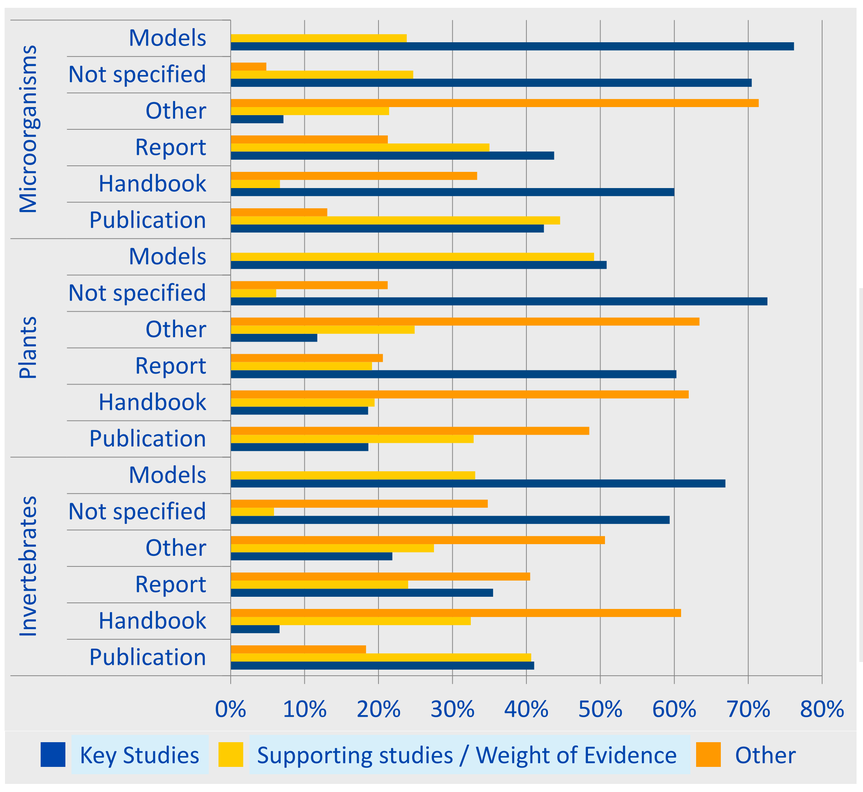
Journal	Reference Count
Environmental Toxicology and Chemistry	79
Ecotoxicology and Environmental Safety	48
Chemosphere	42
Environmental Pollution	37
Soil Biology and Biochemistry	31

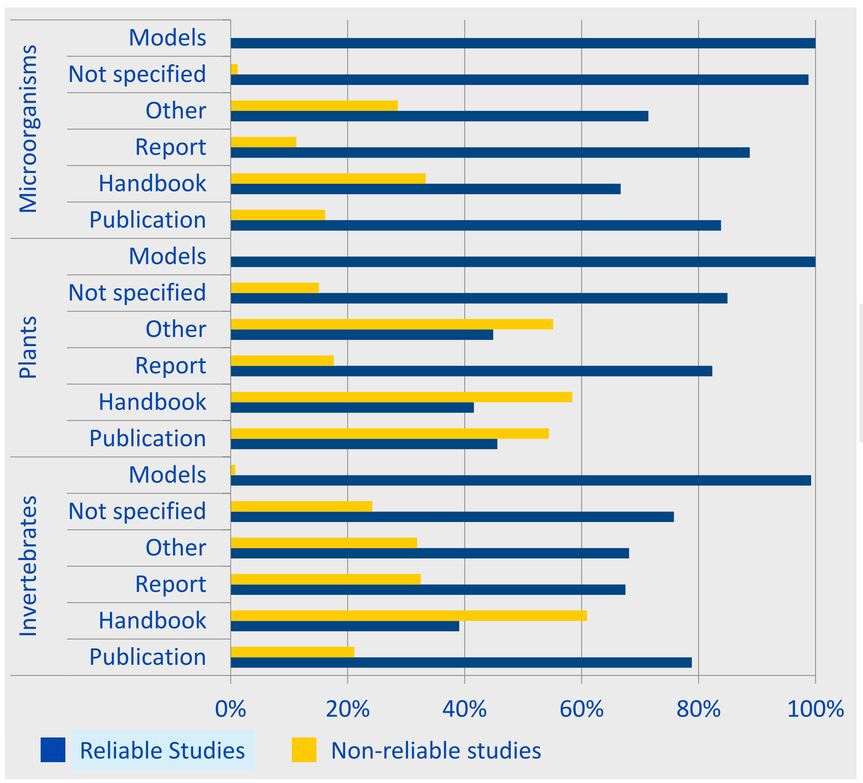
According to the REACH Regulation, ECHA shall check the compliance of at least 5 % of registration dossiers received by the Agency for each tonnage band, and may request further studies if considered necessary. Therefore, when interpreting the findings of the current analysis, it should be noted that in principle the current results may be affected by the outcome of the dossier evaluation work.

Available studies submitted within REACH: Number of endpoint study records, technical dossiers, and substances in the REACH database for each terrestrial trophic level

	Invertebrates	Plants	Microorganisms
ESR	5 209	7 139	3 869
Dossier	859	926	690
Substance	722	780	567







Endpoint study record (ESR): Record of the technical dossier used to report (robust) study summaries of the information derived for the specific endpoint from the original study report. For example, an endpoint study record is produced for an individual experimental study.

Read-across (RA): An approach for filling data gaps for a substance by using information from similar substances.

The majority of data comes from publicly available studies

For studies submitted both within the read-across approach and as experimental data, publicly available studies account for more than 60 % of endpoint study records in the REACH database for all three terrestrial trophic levels.

Key study: A study generally expected to be the most adequate, reliable and relevant for a specific element/ endpoint study section. If properly reported, key study may fulfil a REACH information requirement on its own.

Supporting study: A study that is considered "supportive" of the key study or key studies. A supporting study cannot fulfil a REACH information requirement on its own.

Weight of evidence: The process of considering the strengths and weaknesses of various pieces of information in reaching and supporting a conclusion concerning a property of the substance. This approach always combines a number of individual studies, and none of them can fulfil a REACH information requirement on their own.

The majority of publicly available studies are being considered as key studies by the registrants

In the majority of cases, registrants report studies from publicly available sources as key studies, meaning that they consider them as being able to fulfil a REACH information requirement on their own.

Reliable study: A study conducted according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which all parameters described are closely related to a guideline method. Alternatively, a study in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable.

The majority of publicly available studies are being classified as reliable studies by the registrants

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