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multi-Risk sciEnce for resilienT commUnities undeR a changiNgclimate

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Return

REPORT, METANALYSIS AND DATA BASE ON EFFECTS OF CONTAMINANTS AND MIXTURES.

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2.1.1 Document history

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ABSTRACT

Literature review and evaluation of existing ecotoxicological data represent an essential step to screen ecotoxicological hazard and, depending on the case, to evaluate ecological risks (at screening level or as higher tier study). To support these evaluations, over the years several ecotoxicological databases have been developed by environmental agencies and institutions. Ecotoxicological databases can be characterized by different purposes (e.g. for validation of regulatory dossiers, tools to support studies focused on contaminated site assessment and management, compilation of screening values for general environmental evaluation) and can have been developed adopting different methods and criteria to evaluate the reliability of the studies used for the database compilation. Additionally, databases represent a useful tool to organize and structure results and data, including those from site-specific investigations.

The document is aimed to summarize methodologies and best practices for the use and preparation of ecotoxicological databases (including also database for the management of site-specific data and, when useful and possible, integrating information for the evaluation of climate change exposure scenarios). Specifically, the document includes the following content:

- Methods to assess reliability and data quality check;
- Recommendations for the organization and compilation of ecotoxicity database;
- Template and example of compilation of database.

Table of contents

Technical references 2
2.1.1 Document history 3
ABSTRACT 5
Table of contents 6
1. Introduction and scope of work 7
2. Data quality assessment: evaluating reliability and relevance of ecotoxicity data 8
2.1 Reliability 8
2.2 Relevance 10
3. Source of information: data source and path forward 12
3.1 Existing database and other data sources 12
3.2 Ecotoxicology and climate change: a current challenge 17
4. Organization and compilation of new databases and data compilation 19
4.1. Examples 19
4.2. Template proposal 25
5. Conclusions 27
References 28

Annex 1: Criteria for Reporting and Evaluating Ecotoxicity Data (CRED)
Annex 2: Example – database for metals (Cd, Hg, Ni, Pb) from WFD technical documentation
Annex 3: Example –database with Hg toxicity data on marine organisms
Annex 4: Template – proposal to support database development

1. Introduction and scope of work

Literature review and evaluation of existing ecotoxicological data represent an essential step to screen ecotoxicological hazards and, depending on the case, to evaluate ecological risks (at screening level or as higher tier study). To support these evaluations, over the years several ecotoxicological databases have been developed by environmental agencies and institutions. Ecotoxicological databases can be characterized by different purposes and can have been developed adopting different methods and criteria to evaluate the reliability of the studies used for the database compilation.

As example, ecotoxicological database can serve as tool for:

- Validation/consultation of regulatory dossiers,
- Supporting studies focused on contaminated site assessment and management,
- Compilation of screening values for general environmental evaluation (under different environmental scenarios, e.g. freshwater/saltwater etc),
- Analysis of potential effects in ecological risk assessment,
- Organization and compilation of results and data derived from various studies, including those from site-specific investigations.

The scope of this work is to prepare a document summarizing methodologies and best practices for the use and preparation of ecotoxicological databases (including also database for the management of site-specific data and, when useful and possible, integrating information for the evaluation of climate change exposure scenarios). Specifically, the document includes the following content:

- Methods to data quality assessment (Chapter 2); data quality assessment is an essential step in the evaluation of existing data. Additionally, the same criteria provide a useful framework in the reporting and documenting new experimental data and in the preparation of new database;
- List of the main existing ecotoxicological database and data source (Chapter 3);
- Recommendations for the organization and compilation of new databases (Chapter 4);
- Template and example of compilation of database (Chapter 5).

2. Data quality assessment: evaluating reliability and relevance of ecotoxicity data

The evaluation of data quality represents a key step for the selection of appropriate ecotoxicological data, which should be assessed and selected considering the scope of the work and purpose of the ecotoxicological assessment. Indeed, in hazard and risk assessment a transparent evaluation process is needed, and clear documentation helps with understanding regulatory decisions and, more generally, to support any decision-making process.

Specifically, the requirements for effect assessment differ between environmental compartments and, for the same environmental compartment, may differ between regulatory frameworks. In most regulatory frameworks, available ecotoxicological data must be subjected to an evaluation of reliability and relevance. A proper assessment of data quality can also be useful to ensure transparency and robustness to any ecotoxicological assessment, independently by the regulatory frameworks; however, these evaluations are essential especially for the studies supporting the decision-making process, and, more generally, for studies with important implications in terms of management choices.

Under this context, a data quality assessment is strongly recommended in the evaluation of existing data (and existing database); the same evaluation criteria provide also a useful framework in the reporting and documenting new experimental data and in the preparation of new database.

Along years, several frameworks have been developed to support the evaluations of ecotoxicity studies, with focus both on relevance and reliability criteria, defined as follows (Klimisch et al. 1997, ECHA, 2011):

- **reliability** indicates the inherent quality of a test report or publication relating to preferably standardized methodology and the way the experimental procedure and results are described to give evidence of the clarity and plausibility of the findings. Reliability of data is closely linked to the reliability of the test method used to generate the data.
- **relevance** is defined as the extent to which data and tests are appropriate for a particular hazard identification or risk characterization.

Additionally, Klimisch et al. (1997) defined **adequacy** as the usefulness of data for the purpose of hazard and risk assessment (in other words, whether the available information allows clear decision-making); when there is more than one set of data for each effect, the greatest weight should be attached to the most reliable and relevant. The evaluation of adequacy strongly depends on the purpose of the assessment and on data availability; therefore, this aspect is not further discussed in this document, while additional information can be found in scientific literature (e.g. Hjorth et al., 2017) and regulatory guidance (e.g. ECHA, 2011).

A short description of the main approaches to assessing reliability and relevance of ecotoxicity studies is reported below.

2.1 Reliability

Reliability indicates the inherent quality of a test and the way the experimental procedure and results are described to give evidence of the clarity and plausibility of the findings. Reliability assessment represents a key step for the evaluation of data quality and is based on a careful assessment of the quality of the study, the method, the reporting of the results, and the conclusions that are drawn. Reasons why existing study data may vary in quality include the use of outdated test guidelines, the failure to characterize the test substance properly (in terms of purity, physical characteristics, etc.), the use of crude techniques/procedures that have since become refined, and the fact that certain endpoint information (now recognized as important) may not have been recorded or measured. Moreover, other reasons could be poor reporting of information and poor-quality assurance (ECHA, 2011).

The **Klimisch codes** (Klimisch et al. 1997) historically represent one of the first systematic approaches specifically developed to assess reliability; the method has been widely used in the European Union regulatory frameworks, and it is still recommended in the REACH guidance (ECHA, 2011).

The Klimisch approach introduces definitions for reliability, relevance, and adequacy of data; a systematic documentation of evaluating reliability especially for use in the IUCLID database was proposed, differentiating reliability into four categories. Specifically, a scoring system was developed to assess the reliability of data, particularly from toxicological and ecotoxicological studies[1] (Table 1).

