

# Database Compilation on Pesticide Ecotoxicological Tier 1 Study Endpoints Using IUCLID 5.2 as Data Entry Software

Karin M. Nienstedt<sup>1\*</sup>, Jane Richardson<sup>1</sup>, Valeria Croce<sup>2</sup>, Stefania Barmaz<sup>2</sup>, Sandro Maroncelli<sup>2</sup>, Chiara Neri<sup>2</sup>, Stephanie K. Bopp<sup>1</sup>

<sup>1</sup>EFSA European Food Safety Authority, Largo N. Palli 5/A, 43121 Parma (PR), Italy

<sup>2</sup>ChemService S.r.l., Via F.lli Beltrami 15, 20026 Novate Milanese (MI), Italy

\*Present address: European Commission, DG SANCO

## Background

In 2009 EFSA has received mandates for revising the current Guidance Documents (GDs) on Aquatic Ecotoxicology (SANCO/3268/2001) and Terrestrial Ecotoxicology (SANCO/10329/2002) regarding the placing of plant protection products (PPPs) on the market. In this context, the validation of Toxicity Exposure Ratios (TERs) used in these GDs is needed. As a requisite for this, a database was created on ecotoxicological properties assessed at Tier 1 level for all available active substances and PPPs dossiers submitted under Directive 91/414/EEC, that contain also higher Tier ecotoxicology studies. The data entry has been outsourced in 2009 according to EFSA procurement procedures and fully carried out at EFSA premises by ChemService.

### Database content and properties

- Compilation of all available Tier 1 study endpoints for aquatic organisms, bees, non-target arthropods, non target plants and soil organisms, for the dossiers where higher Tier ecotoxicology data for any of these taxa are available (Figure 1 and 4).
- This amounts to 227 dossiers corresponding to 104 active ingredients and 123 PPPs, with an overall 3679 studies entered.
- For 86% of the studies the highest reliability score was assigned (Figure 2).

### Data entry and quality check

- The database uses IUCLID 5.2 software, based on the OECD harmonised template for reporting chemical test summaries. The IUCLID interface allows for queries and statistical analysis; the query plug-in tool assists in data quality checks. IUCLID allows the export of data in XML format to facilitate data sharing (Figure 3).
- Data entry was performed according to a standard operating procedure (SOP) developed in the beginning of the project.
- Data entry quality was investigated by checking 20% of data entries according to a SOP. The error frequency reached was 5-10%.

### Intended use of the database and further data to be included

- The database will be further populated with Tier 1 study and risk assessment endpoints covering all available dossiers, i.e. also those not containing related higher Tier studies.
- Data are intended to be used by the EC and the European Member States in the context of Regulation (EC) 1107/2009 concerning the placing of plant protection products on the market, Regulation (EC) No 1185/2009 concerning statistics on pesticides, and Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides.
- The large data set compiled can be used for statistical analysis and could potentially also be used for predicting effects/developing QSARs.

