DANTES

Demonstrate and Assess New Tools for Environmental Sustainability

Methods and Tools for Assessment of Environmental Risk

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Introduction

This report was prepared within the DANTES project supported by the EU Life-Environment Program. One of the project's goals is to assess and demonstrate sustainability tools such as Environmental Risk Assessment (ERA) by studying methods and tools available today and performing simplified as well as comprehensive environmental risk assessments.

The aim of this report is to give an overview of different methods and tools for ERA. It also provides general information on the environmental risk such as definitions, use and application of risk assessment.

In the report the ERA practices in the European Union and United States are compared. The two major sources of information used are the Commission of the European Communities' "Technical Guidance Document in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No. 1488/94 on Risk Assessment for Existing Substances" and the United States Environmental Protection Agency's (US EPA) "Proposed Guidelines for Ecological Risk Assessment". The results of the comparison in a comprehensive form are presented in Chapter 4. A brief introduction to the new EU regulatory system REACH (Registration, Evaluation and Authorization of Chemicals) is also given.

Moreover, a description of tools, such as EUSES (The European Union System for the Evaluation of Substances), ECETOC screening risk assessment tool, EcoFate, etc., devised to carry out full as well as simplified Environmental Risk Assessments can be also found in the report.

1. Introduction to Environmental Risk Assessment

Risk assessment techniques are currently used in a wide range of areas starting from engineering to determine the likelihood and effect of failure of components to the assessment of social risks posed by, for example, anti-social behaviour of clients. In the last decades, risk assessment has become a commonly used approach in examining environmental problems mainly caused by human activities.

Some basic definitions of risk assessment are necessary to give in order to better understand the content of the report. Definitions of risk assessment vary substantially from one source to another. This is mainly due to the wide range of approaches and meanings of terms used by different groups of experts and practitioners.

The following definitions are commonly used:

Risk is the combination of the probability, or frequency, of occurrence of a hazard and the magnitude of the consequences of the occurrence. *Hazard* is commonly defined as "the potential to cause harm". The distinction between hazard and risk can be made clearer by the use of a simple example with acids. A large number of chemicals have hazardous properties. Acids, for example, may be corrosive or irritant to human beings. However, the acid is only a risk to human health if humans are exposed to it. The degree of harm caused by the exposure will depend on the specific exposure scenario. Thus, if a human comes into contact with the diluted acid, the risk of harm will be minimal but the hazardous property of the chemical will remain unchanged [1].

Risk assessment is the scientific process in which the risks posed by inherent hazards involved in the process or situations are estimated either quantitatively or qualitatively [1]. For instance, in the life cycle of a chemical risks can arise during manufacture, distribution, use, recycling or disposal processes. Risk assessments are carried out to examine the effects of a substance on humans (Health Risk Assessment) and ecosystems (Environmental Risk Assessment)[1].

Environmental risk assessment (ERA) is a process of identifying and evaluating the adverse effects on the ecosystems, animals and people, exposed thorough the environment, resulting from technological activities.

Risk assessment is carried out to identify a potential risk and to enable risk management decisions to be made. *Risk management* is the process of identifying, evaluating, selecting, and implementing actions to reduce risk to human health and ecosystems [10]. Risks can be managed in many ways. They can be eliminated, transferred, retained or reduced.

ERA mainly deals with assessment and management of effects caused by human activities. This is because almost all routes by which the ecosystems are pollutes are related to human activities.

The uses of risk assessment are wide and varied. The attention to ERA issues is increased in industry partly as a result of the use of ERA in regulations. ERA is used in the industry in the following [1]:

- Compliance with legislation

[1] Europe: Environmental Risk Assessment; USA: Ecological Risk Assessment

- Product safety
- Financial planning
- Site-specific decision making
- Prioritisation and evaluation of risk reduction measures.

Risk assessment process is usually hampered by four types of uncertainty [10]:

1. Lack of information – basic data is lacking or inadequate to make precise prediction.
2. Measurement uncertainties – these may include low statistical power due to insufficient observations, difficulties in making measurements, inappropriateness of measurements and/or human error.
3. Observation conditions – such as spatiotemporal variability in climate, soil type, sensitivity, ecosystem structure, differences between natural and laboratory conditions, and differences between tested or observed species and species of interest for risk assessment.
4. Inadequacies of models – may include fundamental lack of knowledge concerning underlying mechanisms, failure to consider multiple stressors, responses of all species, extrapolation beyond the range of observations, and/or instability of parameter estimates.

Thus, risk assessment is an iterative process. As conditions change and new information becomes available in the course of the study, the assessment is revised and improved where needed.