The use of the Klimisch approach allows ranking the information and organizing it for further review. This implies focusing on the most relevant ones, taking into account the endpoint being measured or estimated. The evaluation of the reliability is performed considering certain formal criteria using international standards as references. In the last years, this method has also been criticized for being biased toward interests of industry and for promoting use of guideline studies performed according to good laboratory practices (GLP) (Moermond et al., 2016). As alternatives, some improved evaluation methods based on the Klimisch approach were developed along years, to improve its limited guidance and to decrease dependency of the evaluation on expert judgment (see reviews by Moermond et al., 2017; Roth & Ciffroy, 2016). Among the most recent approaches, it is relevant to mention the **Criteria for Reporting and Evaluating Ecotoxicity Data (CRED)** (Moermond et al., 2016, Casado-Martinez et al., 2024), recently developed on the basis of the Klimisch method and already used in regulatory practice at EU level (Roth & Ciffroy, 2016). The CRED approach is aimed at providing detailed guidance for the evaluation of reliability and relevance of ecotoxicity studies; the approach has been implemented for study on aquatic compartments (Moermond et al., 2016) and, more recently, for studies on soil/sediment compartments (Casado-Martinez et al., 2024). Also, the CRED criteria are meant to support the assessor to classify the study in different reliability categories (summarized in Table 1), that are comparable to the Klimisch ones. The CRED method can be considered a suitable replacement for the Klimisch method, providing a more detailed and transparent evaluation of relevance and reliability (Kase et al., 2016).

The CRED criteria for reliability assessment are summarized in Table 2 while templates for CRED evaluations are fully reported in Annex 1 (templates available from Moermond et al., 2016 and Casado-Martinez et al., 2024). A similar approach was also developed to assess ecotoxicity data for nanomaterials (Hartmann et al., 2017).

Table 1: definition used for reliability categories

	Klimisch codes		CRED	
Categories	**Score and Description**		**Score and Description**	
Reliable without restrictions	**1**	Studies or data [...] generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters documented are based on a specific (national) testing guideline [...] or in which all parameters described are closely related/comparable to a guideline method	**R1**	All critical reliability criteria are fulfilled. The study is well designed and performed, and it does not contain flaws that affect the reliability of the study.
Reliable with restrictions	**2**	Studies or data [...] (mostly not performed according to GLP), 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.	**R2**	The study is generally well designed and performed, but some minor flaws in the documentation or setup may be present.
Not reliable	**3**	Studies or data [...] in which there were interferences between the measuring system and the test substance or in which organisms/test systems were used which are not relevant in relation to the exposure (e.g. unphysiological pathways of application) or which were carried out or generated according to a method which is not acceptable, the documentation of which is not sufficient for assessment and which is not convincing for an expert judgment.	**R3**	Not all critical reliability criteria are fulfilled. The study has clear flaws in the study design and/or how it was performed.
Not assignable	**4**	Studies or data [...] which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.).	**R4**	Information needed to make an assessment is missing. This concerns studies that do not give sufficient experimental details and that are only listed in abstracts or secondary literature or studies for which documentation is not sufficient for assessment of reliability of one or more parameters.

Tab. 2: CRED (Criteria for Reporting and Evaluating Ecotoxicity Data) evaluation method for RELIABILITY (Moermond et al., 2016, Casado-Martinez et al., 2024)
Test set up
Is a standard method (e.g., OECD/ISO) or modified/adapted standard used?

[1] the same approach may be extended to physico-chemical and environmental fate and behaviour studies

Is the test performed under GLP conditions?
If applicable, are validity criteria fulfilled (e.g., control survival, growth)?
Are appropriate controls performed? Are test item replicates compared to the appropriate controls (e.g., to the solvent control if a solvent was used)?
Were there other non-standard effects observed in the controls, like behavioral changes or morphological alterations? Were there signs of harm or damage to the organisms in the control checked/reported?
Test compound
Is the test substance identified clearly with name or CAS number? Are test results reported for the appropriate compound?
Is the purity of the test substance reported? Is the source of the test substance trustworthy?
If a formulation is used or if impurities are present: Do other ingredients in the formulation exert an effect? Is the amount of test substance in the formulation known?
Are there physico-chemical characteristics that may have influenced the behavior of the compound during the study (e.g., solubility, volatility, stability [hydrolysis, photolysis, degradation], log Kow, adsorption) and are they appropriately addressed?
Test organism
Are the organisms well described (e.g., scientific name, weight, length, growth, age/life stage, strain/clone, sex if appropriate)?
Are the test organisms from a trustworthy source and acclimatized to test conditions? Have the organisms not been pre-exposed to test compounds or other unintended stressors?
Exposure conditions
Is the experimental system (e.g., exposure schedule, gas exchange, test vessel material, etc.) appropriate for the test substance, taking into account its physico-chemical characteristics?
Is the experimental system (e.g., container size and volume of test soil, temperature, light/dark conditions [intensity, cycle duration], air humidity, gas exchange/test vessel aeration, feeding) appropriate for the test organism? Have conditions been stable during the test?
(for testing on aqueous phase) Were exposure concentrations below the limit of water solubility (taking the use of a solvent into account)? If a solvent is used, is the solvent within the appropriate range and is a solvent control included?
(for testing on solid phase) Is the test soil properly characterized and appropriate for the test organism (e.g., choice of medium or test water, feeding, water characteristics, temperature, light/dark conditions, pH, oxygen content, soil/sediment type, texture, organic matter/carbon content, soil moisture (% water holding capacity), pH, humidity, origin for natural soils)?
Is the method for spiking appropriate (e.g. spiking procedure)? If a solvent is used, is the solvent within the appropriate range and is a solvent control included? Have conditions been stable during the test?
Is a correct spacing between exposure concentrations applied?
Is the exposure duration defined? Is the exposure duration adequate for the test species and endpoints?
Are chemical analyses conducted? If chemical analyses are conducted, are they adequate to verify substance concentrations over the duration of the study?
Is the number or biomass loading of the test organisms in the test system within the appropriate range?
Statistical design and biological response
Is a sufficient number of replicates used? Is a sufficient number of organisms per replicate used for all controls and test concentrations?
Are appropriate statistical methods used?
Is a concentration-response curve observed? Is the response statistically significant?
Are sufficient data available to check the calculation of endpoints and, if applicable, of validity criteria (e.g., control data, concentration-response curves)?

In addition to above-described methods (widely adopted at EU level), it is relevant to mention also the guidelines developed by the US Environmental Protection Agency (USEPA) for ecological toxicity data evaluation (USEPA, 2011), that provide general information and clarification to assist in screening, reviewing, and evaluating ecotoxicity data from the available open literature, and the OECD guidance document on the validation and international acceptance of new or updated test methods for hazard assessment (OECD, 2005).

2.2 Relevance

Relevance is defined as the extent to which data and tests are appropriate for a particular hazard identification or risk characterization; in this sense, it is clear that the evaluation of relevance strongly depends on the purpose of the assessment and concerns the way the study will be used for a specific scope. Thus, relevance may change depending on the use of the study.