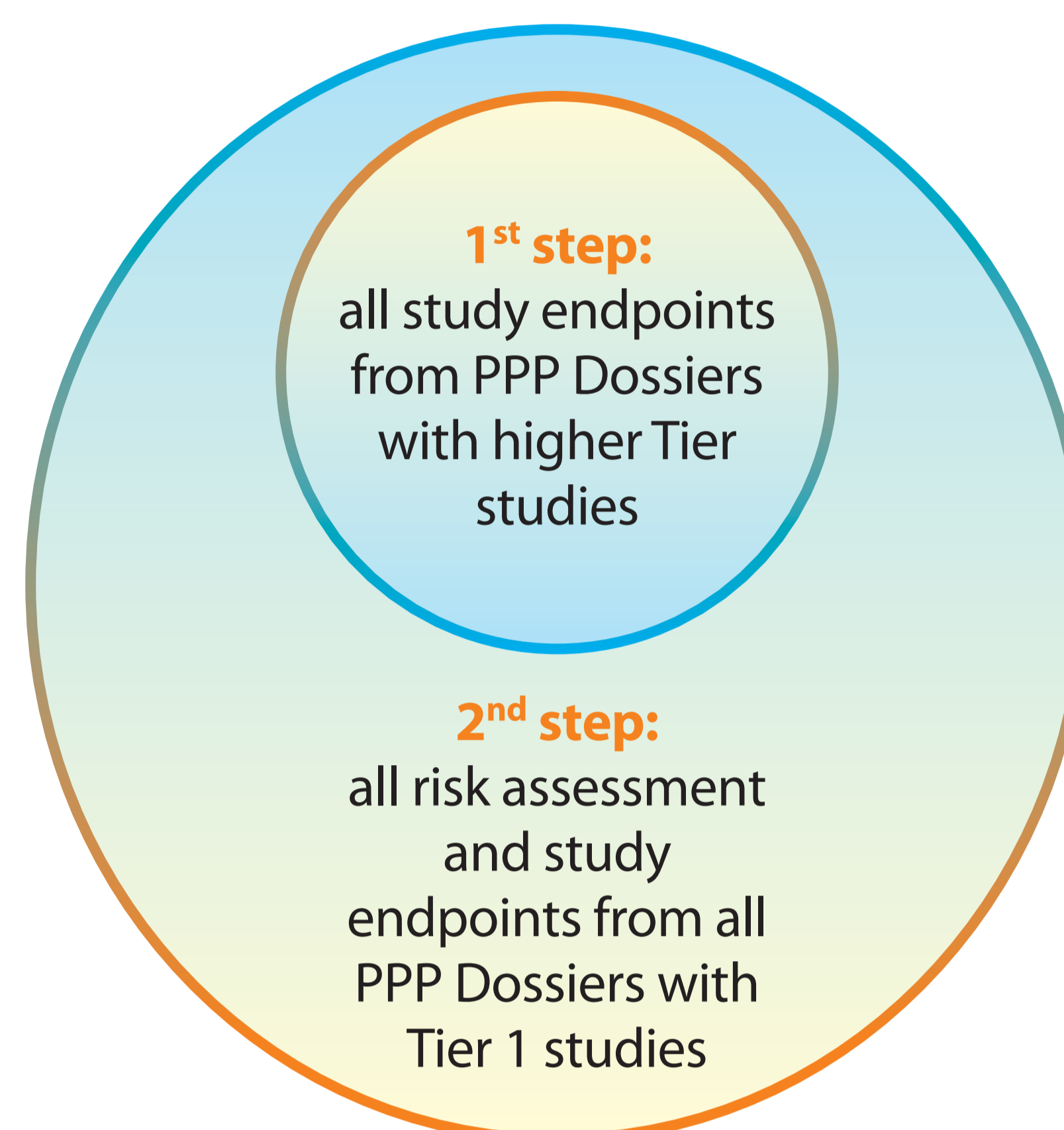


Figure 1. Data entry for Tier 1 study endpoints for aquatic organisms, bees, non target arthropods, non target plants and soil organisms.

