Analysis of the ecotoxicity data submitted within the framework of the REACH Regulation. Part 2. Experimental aquatic toxicity assays

Jose V. Tarazona *, Marta A. Sobanska, Romanas Cesnaitis, Tomasz Sobanski, Vincent Bonnomet, Bram Versonnen, Wim De Coen

European Chemicals Agency, Annankatu 18, FI-00121 Helsinki, Finland

HIGHLIGHTS

- The analysis was performed on data submitted by industry in the framework of REACH.
- Offers the full picture of the data considered by industry in their registrations
- Most studies were OECD tests on standard species suitable for QSAR developments.
- Non-guideline fish & invertebrate studies offer large coverage of species and taxa.
- Detailed information on reporting aquatic ecotoxicity data in IUCLID5 is presented.

ABSTRACT

This paper summarises the aquatic ecotoxicity data submitted in the REACH[1] registration dossiers and disseminated by the European Chemicals Agency (ECHA[2]). The analysis describes both the guidelines and the species mostly used by registrants. Non-OECD guidelines have been extensively used, in particular in covering of fish and aquatic invertebrate studies, but the main concern is that in 22–36% of the cases, depending on the endpoint, no information on the methodological approach and potential equivalences to test guidelines has been provided. As expected, most studies were conducted with those species typically used in laboratory ecotoxicity testing; nevertheless, the database provides a broad range of available species, covering the most relevant taxonomic groups for both freshwater and marine systems, although most are just occasionally used. This species diversity is essential for higher tier testing strategies, including the use of Species Sensitivity Distribution approaches. The assessment suggests that collecting available information has been the main approach used by registrants to fulfil their REACH information requirements for this first REACH registration deadline. Many studies are disclosed for the first time, and all are available through searchable web tools.

1. Introduction

Information on the toxicity of chemicals for aquatic organisms has received particular attention in the regulatory context, as the aquatic compartment is a typical sink for industrial pollution due to direct releases and indirect emission pathways. The process of hazard identification is supported through the development of standardised test guidelines. In 1981, the OECD published the first set of test guidelines, covering the "basic data set" with the OECD TG 201, 202 and 203 measuring effects on algal growth inhibition, Daphnia acute inhibition and 14-day reproduction, and fish acute toxicity, respectively. Since then, the publication

of new guidelines and the update of those previously published have been continuous and test methods on aquatic organisms have maintained a clear priority.

Most regulatory approaches have been focused on a limited number of chemicals, and consequently the compiled information tends to be in the range of hundreds of substances at the most (e.g. Licht et al., 2004; von der Ohe et al. 2011). The capacity of the EU REACH Regulation to disclose existing information from industry sponsored studies and to generate new data has created new expectations due to the very broad coverage (e.g. Van der Wielen, 2007; Williams et al., 2009; Tarazona, 2013).

Ensuring accessibility to publicly available (eco)toxicological information on marketed chemicals, and its use for setting appropriate risk management measures, were overriding goals for developing REACH (European Commission, 2001). In this sense, gathering chemical toxicity information was considered a priority under REACH, and regarding ecotoxicity data, this is particularly true for aquatic toxicity.

Table 1
Standard information requirements for aquatic toxicity data.

Tonnage test	Type[a]	1–10 tonnes/year	10–100 tonnes/year	100–1000 tonnes/year	Over 1000 tonnes/year
Short-term toxicity testing on invertebrates (preferred species *Daphnia*)	M	Y	Y	Y	Y
Growth inhibition study aquatic plants (algae preferred)	M	Y	Y	Y	Y
Short-term toxicity testing on fish	M		Y	Y	Y
Long-term toxicity testing on invertebrates (preferred species *Daphnia*),	TP			Y	Y
Long-term toxicity testing on fish	TP			Y	Y

[a] M: Mandatory, the data should be provided in the registration dossier. TP: The data should be included if available. A testing proposal should be submitted before conducting new studies.

The REACH Regulation established the submission of aquatic ecotoxicity data for all registered substances. The minimum aquatic data set, defined by the "Standard Information Requirements", depends on the annual tonnage per registrant. Table 1 summarises these requirements. As a minimum, data on algae and short-term data on aquatic invertebrates should be expected for all registered chemicals, unless there are clear indications to support that aquatic toxicity is unlikely to occur. The full data set, including long-term studies on fish, invertebrates and algae is expected to be available for substances manufactured or imported, by at least one company, above 100 tonnes. As for all other endpoints, the standard information requirements can be attained using specific rules (Column 2 in REACH Annexes VII to X) and general adaptations (Annex XI of REACH), which include the use of existing data, weight of evidence (WoE[3]) approaches, Qualitative or Quantitative structure–activity relationship ((Q)SAR[4]), in vitro methods, grouping of substances and read-across, tailored exposure-driven approaches or indications that testing is technically not possible. Through the dossier evaluation process, checking that the information has been submitted, or that a proper adaptation/justification has been provided, is the first step of the compliance checks done by ECHA.