Klimisch et al. (1997) provided some indications on main aspects to consider for an evaluation of the relevance, without a specific framework; these general criteria were further developed and structured in the **CRED evaluation method** (Moermond et al., 2016, Casado-Martinez et al., 2024), that introduced also different categories to classify the relevance of ecotoxicity studies. Categories and CRED criteria defined for relevance are summarized in Table 3 and Table 4, while templates for CRED evaluations are fully reported in attachments (templates available from Moermond et al., 2016 and Casado-Martinez et al., 2024).

Table 3: definition used for relevance categories

	CRED	
Categories	**Score and Description**	
Relevant without restrictions	**C1**	The study is relevant for the purpose for which it is evaluated.

Relevant with restrictions	**C2**	The study has limited relevance for the purpose for which it is evaluated.
Not relevant	**C3**	The study is not relevant for the purpose for which it is evaluated.
Not assignable	**C4**	Studies that do not give sufficient details since the result is presented in abstracts or secondary literature (books, reviews, etc.) or studies of which the documentation is not sufficient for assessment of relevance for one or more vital parameters.

Tab. 4: CRED (Criteria for Reporting and Evaluating Ecotoxicity Data) evaluation method for RELEVANCE (Moermond et al., 2016, Casado-Martinez et al., 2024)
Biological relevance
Is the test species relevant for the compartment under evaluation?
Are the organisms tested relevant for the tested compound?
Are appropriate life-stages studied?
Are the reported endpoints appropriate for the regulatory purpose?
Are the reported endpoints appropriate for the investigated effects or the mode of action of the test substance?
Is the exposure duration relevant and appropriate for the studied endpoints and species?
Is the effect relevant on a population level?
Is the magnitude of effect statistically and biologically significant and relevant for the regulatory purpose (e.g., EC10, EC50)?
Are the experimental conditions relevant for the tested species?
If recovery is studied, is this relevant for the framework for which the study is evaluated?
Exposure relevance
Is the tested exposure scenario, including test substrate, relevant for the species?
Is the tested exposure scenario relevant for the substance?
Is the purity of the test substance reported? Or, is the source of the test substance trustworthy?
In case of a formulation, other mixture, salts or transformation products: Is the substance tested representative and relevant for the substance being assessed?

3. Source of information: data source and path forward

3.1 Existing database and other data sources

Literature review and analysis/compilation of existing studies represent the first step in deriving a dataset of ecotoxicity data. The scope of the search can greatly vary depending on the purpose of the work, availability of data for a particular contaminant and receptor groups, complexity of the study and level of effort available for the evaluation. Several sources can be consulted during a literature review; some of these are yet structured as ecotoxicological databases or include data summary yet verified/assessed in terms of reliability/data quality. Main data sources include the following:

- Electronic database search engines (e.g., Web of Science, Science Direct etc) can be used to obtain primary reference lists for scientific paper and (in some case) grey literature (reports, datasheet, data summary and expert analysis etc);
- Electronic toxicological databases (e.g., EPA Ecotox) often allow to obtain data summaries and references from a large, compiled dataset. As example, ECOTOX allows to set selection criteria (e.g., species, contaminants, effects etc) and to download data structured in tables;
- Reference lists from secondary sources, such as technical documents for regulatory guidelines (e.g., the datasheets for priority substance prepared under the Water Framework Directive, EFSA reports, CCME and US EPA environmental quality guidelines, etc), data compilations (e.g., ATSDR toxicological profile[2]), citation lists from journal articles and other compiled sources (books, reports, previously published or accessible risk assessment).

The following table provides information on some common sources of databases reporting information about ecotoxicological studies; it is relevant to note that, regardless of the literature review method used, primary literature sources should be retrieved and consulted to ensure that there are no transcriptional errors, and that data are interpreted and applied consistently to the final scope of the assessment. This requirement also allows the users to assess the study design and data quality (FCSAP, 2012).

[2] Agency for Toxic Substances and Disease Registry https://www.atsdr.cdc.gov/ https://www.atsdr.cdc.gov/toxicological-profiles/glossary/index.html

Tab. 5: List of existing databases and data source useful (ecotoxicological studies)

Source	Type	Receptors covered	Exposure pathways	Contaminants covered	Ecological endpoints	Advantages	Limitations
EPA ECOTOX database	Database: data summaries and primary literature reference lists	Aquatic and terrestrial species (no microorganisms)	Various (water, soil, dietary ingestion); sediment only exposure not included	Multiple	Accumulation, cellular, mortality, behavior, ecosystem, physiology, biochemical, growth, population, reproduction	Very comprehensive dataset Updated on regular basis	It is recommended that primary literature sources be consulted to understand the context of the data retrieved from the database
Integrated Risk Information System (IRIS)	Oral reference dose, inhalation reference concentration, carcinogenicity assessment	Humans (but often based on mammalian data)	Dietary ingestion (including drinking water), inhalation exposure	Multiple	Carcinogenic and noncarcinogenic endpoints including reproduction, development and other sublethal effects	Studies on mammals are reported; comprehensive peer-review process	Aimed to human health risk assessment
California EPA Wildlife Exposure Fator and Toxicity Database	Database: data summaries and primary literature reference lists	Terrestrial species, birds, mammals, amphibians, reptiles	Various (tissue concentration, soil, dietary ingestion)	Multiple	Accumulation, cellular, mortality, behavior, growth, population, reproduction	Effects descriptions provide more details than EcoTOX; also provides biological information	It is recommended that primary literature sources be consulted to understand the context of the data retrieved from the database
EPA Aquatic Toxicity/Tissue Residue Database	Database: data summaries and primary literature reference lists	Aquatic organisms	Various (water, sediment, food, injection)	Multiple	Survival, growth, reproduction	Useful information	It is recommended that primary literature sources be consulted to understand the context of the data retrieved from the database. Organized by chemical but difficult to navigate through and does not generate report
EPA PCB Residue Database	Database: data summaries and primary literature reference lists	Mostly aquatic and aquatic-dependent species (including birds and mammals)	Tissue concentration (critical residues) resulting from water, dietary, gavage and injection exposure	PCBs, dioxins, furans	Behavior, biochemical, cellular, mortality, growth, physiology, population, reproduction	User-friendly database search; results can be easily reported	It is recommended that primary literature sources be consulted to understand the context of the data retrieved from the database
Enviro Tox	Aquatic Toxicology Database	Aquatic; based on the EPA ECOTOX database, applied for PNEC derivation. See also details for EPA ECOTOX Database					

Tab. 5: List of existing databases and data source useful (ecotoxicological studies)

Source	Type	Receptors covered	Exposure pathways	Contaminants covered	Ecological endpoints	Advantages	Limitations
ECHA Database	Database for substances registered under the REACH context	Various (humans, aquatic/terrestrial)	Various (mainly aquatic exposure for ecological receptors)	Multiple	Growth, survival, reproduction + others	Toxicity testing performed for regulatory purpose (high quality of data in terms of reliability)	Organized by chemical, does not generate excel report or data summary
NORMAN Database	NORMAN organises the development and maintenance of various web-based databases, including also ecotoxological information	Various (mainly aquatic)	Various (mainly aquatic exposure for ecological receptors)	Multiple	Growth, survival, reproduction + others	NORMAN organizes the development and maintenance of various web-based databases for the collection & evaluation of data / information on emerging substances in the environment	It is recommended that primary literature sources be consulted to understand the context of the data retrieved from the database; not easy to navigate through
EFSA Database	Database on ecotoxicological properties of active substances and plant protection products	Various (aquatic/terrestrial)	Freshwater and soil	Active substances and plant protection products	Growth, survival, reproduction	Data yet verified and compiled in IUCLID 5.2; an extract of relevant data publicly available	It is recommended that primary literature sources be consulted to understand the context of the data retrieved from the database; not easy to navigate through. Endpoints are not clearly detailed.