2. ERA in Europe

The following definition of risk assessment agreed at the Earth Summit, UNCED, in Rio de Janeiro was taken as a starting point in the development of the European process of risk assessment [10]:

"Chemical risk assessment is a scientific process which identifies, characterizes and quantifies the potential adverse effects on human health or ecosystems of defined exposures to a chemical substance or mixture or to a chemically hazardous process or situation. Risk itself is the probability of a defined adverse effect occurring in a defined group in defined circumstances."

EU legislation specifically requires that risk assessment is carried out on all newly notified substances and on priority existing chemicals. There are two directives on risk assessment of chemicals developed by the European Commission:

- Commission Directive 93/67/EEC on Risk Assessment for new notified substances - laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC;
- Commission Regulation (EC) No. 1488/94 on Risk Assessment for existing substances – laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation No. 793/93/EC.

The risk assessment in the EU is conducted according to the detailed methodology laid down in the Technical Guidance Document on Risk Assessment for New and Existing Substances (TGD) [2].

The ERA consists of four steps (see Figure 1):

- hazard identification – where the adverse effects that a chemical has an inherent capacity to cause are indicated;
- dose - response assessment - the relationship between dose or level of exposure of the substance and the severity of an effect are estimated;
- exposure assessment – estimation of the concentration to which environmental compartments are or may be exposed. The sources, emission routes and degradation pathways of the chemical are also determined;
- risk characterization - estimation of the incidence and severity of the effects likelihood to occur in an environmental compartment due to actual or predicted exposure to a chemical. Risk Characterization Ratio (RCR) is calculated by PEC/ PNEC, i.e. Predicted Environmental Concentration versus Predicted No-Effect Concentration for environmental compartments.

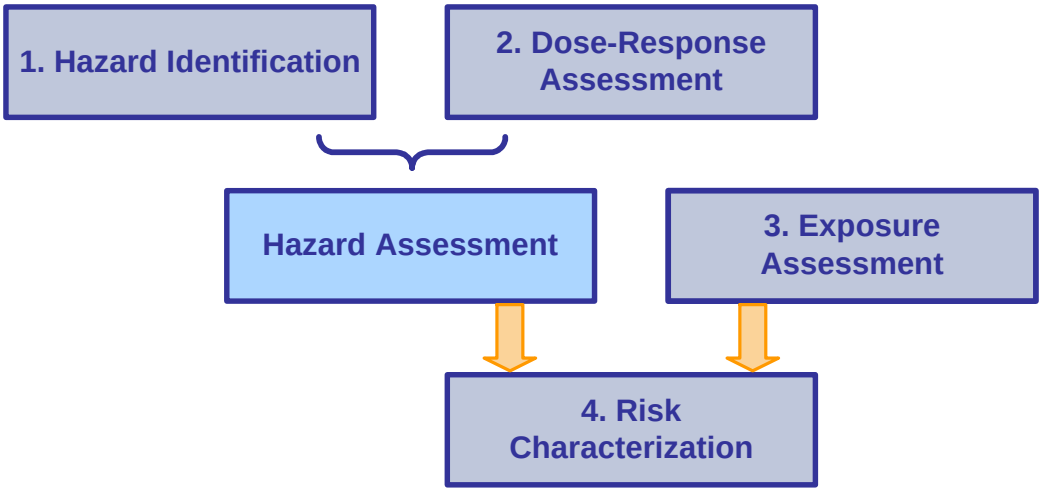

Figure 1. The interrelation of four steps of ERA [4]

The basic philosophy of the EU procedure is initially to evaluate the PEC/PNEC ration using very simple data and conservative assumptions. If these data and assumptions lead to the conclusion that there may be a problem (PEC/PNEC > 1), then refinement of either PEC and/or PNEC may be carried out. This refinement could well be in several stages using progressively more elaborate data and correspondingly less conservative assumptions. Finally, a conclusion is reached on the PEC/PNEC ratio against local and regional exposure scenario. If the PEC/PNEC ratio is greater than one, some form of risk management may be deemed necessary [3].

In order to adequately characterize the exposure concentration of a substance, its concentration for each environmental compartment is calculated for all the stages of the substance's life cycle from production, through processing, formulation and use, to recycling and disposal.

The detailed procedures recommended for environmental risk assessment within the EU are given within the environmental section of the TGD. The stated intention is that the TGD may easily be changed and updated in the light of experience with its use and with new developments in risk assessment methods [3].