As a consequence of the different waiving options, the real aquatic database compiled from the REACH registration dossiers does not always contain all elements indicated in Table 1. An overall view of the submitted information regarding ecotoxicological data has been presented in the first paper of this series (Sobanska et al., 2013). This paper presents a summary of the submitted information, highlighting the main characteristics of the aquatic toxicity information, which is accessible through the ECHA dissemination website. It focuses on the testing methods and aquatic species mostly used by registrants, describes the use of protocols standardised by different international and national organisations, and discusses the approaches selected by the registrants, as well as the possibilities for using the REACH database as source of aquatic ecotoxicity data for further developments.

2. Material and methods

2.1. Source of analysed data

The scope of the analysis and details on methodology applied for the data extraction as well as the results of the general analysis of ecotoxicological data availability were presented in (Sobanska et al., 2013).

As explained in detail in Sobanska et al., 2013, the source of data for the current analysis consisted of the content of the registration dossiers submitted to ECHA from 1 June 2008 until 28 February 2011.

In total, 24 560 registration dossiers for 4599 substances have been successfully submitted to ECHA during the mentioned period (ECHA, 2011). Submission types, not subject to the standard information requirements of Table 1, have been excluded from the current analysis. Therefore from the original 4599 substances, the current analysis covers 2887 substances that are 'regular' registration dossiers and contain information on ecotoxicology.

As dossiers may be updated by registrants at any time after the submission, only the data available to ECHA up to the cut-off date of 28 February 2011 were used for the analysis. Similar analyses on sediment and terrestrial toxicity data provided for REACH registration purposes are summarised in Cesnaitis R, et al. (2013) and in Versonnen B, et al. (2013).

2.2. Methods used for the test guideline and species analysis

The data analysis in the current paper was related to the analysis of the test methods applied in the experimental studies for endpoints related to aquatic toxicity. Table 2 summarises the "pick up" options offered for filling the relevant IUCLID entries. The guideline qualifiers "according to" and "equivalent or similar to" were grouped. The registrants' flags for "purpose: key study" and "reliability" (Klimisch score) were not used in the final assessment. The free text for "guideline = other" was analysed identifying other reported guidelines. The names reported for the species were checked, correcting clear editorial errors and updating the species' names. The following online services were used for grouping species/genus into larger taxonomic groups: Encyclopaedia of life (http://eol.org/ last access 26 August 2013); Species 2000 & ITIS Catalogue of Life (http://www.catalogueoflife.org/ last access 26 August 2013); NCBI Taxonomy (http://www.ncbi.nlm.nih.gov/taxonomy last access 26 August 2013); Integrated Taxonomic Information System (http://www.itis.gov/ last access 26 August 2013); FishBase (http://www.fishbase.org/ last access 26 August 2013) and World Register of Marine Species (http://www.marinespecies.org/ last access 26 August 2013). The larger difficulty was for algae studies, the Algaebase (http://www.algaebase.org/ last access 26 August 2013) was used as a reference source for algae taxonomy.

3. Results

There was a large coverage of acute fish toxicity data, mostly based on the standard 96 h acute lethality test. The distribution of the reported guidelines is presented in Fig. 1A. Nearly half of the studies were reported as the OECD[5] 203 TG, this number includes data reported using the equivalent EU C.1 method. About 20% of the studies were conducted using national guidelines, and no data was reported for 30%. Among the national guidelines, the US methods were the most frequently reported, in particular US EPA[6] short-term fish tests and those from ASTM[7] and APHA.[8] The German DIN[9] 38412 covered 5%, while the Japanese K 0102-1986-71 and the Canadian method were indicated in about 1% of the cases. The typical test duration for short-term fish was 96 h as indicated in most guidelines. A test duration of 48 h was particularly frequent in the Japanese (79%) and German (27%) guidelines.

In total, over a hundred fish species from 93 genera and 51 families have been used in the reported short-term studies under REACH; Fig. 1B summarises the species distribution and detailed information is

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[3] Weight of Evidence.
[4] Quantitative structure–activity relationship.

[5] Organisation for Economic Cooperation and Development.
[6] United States Environmental Protection Agency.
[7] American Society for Testing and Materials.
[8] American Public Health Association.
[9] Deutsches Institut für Normung.