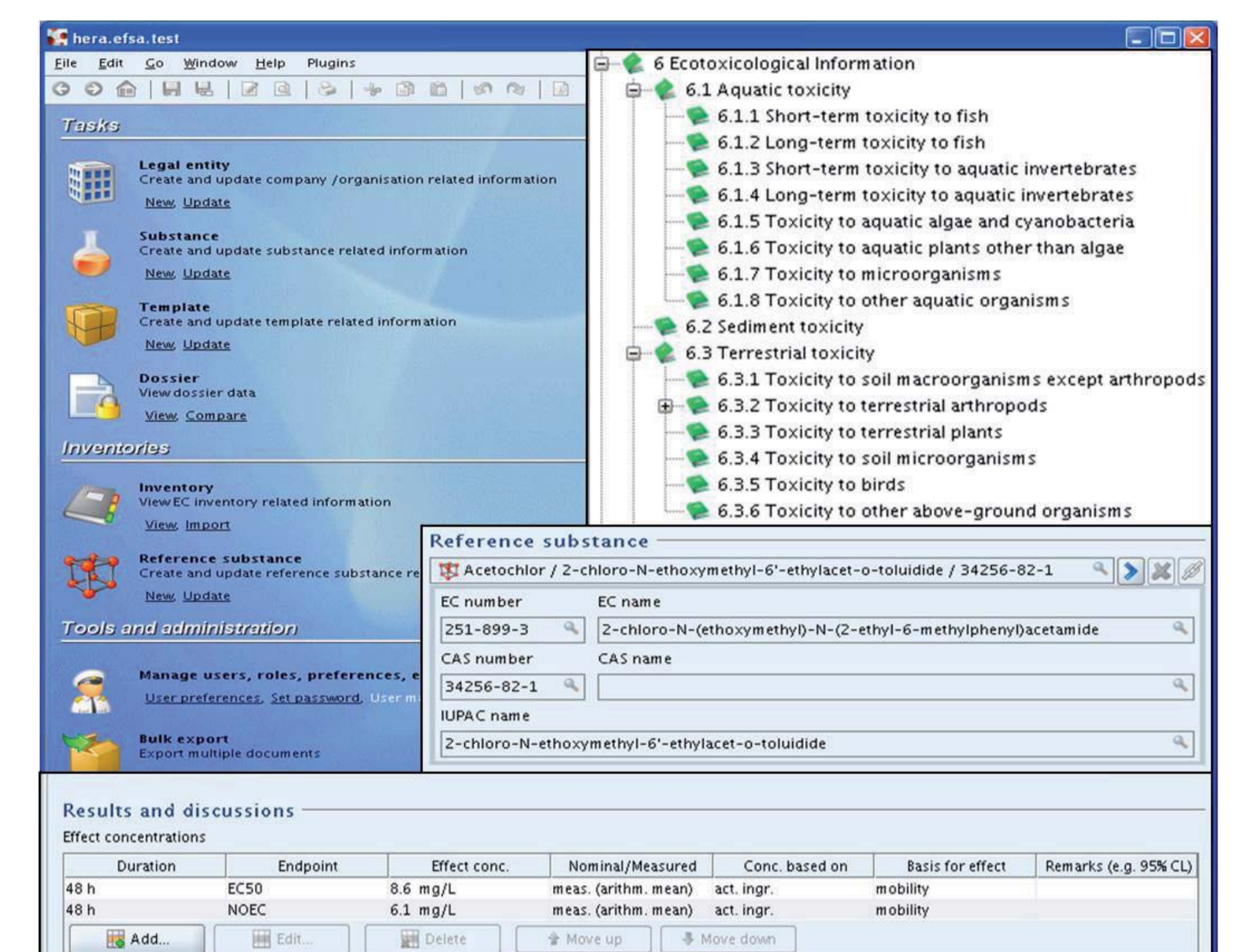


Figure 3. Screenshot of IUCLID 5 software used for database compilation.