2.1. REACH

In October 2003 the European Commission adopted a legislative proposal for implementing a new EU chemicals policy. The new regulatory system, known as REACH (Registration, Evaluation and Authorization of Chemicals), comprises four procedures [7]:

1. *Registration* of chemicals, documenting that risks are adequately controlled. Manufacturers and importers of chemicals in the EU must register those substances that they produce or market in quantities above 1 tonne per year (tpa). Phase-in periods are proposed for some 30000 existing substances, with substances manufactured or imported in tonnage above 1000 tpa being registered first, followed by 100 tpa and 1 tpa. In order to avoid multiple testing of the same substance, REACH aims to encourage industries to form consortia and gather information into a central database [7]. The registration system will result in the rules for the notification of new substances placed on the market in Directive 67/548/EEC being repealed [12]. However, the classification rules will not be changed.
2. *Evaluation* of the registration dossiers, considering mainly testing proposals. Member-state authorities will evaluate testing proposals for all substances manufactured or imported in quantities above 100 tpa (dossier evaluation) and any other prioritized substances if deemed necessary (known as a substance evaluation).
3. *Authorization* of substances of very high concern. These include substances that are carcinogenic, mutagenic or toxic to reproduction and substances with a potential for persistence and bioaccumulation combined with high (eco-)toxicity (PBT substances) or very persistent and very bioaccumulative substances (vPvB substances). Industries that wish to use this kind of substances for a particular purpose or as a component of a product must have a specific permission before such a substance can be used.
4. *Restriction* of substances at the level of the European Community when risk reduction measures proposed by industry are not sufficient. Restrictions can be considered as a "safety net" allowing EU member states and/or the Commission to address risks that are not managed adequately by other parts of the REACH system. For example, in situations where the aggregated tonnage of multiple registrations causes concerns that were not foreseen in the individual safety assessments or when it is necessary to accelerate the risk reduction of specific uses of specific substances.

REACH will implement the objectives set out in the "White paper: Strategy for a Future Chemicals Policy" [11]. It will give industry the responsibility for ensuring and demonstrating the safe manufacture, use and disposal of chemicals. This represents a shift of responsibility to demonstrate and manage risk(s) associated with the use of chemicals from authorities to the actors in the chemical supply chain. As a result, manufacturers and importers of chemicals are required not only to control risks present during those stages of a substance's life cycle under their direct control but also to give guidance for use by downstream users on the safe handling and use of the substance.

For the user of this new regulatory system it may be interesting to know how the environmental risk assessment process will be carried out. The goal of the environmental hazard assessment

according to REACH will be to determine the classification and labeling of a substance in accordance with Directive 67/548 and to identify the concentration of the substance below which adverse effect in the environmental sphere of concern are not expected to occur, e.g. PNEC [13].

The environmental hazard assessment will consider the potential effects on the environment, comprising the aquatic, terrestrial and atmospheric compartments, including potential effects that may occur via food-chain accumulation. In addition, the potential effects on the microbiological activity of sewage treatment systems will be considered.

The hazard assessment will comprise the following three steps:

1. Evaluation of data – this includes the hazard identification based on all available data and the establishment of the quantitative dose (concentration) – response (effect) relationship;
2. Classification and labeling – comprises presentation and justification of the appropriate classification and labeling in accordance with the criteria in Directive 67/548;
3. Derivation of the predicted no-effect concentration (PNEC) – based on the available data, the PNEC for each environmental compartment will be established. [13]

Exposure scenarios, a set of information and/or assumptions describing one or more processes in which a substance is involved, will form an integral part of the Chemicals Safety Reports (CSR). They will be communicated to downstream users as an annex to the safety data sheets [11].

The Regulation is expected to come into force in 2006 – beginning of 2007 and requires no domestic implementing legislation. However, further developments within and beyond REACH such as improvements to risk assessment methodologies and data generation tools must be expected.

2.2. Tools

There are a number of tools for carrying out full as well as simplified Environmental Risk Assessments. Two different tools, EUSES (The European Union System for the Evaluation of Substances) and screening risk assessment tool that is under development by ECETOC are described in this chapter.

EUSES

The European Union System for the Evaluation of Substances (EUSES) is a computer program for conducting risk assessments [4]. The EUSES was developed for quantitative assessment of the risks posed by new and existing chemical substances to the environment.

The data set available for new and existing chemicals is called a “base set”. The availability of data differs depending on the type of the substance evaluated. EUSES can work with very limited data sets. For example, the following data are needed for the model calculations in EUSES:

- Tonnage substance produced in EU
- Tonnage substance used in EU
- Molecular weight
- Vapor pressure
- Log octanol-water partition coefficient
- Water solubility
- Aquatic toxicity
- Biodegradability

Risk assessment in EUSES is carried out in a stepwise procedure encompassing the following stages (see Figure 2):

1. *Exposure assessment:* estimation of the concentrations/doses to which environmental compartments are or may be exposed.