Tab. 5: List of existing databases and data source useful (ecotoxicological studies)

Source	Type	Receptors covered	Exposure pathways	Contaminants covered	Ecological endpoints	Advantages	Limitations
ETOX Database	The ETOX database allows access to effects information from aquatic and terrestrial ecotoxicology. Furthermore, ETOX contains information on various national and international environmental quality guidelines, targets, standards, criteria, and limit values.	Various (aquatic/terrestrial)	Water, biota, sediment and soil	Various	Various	It includes also information on environmental quality standard and guideline	It is recommended that primary literature sources be consulted to understand the context of the data retrieved from the database; substances/endpoints/organisms are not clearly described (for each search you have to put details without knowing what is the exact content of the database).
ECOTOX Centre Database	Database of environmental quality criteria (EQS) derived by the Ecotox Centre	Aquatic	Water	Various	Various (acute/chronic)	New values are added on a regular basis; used also to feed the NORMAN database. For each substance, there is a dossier describing full details of the dataset used for EQS derivation	Report written in German; ecotoxicological data reported in the dossier (pdf)
EU Commission - Circa library	EQS dossiers prepared under the WFD (revision existing PS, candidate PS, substance dossiers)	Aquatic (marine and freshwater)	Water; also some data on sediments are included	WFD Priority Substance	Various (acute/chronic)	Prepared by the expert panel working for the EU Commission; the dossiers represent the basis to set EQS under the WFD.	Ecotoxicological data reported in the dossier (word document or pdf); some differences in data format and information among the various dossiers

Tab. 5: List of existing databases and data source useful (ecotoxicological studies)

Source	Type	Receptors covered	Exposure pathways	Contaminants covered	Ecological endpoints	Advantages	Limitations
OECD eChem Portal	Prepared by OECD, it provides free public access to information on chemical properties and direct links to collections of information prepared for government chemical programs at national, regional, and international levels.	Various (aquatic/terrestrial)	Various	Various	Various	Worldwide source of information about chemicals from authorities and international organizations; it included link to various existing databases	Different data sources in eChemPortal use different methods to maintain their data in eChemPortal. It is recommended that primary literature sources be consulted to understand the context of the data retrieved from the database.

3.2 Ecotoxicology and climate change: a current challenge

Climate change can exert a significant influence on ecological status and ecotoxicological responses to anthropic pressures, by directly altering the exposure scenarios (e.g. influencing the exposure conditions in terms of monitored parameters such as temperature, salinity, oxygen concentrations, pH, that can also consequently influence chemical bioavailability and toxicity) as well as enhancing pressure interactions on the ecological receptors, thus introducing additional stress factors (e.g. for temperature, pH variation etc) that can modify/enhance/influence the ecotoxicological response of the tested organism to the contaminant of concern. Aquatic systems and ecological receptors respond holistically to climate change, with different pressures having additive, synergistic, or antagonistic interactions (Bissett and O'Hare, 2025). Additionally, as reported in Suter (2023)**,** climate change creates problems for causal assessments, thus complicating the evaluation of causal link and dose/response relationships, especially in field experiments. In this sense, it is important to know what health and ecological effects are caused by climate change and which are caused by other agents or by interactions between climate and other agents.

The relationship among climate change and the environmental toxicology has been firstly explored in the SETAC Pellston workshop "Influence of Global Climate Change on the Scientific Foundation and Application of Environmental Toxicology and Chemistry", held in 2011 in Racine, Wisconsin, USA (details in the special series of the journal "Environmental Toxicology and Chemistry", 2013, Vol. 31 -1); the same topic was recently discussed in the SETAC Pellston workshop "Integrating Global Climate Change in Ecological Risk Assessment", held in June 2022 in Oslo.

Among the main criticisms, it has been postulated that, from its inception, risk assessment has been a contaminant-centric process and there is limited experience with applying the framework to changing landscapes and multiple drivers (including noncontaminant stressors, e.g. physical or biological stressors) (Landis et al., 2013). This approach has also been translated into legislation. As an example, climate change impacts are not explicitly addressed in the WFD and most of the evaluation (e.g. for the ecological status, setting of environmental quality standards) done under the WFD refer to the evaluation of reference conditions or unaltered conditions defined considering current conditions or those of the recent past, while in the context of climate change scenarios, one of the first questions is: to what extent will current conditions (including also reference conditions) be altered? How will climate change influence the occurrence, emissions, fate and distribution of chemicals, toxicological effects and ecological dynamics, whose comprehension is mainly based on data available for current conditions and, for ecotoxicological aspects, considering standard exposure scenarios?

With special regards to ecotoxicological aspects, Landis et al. (2013) highlighted four fundamental considerations:

- **Ecological Risk Assessments must consider interactions among contaminant and noncontaminant stressors**. With new regimes of temperature and precipitation at specific geographic sites, novel ecosystems with novel hydrologic processes will be created that will trigger novel responses to lethal and sublethal doses of chemical stressors.
- **Changing climate requires a shift not only in science but also in regulatory programs**. For example, traditional ERAs, especially those focused only on chemicals, often rely on simple tools such as hazard quotients, which are not adequate for evaluating multiple stressors and associated interactions. These hazard quotients (defined as the ratio between observed contaminant levels and a regulatory guideline) are often used to rank risks from chemicals in natural systems. However, this regulatory criterion derives from a series of exposure–response curves that are generated with a few model species exposed in artificial waters and have minimal resemblance to natural waters. Although useful in some screening ERAs, such simplistic representations cannot fully characterize risk, nor can they characterize the full range of possible exposure responses and their associated uncertainty.
- **Greater emphasis on and understanding of stochasticity, tipping points, and multi-stressor interactions is needed**. These interactions include the interactive effects of physical and biological stressors such as more frequent spikes in contaminant input because of greater storm frequency and intensity or greater competition for resources from invasive species. Resource managers are well

acquainted with the dynamic nature of ecosystems, recognizing that baselines are irrevocably changed with compounded perturbations (i.e., the shifting baselines concept). However, that construct infers that all change will be negative, when impacts from climate change will actually be both negative and positive. Therefore, managers must focus on adaptation strategies that take into account current and changing resources as affected by contaminant and noncontaminant stressors. This process needs to be embraced and expanded and can be accomplished by implementing a regional risk-assessment approach. Regional risk assessment is structured to address multiple stressors and their impacts on multiple ecological services.