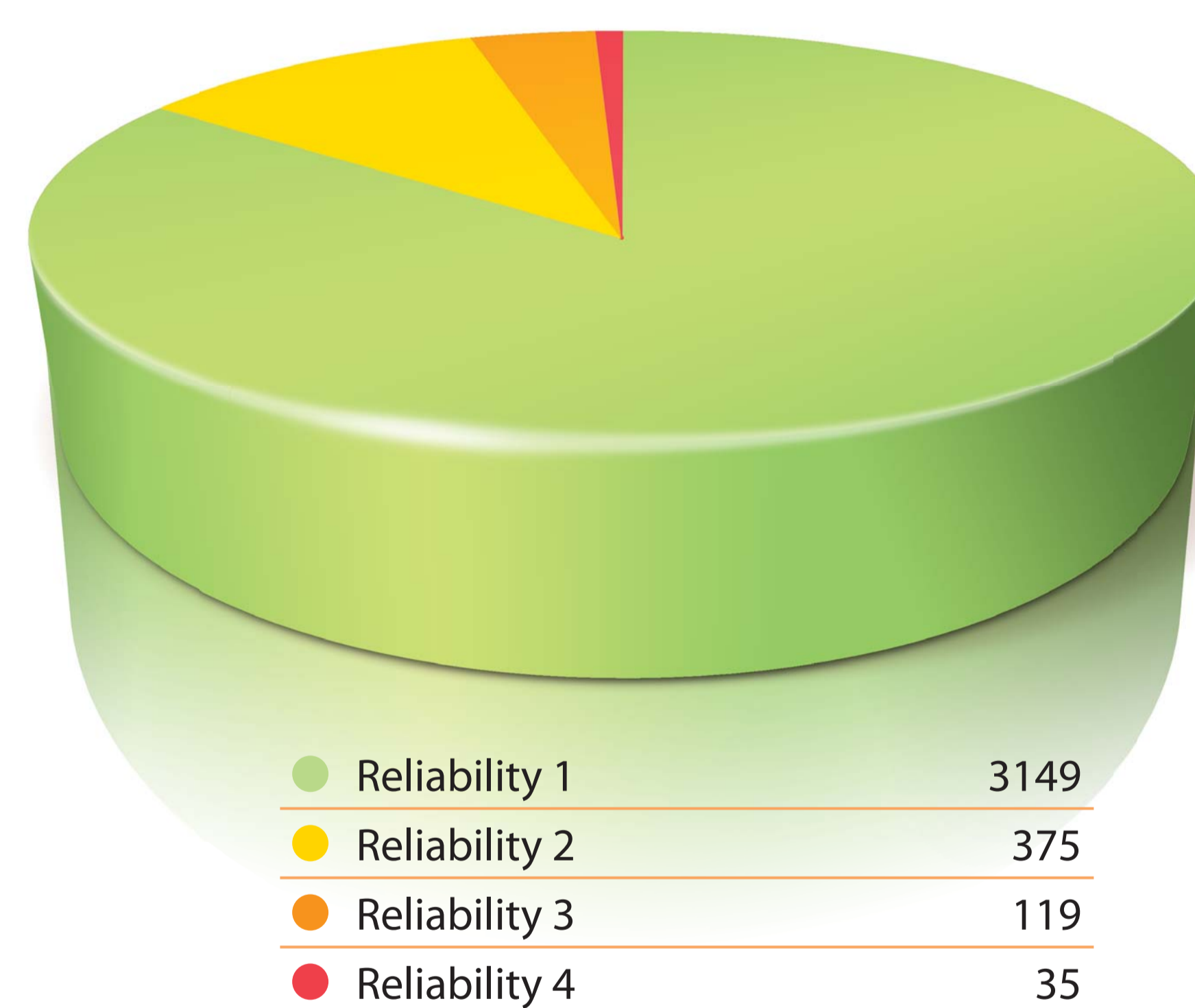


Figure 2. Number of studies in different reliability classes with 1 being the highest and 4 being the lowest reliability score as defined in IUCLID.

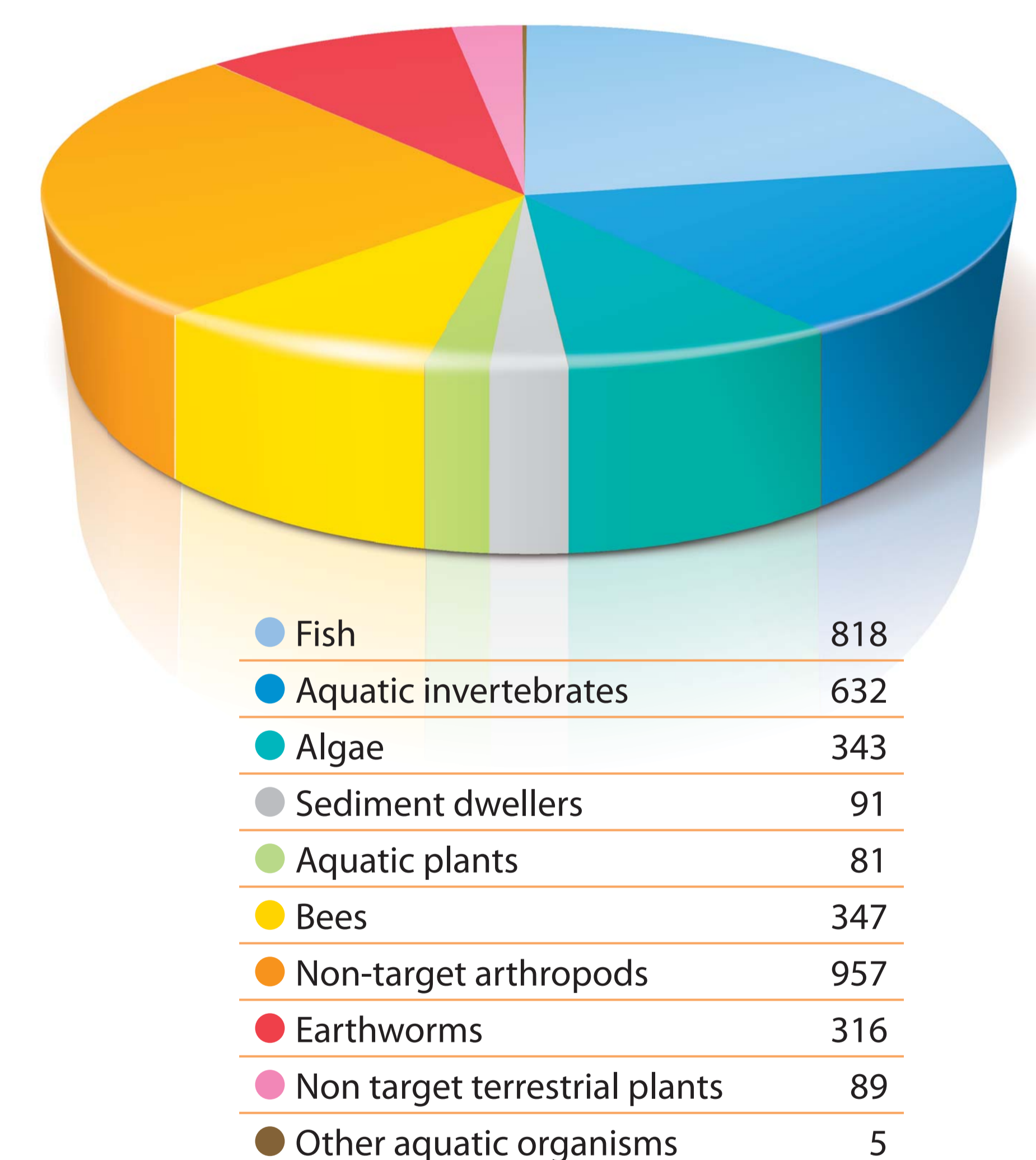


Figure 4. Overview of the number of entered Tier 1 study endpoints per organism group.