- Emission module: based on the known properties, uses and functions of a substance, default emission factors for various life cycle stages chosen from the database.
- Distribution module: this contains all the models necessary to estimate the distribution of a substance in the environment.
- Exposure module: based on estimated environmental concentrations. This module calculates the exposure levels for predating birds, mammals and humans.

2. *Effects assessment*, comprising

- hazard identification: identification of the adverse effects which a substance has an inherent capacity to cause; and
- dose-response assessment: estimation of the relationship between the level of exposure to a substance (dose, concentration) and the incidence and severity of an effect.

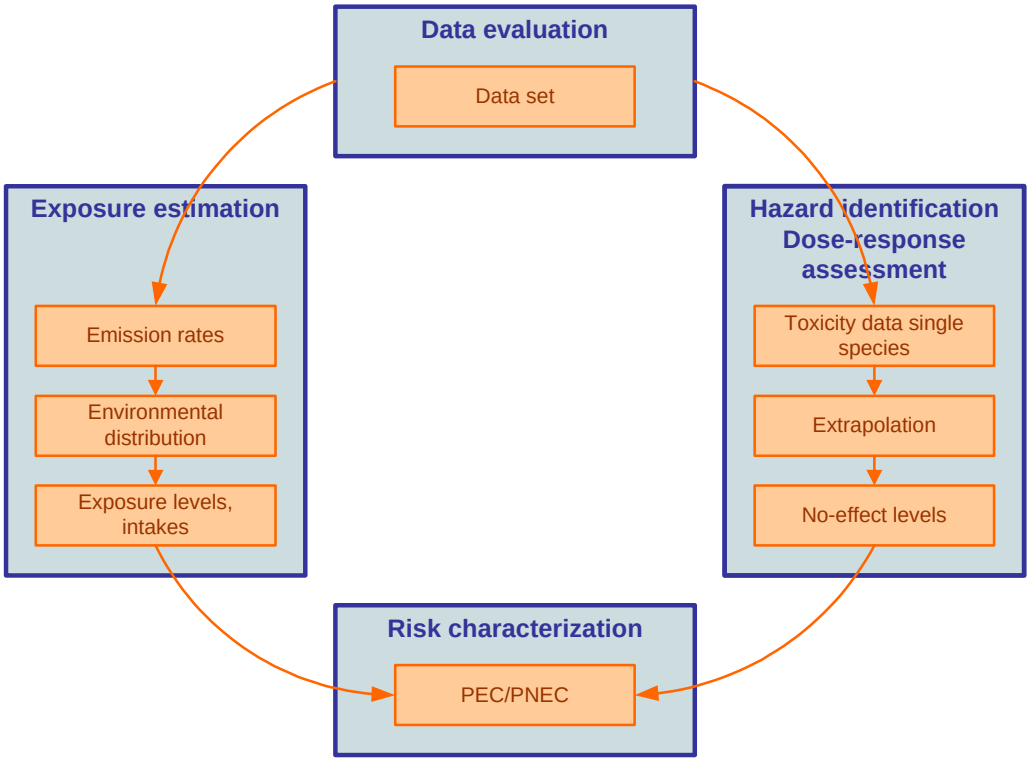

Figure 2. EUSES risk assessment procedure

3. *Risk characterization:* estimation of the incidence and severity of the adverse effects likely to occur in environmental compartment due to actual or predicted exposure to a substance. This procedure will result in a quantitative comparison per substance of the outcome of the exposure assessment and that of the effects assessment: this will be a PEC/PNEC, i.e. Predicted Environmental Concentration versus Predicted No-Effect Concentration for environmental compartments. The generic name for PEC/PNEC in EUSES is: Risk Characterization Ratio (RCR).

The new EUSES 2.0 version will be released in January 2004 and can be downloaded from ECB web site at http://ecb.jrc.it/existing-chemicals/. The new tool will be updated according to the revision of the TGD on Risk Assessment. Please note that the EUSES software is intended mainly for initial and refined rather than comprehensive risk assessments.