- **Realizing that biological responses to environmental stressors likely will be nonlinear, especially under global climate change, the previous reliance on null hypothesis models needs to be discarded.** Traditionally, ERAs evaluated whether there is a change in risk relative to a reference site or condition where only one variable is being considered. Because ecological conditions will change unpredictably with global climate change, the interactions among variables are dynamic and response to climate change will evolve; therefore, simplistic assumptions of static conditions and unidirectional change may be no longer appropriate.

Under this context, more work is needed to better understand and evaluate the ecotoxicological response, evolving from simple models for single stressors to more complex multi-stressor models. In this sense, ecotoxicological databases should be adapted/modified in order to allow a more precise definition of exposure scenarios and observed effects, also in multi-stressor context.

As an example, the database EPA ECOTOX is one of the most comprehensive tools among available sources, summarizing the ecological effects of single chemicals to aquatic and terrestrial plants and animals (http://cfpub.epa.gov/ecotox/). ECOTOX was developed by EPA's Office of Research and Development's Mid-Continental Ecology Division (ORD/MED), which routinely conducts literature searches for pesticides undergoing Registration Review as well as for litigation-related endangered species assessments. Although the ECOTOX database represents, undoubtedly, an important data source for any ecotoxicological evaluation, it must be recognized that this tool does not specifically address the issues raised by the need to evaluate the influence of climate change scenarios.

Specifically, the database does not clearly include information about technical details on the exposure scenarios (e.g. temperature range, pH variation, oxygen concentrations etc; or the presence of different exposure scenarios in the ecotox study) that can be relevant for the assessment of future scenarios; to evaluate this information, a direct evaluation of the original source (cited in the database) is always needed. Additionally, the ECOTOX database does not specifically include multi-contaminants studies, being mainly focused on toxic effects related to single chemical exposure.

Under this context, depending by the scope of the project and overall data availability, it may be useful to prepare and organize ecotoxicological data in new databases or in structured data compilation, in order to clearly trace useful information for the scope of the assessment; possible criteria for data compilation and some examples are reported in the following chapters.

4. Organization and compilation of new databases and data compilation

As anticipated, the organization of ecotoxicological data in new databases or, more simply, in structured data compilation represents an important step to support data analysis and to clearly trace useful information for the scope of the assessment; the level of effort and details can vary depending by the scope of the project and overall data availability, as well the complexity of the study.

Under this context, this chapter reports some examples of ecotoxicological data compilation (section 4.1) and illustrates a template proposal (section 4.2) specifically developed to support the compilation of ecotoxicological data resulting from experimental activities focused on evaluation of climate change scenarios.

4.1. Examples

This section reports some examples of ecotoxicological data compilation performed under the context of different projects, and thus with different aims and goals. The results from these different studies are meant to represent examples of preparations of ecotoxicological dataset and related applications and use.

Example 1: ammonia toxicity considering a sensitive endpoint (embryotoxicity) under different exposure conditions

In a recent study (Bizzotto et al., 2025), authors investigated the influence of ammonia on sediment toxicity, in order to better address and optimize sediment management. Specifically, the scope of the work was to provide an overview of the toxic effects of ammonia focusing on embryotoxicity endpoints, enabling a proper evaluation of sediment toxicity, discussing the role of ammonia on sediment quality classification, and contributing to improve the management options. In this sense, the paper presents the results of an experimental activity aimed at evaluating the role of ammonia on sediment toxicity, jointly to a literature review.

Specifically, a literature review was carried out to delineate the range of ammonia toxicity thresholds on embryo-larval development bioassays focusing on oysters, mussels and sea urchins that are currently used for sediment classification in Italy; the review was aimed to support evaluation of results of an experimental activity aimed at evaluating the role of ammonia on sediment toxicity.

It is relevant to note that, although total ammonia represents the parameter typically investigated in routine monitoring, unionized ammonia (NH_3) is more toxic than the ammonium ion (NH_{4+}) (USEPA, 1989; 1999). The fraction of total ammonia present as unionized ammonia (NH_3) is contingent on the pH, temperature, and salinity of the testing water/sediment (Kennedy et al., 2015); specifically, the percentage of unionized ammonia increases with higher pH and temperature, but it decreases with higher salinity (Emerson et al., 1975).

Under this context, special care was paid to document information related to exposure conditions (temperature, pH as well as measurement of unionized ammonia or total ammonia nitrogen); results of the literature review are reported in the following table (Tab. 6).

Tab. 6: Literature values for effects of Total Ammonia Nitrogen (TAN) and Unionized Ammonia nitrogen (NH3-N) on Larval tests (embryotoxicity; all water-only exposures) (Bizzotto et al., 2025)

Species	NH_3-N mg/l			Total Ammonia Nitrogen mg/l			Test conditions (when reported)	Reference
	NOEC	LOEC	EC50	NOEC	LOEC	EC50		
C. gigas	0.08		0.13	4.68		6.83	48 h, T 15°C, pH 7.5-8.5	USEPA (1993)
		0.019 (EC20)			2.8 (EC20)			Geffard et al. (2002)
			0.29		-	6		Picone et al. (2019)
M. galloprovincialis		0.028 (EC20)	0.036		2.82 (EC20)	3.67	48 h, T 16°C	McDonald (2005)
	0.074°°°	0.125°°°	0.099°°°				48 h	Phillips et al.(2005)
	0.08°°°	0.15°°°	0.19°°°					Tang et al. (1997)
	0.033°°°		0.052°°°					DMMP (2015)
M. edulis	0.099 (EC5) 0.107 (EC10)°°°		0.14°°°				48h, T 15°C	Kennedy et al. (2017)
S. purpuratus	0.049°°°		0.078°°°	4.5		7.2	72h, pH 7.7, 15°C	Greenstein et al. (1996)
	0.054°°°		0.081°°°	2		2.98	72h, pH 8.1, 15°C	
	0.031°°°		0.072°°°	0.61		1.38	72h, pH 8.4, 15°C	
	<0.074°°°		0.099°°°	<0.62		0.08*	72h, pH 8.7, 15°C	
	0.047°°°	0.008°°°	0.06°°°					Bay et al. (1993)
	0.01°°°		0.03°°°					Tang et al. (1997)
	0.051°°°		0.058°°°					DMMP (2015)
Dendraster sp.	0.019°°°		0.026°°°					DMMP (2015)
D. excentricus	0.014	0.019 (EC20)	0.03	1.24	1.63 (EC20)	2.63	48 h, T 15°C, pH 7.5-8.5	USEPA (1993)
P. lividus	0.033 (NOEC) - 0.056 (EC10)°°°	0.066 (LOEC)°°°	0.147°°°				48 h, T 20°C	Saco-Alvarez et al. (2010)
	0.011	0.026	0.061	0.78	1.94	4.43	72 h, T 18°C, pH 7.7	Arizzi Novelli et al. (2003)
	0.011	0.021	0.089	0.39	0.78	3.3	72 h, T 18°C, pH 8.0	
	0.004	0.021	0.127	0.08	0.39	2.41	72 h, T 18°C, pH 8.3	
				0.39 (EC5)°		1.72°	72h	Anselmi et al. (2023)
	0.007 (EC5)°°	0.013 (EC20)°°	0.023°°	0.21 (EC5 NH_4^+-N)	0.37 (EC20 NH_4^+-N)	0.63 (NH_4^+-N)	72h, T 18°C	Sartori et al. (2024)
		0.020 (EC25)**	0.027**		0.51 (EC25)°	0.71°	28 h, T 20°C	Cesar et al. (2002)
A. punctulata	0.037	0.09						Carr et al. (1996)
		0.09	0.06		2.29	1.48		Hooten and Carr (1998)
	0.09						48 h	Carr and Chapman (1992)
A. lixula		0.017 (EC25)**	0.025**		0.45 (EC25)°	0.65°	38 h, T 20°C	Cesar et al. (2002)
S. granularis		0.019 (EC25)**	0.022**		0.49 (EC25)°	0.59°	38 h, T 20°C	Cesar et al. (2002)
P. miliaris	0.042			≤6			48h, T 20°C, pH 8	Stronkhorst et al. (2003)
H. tuberculata				2	3.5	3.9	72h, T 20°C	Adams et al., 2008
M. asperrima				1.4	2.5	2.8	48h, T 18°C	Adams et al., 2008