ECETOC Screening Risk Assessment

ECETOC screening risk assessment is draft software based on the principles of EUSES [5]. It is a simplified tool requiring limited data. The tool can be applied for a first screening at the product portfolio in order to find out substances that require further examination. There are six different variables used in the assessment process (see Figure 3)[2] [6]:

1. Emission scenario
2. Tonnage
3. Hydrophobicity
4. Volatility
5. Biodegradability
6. Ecotoxicity

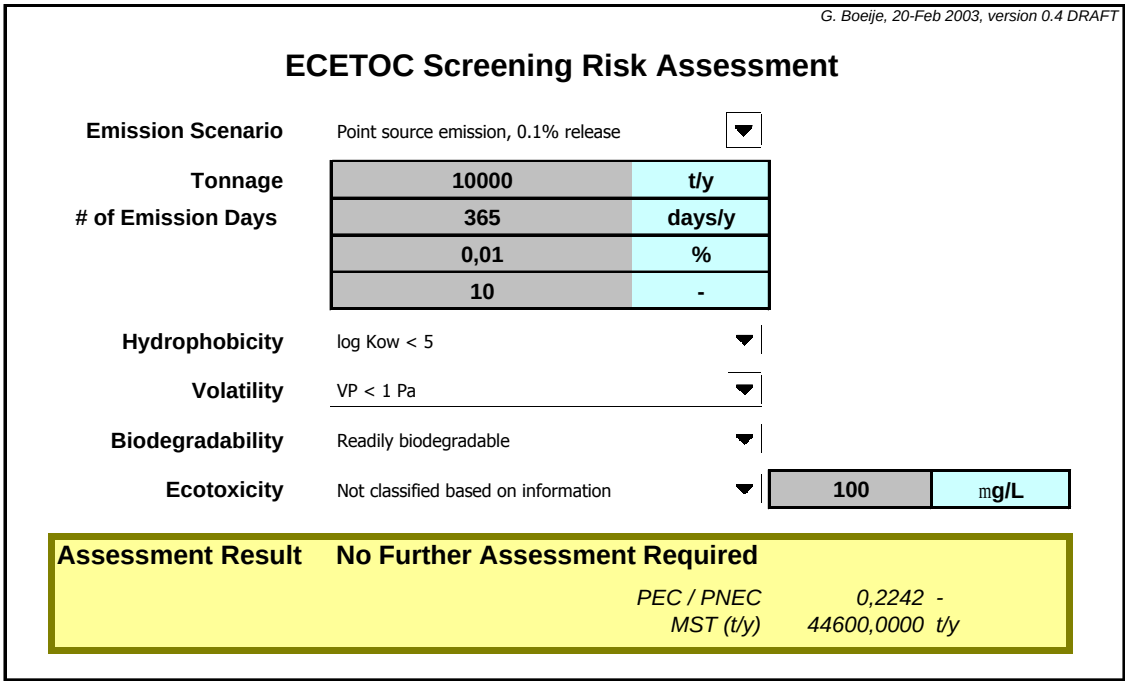

Figure 3. Screen copy from ECETOC Screening Risk Assessment tool, where

PEC = Predicted Effect Concentration

PNEC = Predicted No Effect Concentration

RCR = Risk Characterization Ratio = PEC/PNEC

MST = Tonnage/RCR

1. Emission scenario

One of the most important parameters in the method is the "emission scenario". This is due to its immense influence on the RCR result. The program offers the choice between different emission scenarios mentioned below:

[2] Note: ECETOC software version 0.4 DRAFT was used.

- “Wide dispersive use, 100% release” – this refers to activities that deliver uncontrolled exposure.
- “Point source emission, 0.1% release” – refers to the most controlled, local point source emissions, followed by 1% and 10% releases.

The release factor of 365 days per year is used in the scenarios as a default setting.

2. Tonnage

This is a tonnage of the substance manufactured and/or imported to Europe. The tonnage is given in tons per year. The goal is to examine the total volume of the substance manufactured and/or imported to Europe. However, this type of data is limited and very difficult to obtain.

3. Hydrophobicity

Hydrophobicity shows if the substance is hydrophobic or hydrophilic. The words hydrophobic and hydrophilic literally mean 'afraid of water' and 'fond of water'. Hydrophobic materials have little or no tendency to adsorb water, while the hydrophobic possess low surface tension values and lack active groups in their surface chemistry for formation of "hydrogen-bonds" with water.

The program offers to choose between two values: log K_{ow} is more or less than 5. It should be noted that for some substances a problem of determining the value of hydrophobicity can arise. For example, it is not possible to determine a log K_{ow} value experimentally for surfactants and inorganic substances [6].

4. Volatility

Volatility is the vapor pressure expressed as less than 1 Pa or more than 1 Pa.

5. Biodegradability

Biodegradability is articulated as readily biodegradable or not biodegradable. For example, inorganic substances are not readily biodegradable.

6. *Ecotoxicity*

The goal of ecotoxicity is to understand the concentration of chemicals at which organisms in the environment will be affected. This concentration should be avoided in order to protect the environment.

There are three different risk phrases given in the program to define the ecotoxicity of the substance:

R50	very toxic for aquatic organisms	(LC50 <1 mg/l)
R51	toxic for aquatic organisms	(LC50 =1-10 mg/l)
R52	harmful for aquatic organisms	(LC50 =10-100 mg/l)

The program also gives the opportunity to choose “not classified based on information.”

Our experience

It can be difficult to apply the ECETOC screening tool to surfactants and inorganic substances. This is mainly due to the complexity with the choice of log K_{ow} and biodegradability values. It should be noted that this creates a problem for many chemical producers wishing to use the screening tool.

Moreover, ECETOC screening tool is a very simplified tool, which allows only rough estimations. It should be noted that the tool is still under development. Additional parameters and/or more options added to the ones already existing could result in more accurate RCR values [6].

More information about ECETOC screening tool can be found at the ECETOC website http://www.ecetoc.org/entry.htm. A newly published Technical Report 89 on "(Q)SARs: Evaluation of the commercially available software for human health and environmental endpoints with respect to chemical management applications" that reviews the currently-available, most preferred (Q)SAR-based predictive software can be also obtained from the ECETOC secretariat.

3. ERA in the USA

US EPA defines *Ecological Risk Assessment* as the process that *"evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors"* [8]. An assessment may involve chemical, physical, or biological stressors, and one stressor or many stressors may be considered.

The Ecological Risk Assessment process is based on two major elements: characterization of effects and characterization of exposure. These provide the focus for conducting the three phases of risk assessment [9]:

- problem formulation,
- analysis and
- risk characterization.

The overall ecological risk assessment process is shown in Figure 4. Only problem formulation, analysis and risk characterization stages are described below:

Problem formulation is the first phase of the assessment process. In problem formulation, the purpose for the assessment and the problem are defined, and a plan for analyzing and characterizing risk is determined.

Initial work in problem formulation includes the integration of available information on sources, stressors, effects, and ecosystem and receptor characteristics. From this information two products are generated: assessment endpoints and conceptual models. Both products are needed to complete an analysis plan, the final product of problem formulation.

Analysis is directed by the products of problem formulation. During the analysis phase, data are evaluated to determine how exposure to stressors is likely to occur. This is called characterization of exposure. The potential and type of ecological effects that can be expected (characterization of ecological effects) are also determined. The products from these analyses are two profiles: one for exposure and one for stressor response. These products provide the basis for risk characterization.

During *risk characterization* phase, the exposure and stressor-response profiles are integrated through the risk estimation process. Risk characterization includes a summary of assumptions, scientific uncertainties, and strengths and limitations of the analyses. The final product is a risk description in which the results of the integration are presented, including an interpretation of ecological adversity and descriptions of uncertainty and lines of evidence.