Notes:

xx**:** values expressed as total ammonia (not total ammonia nitrogen)

*estimated from the dose response plot

°values reported in the paper refer to NH_4Cl and were converted to total ammonia nitrogen

°°estimated from NH_4^+ values (on the basis of the test condition: pH 8, T 18 °C)

°°°values reported as NH3 and converted in NH3-N

**estimated on the basis of the test condition: T 20 °C and assuming pH 8

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The results of the literature review were used to develop a Species Sensitivity Distribution, based on EC10/NOEC data only for embryotoxicity endpoints of mollusks and sea urchins (Fig. 1), aimed to support a proper evaluation of sediment toxicity data, contributing to improving the management options. For total ammonia nitrogen, HC5 and HC50 values are respectively 0.127 mg/L and 1.000 mg/L, a wider range of species sensitivity being observed. The HC5 determined for larval stages of molluscs and sea urchins are lower than the water quality guidelines reported in literature (Batley and Simpson, 2009), confirming that larval development endpoints are highly sensitive to ammonia and thus indicating the need of a proper assessment of this substance during the sediment management process. In this sense, the HC5 and HC50 values derived on the basis of embryotoxicity data are not meant to represent, in themselves, a water quality criterion but to support a proper evaluation of sediment toxicity data, contributing to improve the management options. Specifically, the HC5 values from this paper are very similar to USACE (2021) values set for sea urchins as unionized ammonia reference toxicant and purging triggers (respectively, 0.007 mg/L and 0.014 mg/L; the trigger for purging was set to be equal to the NOEC for unionized ammonia), while the same values determined for bivalves (USACE, 2021) are higher than one order of magnitude (0.02 mg/L and 0.04 mg/L, for the reference toxicant and purging triggers for N-NH_3, respectively).

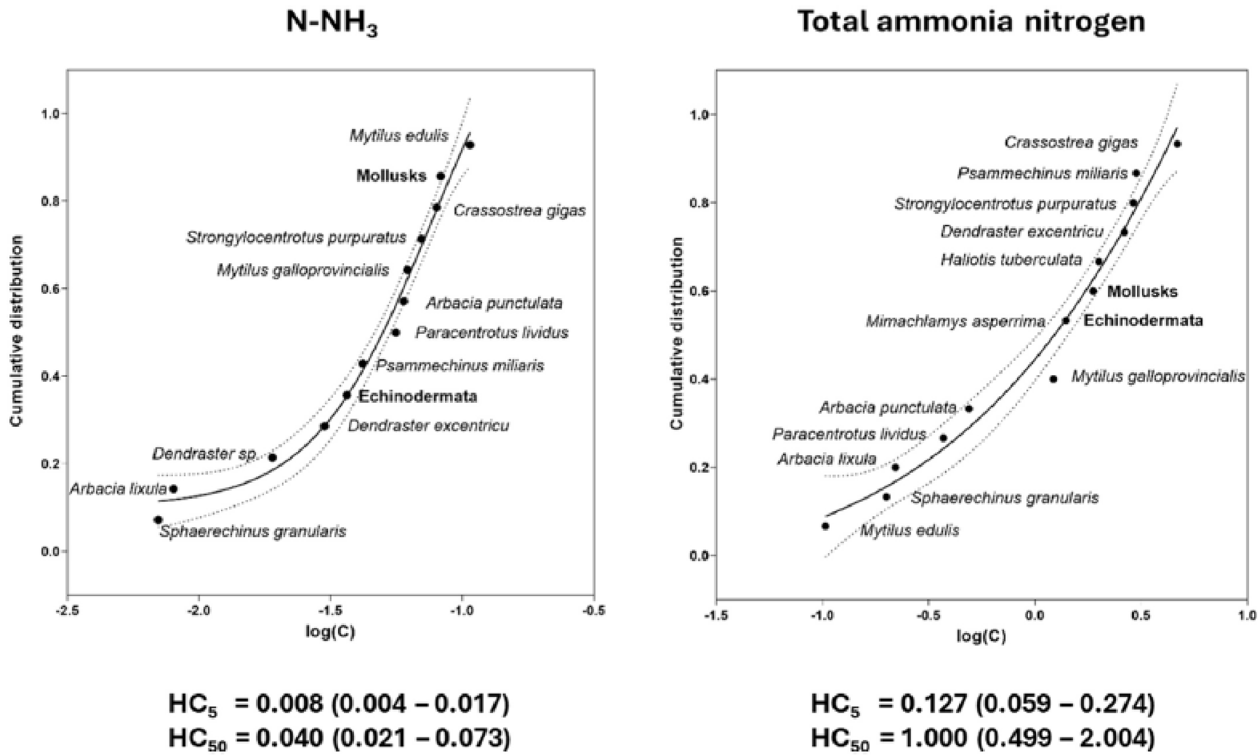

Figure 1: Species sensitivity distribution including all species having embryotoxicity as endpoint to N-NH3 and Total Ammonia Nitrogen

Overall results demonstrated the influence of ammonia on sediment toxicity from a case-study (Venice lagoon), testing methods for toxicity identification evaluation and providing recommendation to support scientific discussion to pursue the most sustainable sediment management, especially when just the embryotoxicity endpoint is responding concomitantly to high ammonia levels, considering that impacts primarily due to nonpersistent contaminants should be managed differently than persistent ones.

Example 2: compilation of toxicity data used to derive Environmental Quality Standards for metals under the WFD

This example is related to the compilation of a database of aquatic toxicity data for metals (cadmium, lead, mercury, nickel), based on the technical documents drawn up by the European Commission under the Water Framework

Directive (WFD). The database (reported in Annex 2) is aimed at facilitating data consultation as well as identifying differences (and data-gap) in the preparation of the metal datasheets.