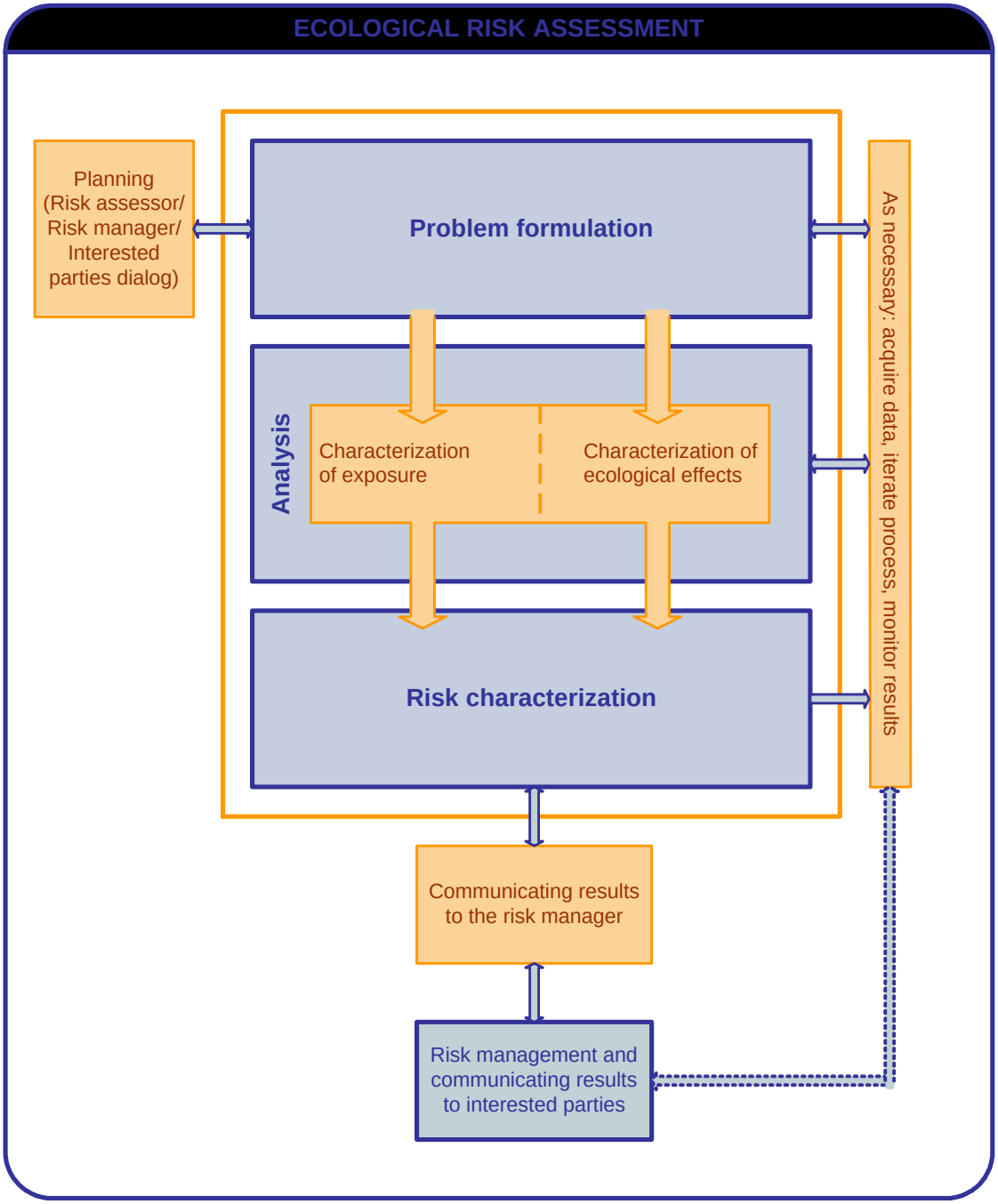

Figure 4. The framework for ecological risk assessment [9]

3.1. Tools for Ecological Risk Assessment

U.S. EPA has developed a number of different tools for ecological risk assessment. In this report, only two of them are described. Links to other tools are also given.

EcoFate

EcoFate is an environmental risk assessment software package for Microsoft Windows.

EcoFate is a software package for conducting ecosystem based environmental and ecological risk assessments of chemical emissions by point and non-point sources in freshwater and marine aquatic ecosystems, including lakes, rivers and marine inlets.

EcoFate is designed to assess the cumulative impact of chemical inputs in terms of contaminant concentrations in water, sediment and biota of an entire ecosystem. The program interprets these concentrations in terms of exceedance of environmental criteria and standards, potential for toxic effects in biota of the ecosystem and risks to human beings exposed to contaminated fish products or contaminated water.

EcoFate consists of a combination of an environmental fate, food-web bioaccumulation, toxicological hazard, and human health risk assessment model. These models are integrated to directly relate chemical emissions to concentrations, toxic effects and human health risks. Each of the models is based on best available knowledge of the mechanisms of chemical distribution, toxicity and risk. The assessments can be done on a time-dependent and steady-state basis.

The main purpose of EcoFate is to investigate whether existing or planned chemical emissions can be expected to pose an ecological or human health risk, meet environmental quality standards or criteria and to identify the assimilative capacity of ecosystems for chemical substances in terms of maximum daily loadings.

The software can be downloaded at http://www.rem.sfu.ca/ecofate/ecofate.html.

EMSOFT

EMSOFT or Exposure Model for Soil-organic Fate and Transport is a computer screening model that may be used

1. to determine concentrations of contaminants remaining in the soil over a given time (when the initial soil concentration is known);
2. to quantify the mass flux (rate of transfer) of contaminants into the atmosphere over time; and
3. to subsequently calculate contaminant air concentrations by inputting mass flux values into atmospheric dispersion models.

EMSOFT can also be used by risk assessors and exposure modelers to calculate average chemical concentrations at a given depth over time.

Through a series of menus the user is prompted for several input choices to select a calculation method, chemical data, soil properties, and layer properties. The various calculation methods include Time-Averaged Flux, Flux vs. Time, Time- and Depth-Averaged Soil Concentration, Depth-Averaged Soil Concentration vs. Time and Soil Concentration vs. Depth. The user also has the option to determine cover layer thickness; the number of contaminant layers and their corresponding thickness; and the time period for averaging flux and soil concentration.

More detailed information about the software and files to download can be found at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=2862

Exposure Assessment models

A number of different groundwater, surface water, food chain and multimedia exposure assessment models have been developed by The Center for Exposure Assessment Modeling (CEAM).

CEAM was established in 1987 to meet the scientific and technical exposure assessment needs of the U.S. EPA as well as state environmental and resource management agencies. CEAM provides proven predictive exposure assessment techniques for aquatic, terrestrial, and multimedia pathways for organic chemicals and metals. For more information see http://www.epa.gov/ceampubl/.