The database represents a useful tool for consulting the toxicity data reported in the dossiers drawn up for the estimation of the Environmental Quality Standards of the WFD; it is relevant to note that for most of the data there is also specific information about data reliability. A summary of the main content of the database reported in Annex 2 is reported below.

Tab. 7: Overview of data reported in Annex 2

Substance	Aquatic compartments	Exposure
Cd	Freshwater – 97 data	Chronic: 49 data Acute: 48 data
	Saltwater – 64 data	Chronic: 64 data Acute: 0 data
Hg (inorganic)	Freshwater – 51 data	Chronic: 29 data Acute: 22 data
	Saltwater – 36 data	Chronic: 23 data Acute: 13 data
Ni	Freshwater – 133 data	Chronic: 31 data Acute: 102 data
	Saltwater – 65 data	Chronic: 30 data Acute: 35 data
Pb	Freshwater – 120 data	Chronic: 72 data Acute: 48 data
	Saltwater –45 data	Chronic: 21 data Acute: 24 data

Example 3: toxicity data for mercury on marine species

This example is related to results from a literature review with a focus on aquatic toxicity of inorganic mercury ($HgCl_2$) towards marine organisms. The research was carried out by consulting the USEPA ECOTOX database and included the check of all the literature studies selected as being of greatest interest on the basis of:

- Selected endpoints (chronic NOEC, acute LC50);
- Experimental design (methodology and duration of exposure),
- Organisms (marine organisms).

The database (reported in Annex 3) indicates also if the selected studies have been considered in the WFD datasheet (see also Annex 2); additionally, the database includes also results cited in the WFD datasheet but not reported in ECOTOX. For these studies, an independent search was performed in order to track (where possible) missing information.

The overall database includes 109 data (34 NOEC/LOEC and 75 LE50/EC50); Figure 2 reports, as example of possible output from data evaluation, the SSD calculated considering both NOEC data (derived from sub-chronic studies) and EC50 data (derived from acute studies). The graphs were derived using the USEPA SSD generator.

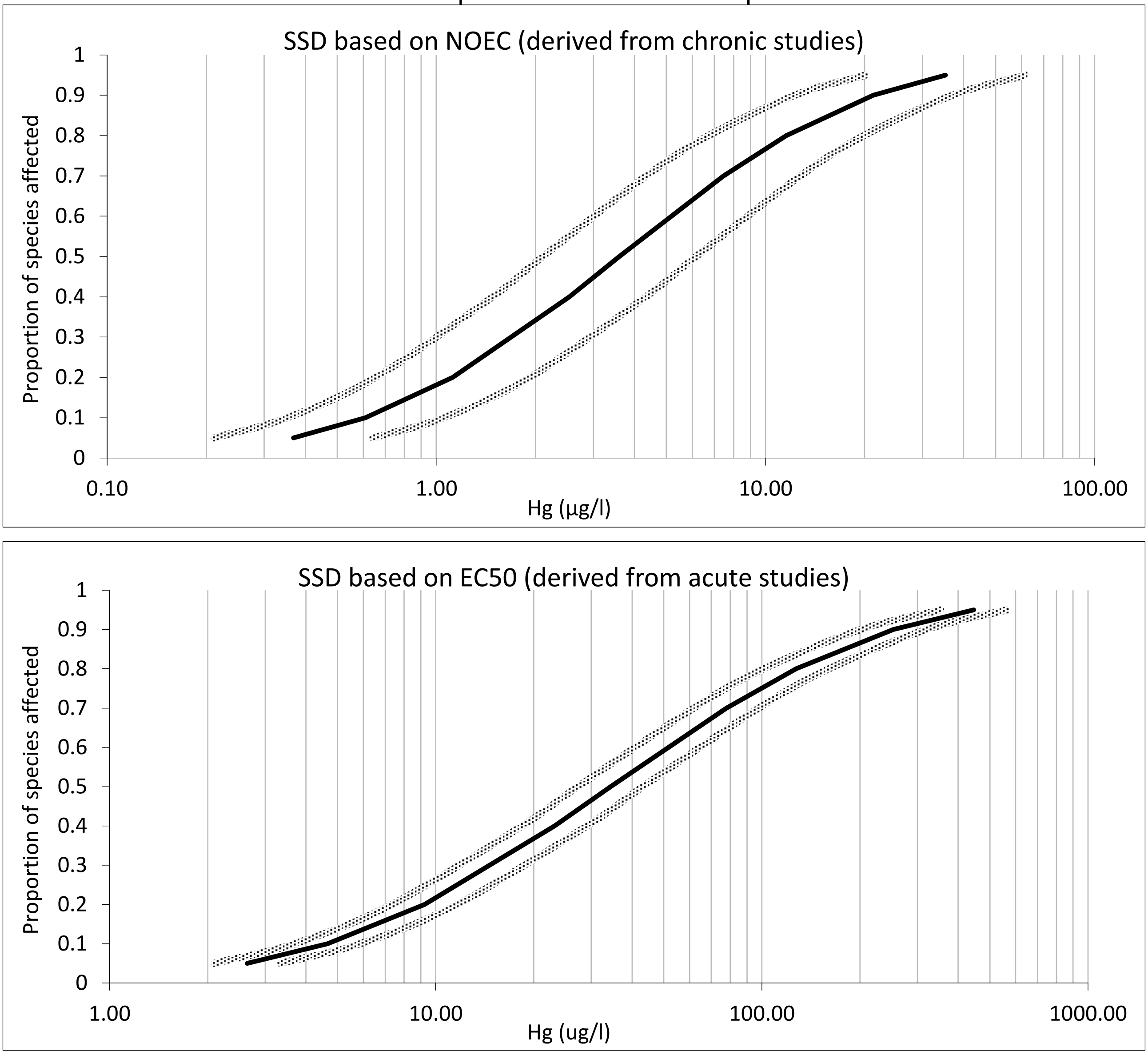

Figure 2: Species Sensitivity Distribution prepared from the dataset reported in Annex 4.

Example 4: Multi-stressor datasets under climate-relevant scenarios (Hg × O_2; OA × contaminants)

Within the RETURN project, structured experimental datasets were generated to evaluate the interaction between chemical contamination (Hg) and climate-relevant variables (oxygen availability and pH).

a) Hyperoxygenation × Mercury - early life stages

Embryo-larval assays were conducted on *Paracentrotus lividus* under factorial conditions:

- O_2 saturation: ~90% (normoxia) vs ~160% (hyperoxia),
- Hg: 0 vs 1 µg/L.

Endpoints included fertilization success, percentage of normal larvae, developmental delay and survival. Oxygen saturation, temperature and pH were recorded as exposure variables. The dataset allows explicit evaluation of O_2 × Hg interactions and illustrates the importance of including oxygen availability as a climate-relevant driver in ecotoxicological databases.

b) Hyperoxygenation × Mercury - adult invertebrates

Adult *Ruditapes philippinarum* and *Paracentrotus lividus* were exposed for 7 days to the same factorial design (O_2 × Hg).

- Measured endpoints included:
- Hemocyte parameters (clams),
- Respiration rate and righting time (sea urchins),
- Antioxidant responses in both species,
- Hg accumulations in both species.

Results showed species-specific responses, with hyperoxygenation enhancing mercury-related cellular alterations in clams, while modifying behavioral and metabolic responses in sea urchins. These datasets highlight the need for databases capable of storing factorial designs and sublethal physiological endpoints.

c) Mussel Watch under natural ocean acidification

A field deployment of *Mytilus galloprovincialis* was conducted at the Ischia CO_2 vent system along a natural pH gradient (mean pH ~8.1 vs ~7.7), during two seasonal periods.

Endpoints included:

- Tissue contaminant accumulation,
- Physiological biomarkers,
- Antioxidant responses in different tissues,
- Water and sediment samples for contaminants measurement,
- Preparation of tissue extracts for in vitro human intestinal exposure (One Health perspective).

This case integrates climate-driven pH variability, seasonal dynamics, and contaminant bioaccumulation within a structured dataset suitable for database inclusion.

Example 5: Ecotoxicological assessment of plastic exposed to different climate stress (acidification; temperature; anthropization)

Within a structured experimental framework, ecotoxicological datasets were generated to evaluate how polymer type interacts with environmental stressors and aging time in determining the toxicity of plastic leachates. The dataset allows the assessment of combined effects between material characteristics (conventional vs bio-based plastics), environmental conditions (acidification, temperature variability, anthropogenic pressure), and exposure duration (3 vs 6 months).

- Toxicity evaluation of the leachates was conducted using two bioassays representing different trophic levels: the microalga Dunaliella tertiolecta and the bioluminescent bacterium Aliivibrio fischeri after 3 and 6 months of environmental exposure of plastics.
• Polymer types: PE, PP (conventional plastics); PLA, Mater-bi (bio-based plastics)
• Aging time: 3 months vs 6 months
• Sites: low-stress (Gelso, Baia di Ponente) vs stressed (Baia di Levante – acidification/anthropization; Pietra del Bagno – temperature/acidification variability)

Endpoint:

- Percentage inhibition of algal growth (72 h)
- Bioluminescence inhibition (30 min)

The combined dataset enables explicit evaluation of:

• Polymer type × environmental stress interactions
• Aging time × site-specific conditions
• Trophic-level–dependent sensitivity patterns

Results indicate that primary producers are more sensitive to early-stage degradation products, while bacteria responses become more pronounced at later stages of polymer aging.
This structured dataset demonstrates the importance of incorporating environmental drivers (acidification, temperature variability, anthropogenic influence) and exposure duration into ecotoxicological databases for plastics, similarly to multi-stressor approaches adopted for climate-relevant contaminant assessments.

4.2. Template proposal

The organization of ecotoxicological data resulting from experimental activities represents an important step to support data analysis and to clearly trace useful information for the scope of the assessment.

Under this context, a template has been developed to support the compilation of ecotoxicological data, with special focus on data resulting from experimental activities focused on evaluation of climate change scenarios. Specifically, the structure of the template (reported in Annex 4 and described below) was prepared considering the following:

- Information typically required in existing databases (e.g. ECOTOX);
- Information useful to document/track any difference in tested conditions relevant for the assessment of climate change scenarios;
- Information is typically required for reliability evaluation. However, the template is meant to complement and not replace the other existing instruments for reliability assessment (such as the CRED criteria): in this sense, there is a column to track/document any reliability evaluation.

Specifically, the CRED reporting recommendations can represent a useful checklist to document details of laboratory assays and also field experiments; the criteria can also be further integrated to better track technical details used for the assessment of future scenarios (e.g., testing evaluating different temperature scenarios). In this sense, the files in Annex 1 include also a checklist of reporting recommendations, provided as support information for researchers to use when designing and publishing water/sediment and soil ecotoxicity studies, to ensure that risk assessors can make the best use of their results. As recognized in Casado-Martinez et al. (2024), this is particularly relevant for soil and sediment, given the limited number of standard test guidelines currently available (especially for sediment tests) and the incomplete reporting of sediment and soil toxicity studies in literature studies. Studies published in scientific literature often report data for endpoints and exposure conditions that cannot be categorized as relevant and reliable with or without restrictions on categories, which means that they cannot be used for regulatory purposes. As a result, a limited dataset on the toxicity of substances to soil and sediment organisms is available, which hampers effect assessments and consequently ecological risk assessments for these environmental compartments.

The table below (Tab. 8) reports the main information currently required in the template; however, it is important to highlight that the template is meant to be a flexible tool, to be adapted and modified according to the study purpose and overall goals.

Tab. 8: Structure of the template reported in Annex 4

Info	Details	Example
Tested organism	**Species Scientific Name**	*Artemia salina*
	Species Common Name	*Brine Shrimp*
	Species Group	*Crustaceans*
	Organism Lifestage	*Adult*
	Organism Age Mean	*xxx*
	Age Units	*xxx*
Test conditions	**Exposure Type**	*Aquatic - static etc*
	Media Type	*e.g. sediment, freshwater, etc*
	Test Location	*Lab*
	Multiple CC relevant scenario?	*Y-N*
	CC variables	*T, pH, O2 etc*

	Set conditions	*Short description of tested CC relevant variables*
	Protocol	*Standard (which), modified etc*
	Observed Duration Mean (Days)	*e.g. 4*
	Observed Duration Units (Days)	*Day(s)*
	Number of Doses	*e.g. 11*
	Range doses	*0-1-5-10 etc*
	Conc Units	*mg/l*
Results	**Effect**	*e.g. Mortality, growth, reproduction etc*
	Effect Measurement	*Mortality*
	Endpoint	*LC50*
	Effect concentration	*Xxxx*
	Notes/ observations	*Any other relevant observations*
Reliability	**Cred score (or similar)**	*Optional*
Reference/ID	**Author**	*Names authors*
	Reference Number	*it should be univocal*
	Title	*Title of the paper/study*
	Source	*ref paper/study*
	Publication/study Year	*e.g. 2025*
	ID scenario	*Optional*

5. Conclusions

Literature review and evaluation of existing ecotoxicological data represent an essential step to screen ecotoxicological hazard and, depending on the case, to evaluate ecological risks (at screening level or as higher tier study). To support these evaluations, over the years several ecotoxicological databases have been developed by environmental agencies and institutions. Ecotoxicological databases can be characterized by different purposes (e.g. for validation of regulatory dossiers, tools to support studies focused on contaminated site assessment and management, compilation of screening values for general environmental evaluation) and can have been developed adopting different methods and criteria to evaluate the reliability of the studies used for the database compilation. Additionally, databases represent a useful tool to organize and structure results and data, including those from site-specific investigations.

This document was meant to summarize methodologies and best practices for the use and preparation of ecotoxicological databases (including also database for the management of site-specific data and, when useful and possible, integrating information for the evaluation of climate change exposure scenarios). Specifically, the document presented the following content:

- Methods to assess reliability and data quality check;
- Recommendations for the organization and compilation of ecotoxicity database;
- Template and example of compilation of database.

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