Superfund Risk Assessment – Calculation tools

Links to databases, software, and other technical tools for conducting a risk assessment can be found at http://www.epa.gov/superfund/programs/risk/calctool.htm.

4. Comparison of the US and the EU risk assessment methods [10]

Category	USA	EU
Scope	1. The methodology is broad in scope, considers chemical and non-chemical stressors. 2. For predictive and retrospective assessments[3]. 3. The methodology is not prescriptive due to its generality. The US method includes the EU method. However, the scope of the method is not unlimited. It does not discuss accidentally or deliberately introduced species, or genetically modified organisms.	1. The EU method is only intended for the assessment of chemicals. 2. Is intended for predictive studies. 3. Methodology is prescriptive due to its specificity (for example, more than 60 equations are given in the guidance).
Separation of risk assessment from risk management	1. The risk assessment is separated from risk management. 2. Risk assessor and risk manager are two different persons.	1. No clear separation between the role of risk assessor and risk manager. This implies that the risk assessor and risk manager may be the same person or persons.
Environmental compartments versus assessment endpoints	1. An assessment endpoint(s)[4] as well as an attribute of the endpoint that is important to protect must be selected and agreed upon for each assessment.	1. Risk posed by chemical to the environment is assessed for all environmental compartments: aquatic ecosystem, terrestrial ecosystem, atmosphere, top predators, and STP microorganisms.
Synergistic effects	1. Synergistic effects of several stressors are considered. 2. US EPA recommends the consideration of toxicities of several stressors to be additive when the modes of action of the chemicals in question are similar.	1. Synergistic effects of chemicals are explicitly excluded from consideration. 2. The EU methodology is intended to assess the risks posed by individual chemical substances to the environment.
Life cycle stages of a stressor	1. Consideration of all life cycle stages is not required. Since the methodology may be used for stressors other than chemicals (e.g. habitat loss), life cycle stages of the stressor may not be relevant. 2. The selection of the appropriate endpoint	1. The concentration of the substance is calculated during all stages of the substance's life cycle: production, formulation, processing, use and disposal/recovery. 2. The assumption here is that emissions may

[3] Predictive assessments estimate exposures and effects of proposed future contaminant releases or other hazardous actions. Predictive assessments begin with an estimate of the source and proceed to model the processes that result in exposure or disturbance. In retrospective assessments the assessor starts with a known source (for example oil spill), exposure, or effect, and assesses the potential risk.

[4] Assessment endpoint – formal expression of the actual environmental value to be protected. The Assessment endpoint is the product of the "Problem formulation" phase of an ERA; it defines the focus of investigation.

	is emphasized. The focus is on the assessment endpoint.	occur at any stage of the chemical's life cycle.
Uncertainty/ Variability[5]	1. Emphasis on characterizing/ quantifying uncertainty and variability.	1. Risk assessment factors over the effects concentrations obtained from a laboratory are used. The magnitude of the assessment factor depends on the degree of uncertainty one has regarding the effects data.
Data requirements	1. No minimum data set is defined in the guidance. 2. The credibility of the decisions is directly proportional to the quantity of representative data used in the analysis.	1. Minimum data requirement for exposure analysis: producers and importers are required to submit a specified data set, the so-called base-set.
Type of data	1. Collection and use of site-specific data is encouraged.	1. Use of standardized/default values as a first approach is preferred. This can lead to overly conservative estimates. The default values represent a worst-case scenario. Site specific data is needed to replace the default values.
Iteration	1. A new iteration is only required if previous iteration could not define the risk in a way to support the management decision.	1. Iteration is based on the result of the PEC/PNEC ratio. If the ratio is more than 1, then iteration is recommended. 2. There is no recommendation to iterate if the ratio is less than 1. 3. The guidance gives elaborate testing strategies to implement if PEC/PNEC ratio is more than 1.
Risk description and presentation	1. Risk(s) can be estimated and described by one or a combination of the following methods: • Single-point estimate: quotient method, • Stressor-response relationship curve, • Estimates incorporating variability in exposure or effects, • Process models.	1. Risk is described and presented as the PEC/PNEC ratio, which is the same as the U.S.EPA single-point method. This clearly limits the risk assessor to one simple method even if other methods would have been more appropriate.
Common points	1. Data gathering is the responsibility of chemical producers and importers. 2. Both support tiered approach to the risk assessment.	

[5] *Variability* – observed differences attributable to true heterogeneity or diversity in a population or exposure parameter. *Uncertainty* – lack of knowledge about specific factors, parameters, or models.

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