MICA
Minerals Intelligence Capacity Analysis

FACT SHEET

Environmental Risk Assessment (ERA)

Description of the method of Environmental Risk Assessment (ERA).

Scope (conceptual model & main characteristics)

Environmental Risk Assessment (ERA) studies are carried out to examine the effects of emissions from processes in plants and factories as well as their products in the broadest sense on human health and on ecosystems, enabling a risk management decision to be made. While Risk Assessment (see separate factsheet) is concerned with disastrous events, Environmental Risk Assessment is oriented at the exposure to chemicals due to continuous low-level emissions. The risk is estimated by quantifying exposure and confronting that with some sort of a no-effect or acceptable level. This may lead to risk acceptance or to the implementation of risk reduction measures that reduce the likelihood of the event or reduce the consequences to a satisfactory level.

Approaches to estimate the risks related to substances, processes and technology are either quantitative or qualitative. ERAs vary widely in scope and application. In broad terms ERAs are carried out to examine the effects on humans (Health Risk Assessment, HRA) and ecosystems (Ecological Risk Assessment, EcoRA).

The process of environmental risk assessment includes four steps: hazard identification, hazard characterisation, exposure assessment, and risk characterization and the first two steps are regarded as the process of hazard assessment:

- Hazard Assessment, identifying and characterising the inherent properties of chemical substances is basically the first step of environmental risk assessment. Environmental hazard assessment (hazard identification and hazard characterisation) involves gathering or generating and evaluating data of chemical substances and concluding on their inherent eco-toxicological effects and environmental fate. In this stap single species tocicity data are extrapolated to no-effect levels.
- Exposure Assessment, another important step of the environmental risk assessment is to estimate or predict the extent of exposure of chemicals to the target species and/or the environment through its production, use and disposal. Emission rates are translated by distribution models into exposure levels and intakes.
- Risk characterisation, the last step in the environmental risk assessment, is the qualitative and, wherever possible, quantitative determination of the probability of occurrence of the adverse effects of chemicals to the environment under predicted exposure conditions. This process is based on outcomes of the previous steps, i.e. environmental hazard and environmental exposure assessment. In many regulatory frameworks environmental risks are often expressed by ratios between PEC (Predicted Environmental Concentration, derived from environmental exposure assessment) and PNEC (Predicted No Effect Concentrations for target ecosystems, an outcome of environmental hazard assessment. (OECD, 2016)

Projects from EEA provide information on the general aspects of ERA, involving its core concepts, definitions and terminology, its use and application, and its limitations and uncertainties (EEA, 1998).

Contexts of use, application fields	-> contexts (e.g., environmental, economic, social assessment) -> which types of stakeholder questions are concerned?

ERA is developed for both industry and authorities (legislators and administrators). The risk assessment focus is on the low-/no-effect end of a hazard scale, and there is a concentrated effort to deal with data requirements supporting this evaluation. Its main application is that it enables risk management.

Usually, ERA only considers the emission of toxic substances. However, there are developments to include the distribution of genetically modified organisms into the ERA framework.

ERA is the main method used by the EU in their REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) system. EC Regulation 1907 / 2006 (EC, 2006) contains detailed descriptions of the methodological steps, required data and interpretation, as well as long lists of substances and their risk classification.

Type(s) of data or knowledge needed and their possible source(s)	-> which types of data are needed to run the method, from which sources could they come… -> could be qualitative data or quantitative data, and also tacit knowledge, hybrid, etc.

Dependent on the amount and the quality of available data, and considering the details required, risk assessment studies have developed into a tiered, step-wise process. A distinction can be made between:

1. a screening phase based on a restricted amount of data, relatively close to the EUbase- set requirements for notification of new chemicals,
2. a refined assessment as an "in-between" stage, carried out by using more details for the exposure as well as the effect descriptions. This is followed by:
3. a comprehensive (or full) risk assessment, which is very demanding on data and documentation. Only a few full scale risk assessment studies have actually been made for individual chemicals (e.g., for some important pesticides), whereas an assessment at this level ought to be the rule rather than an exception when dealing with assessments according to the Seveso-directive.

The risk characterisation based on the PEC/PNEC-ratio is derived from monitoring data, realistic worst cases scenarios and predictive modelling techniques. The gathering of data is a complex task and should consider data on release, transport, fate mechanisms and effect/toxicity. There is a wide range of available databases used in the risk assessment process. The REACH&CLP Helpdesk (2016) gives an overview of a number of databases from the European Chemical Agency and European and other international databases. http://www.reach.lu/en

REACH is a regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals. 'Information on Chemicals' from the 'European Chemicals Agency' is unique source of information on the chemicals manufactured and imported in Europe. It covers their hazardous properties, classification and labelling, and information on how to use them safely. As from 20 January 2016, information on up to 120 000 chemicals is enriched and structured in three layers: infocard, brief profile and detailed source data. http://echa.europa.eu/information-on-chemicals

Model used (if any, geological mathematical, heuristic…)	-> e.g., geological model for mapping -> e.g., mathematical model such as mass balancing, matrix inversion, can be stepwise such as agent -based models, dynamic including time or quasidynamic specifying time series… -> can also be a scenario

In general two types of models are used in environmental risk assessment both making use of dedicated models:

- environmental fate models: models to determine the dispersion and fate of hazardous substances in the environment from the point of emissions, via transport through air, water or groundwater
- exposure models: models to estimate the resulting exposure of humans and/or ecosystems through intake via air, water or food
- effect models: models to estimate the toxic, carcinogenic, mutagenic and teratogenic effects of exposure to hazardous substances on humans, or the effects of exposure on plant and animal species in ecosystems.

To derive no-effect levels, all quantitative toxicity assessments are based on the dose-response concept, which is first of all based on laboratory tests using test organisms. Epidemiological data may also be used, however, such data are most often not available. In the absence of data, sometimes models are used as an approximation: QSAR models, based on the physical and chemical properties of the substances.

Generally, ERA methods and software are based on steady state modelling.

System and/or parameters considered	-> **the system can be described by its boundaries**. These can refer to a geographic location, like a country, or a city, the time period involved, products, materials, processes etc. involved, like flows and stocks of copper, or the cradle-to-grave chain of a cell phone, or the car fleet, or the construction sector, or the whole economy… -> **parameters** could possibly refer to geographic co-ordinates, scale, commodities considered, genesis of ore deposits and others…

ERA analysis emissions of substances by processes, technologies and activities. The main focus is on the assessment of risks derived from substances and how they pose risks to human health and to ecosystems. The system is built around the emitting plant or product and includes the affected surroundings. Although local, it has no set geographical system boundaries. Neither does the system have temporal boundaries. Although the emission can be described as emissions in a period of time, the effects taken into account are often long-term.

Time / Space / Resolution /Accuracy / Plausibility…	-> to which spatio-temporal domain it applies, with which resolution and/or accuracy (e.g., near future, EU 28, 1 year, country/regional/local level…) -> for foresight methods can also be plausibility, legitimacy and credibility…

ERA is usually a "here-and-now"-evaluation: time and location specific. ERA may, however, also deal with exposures over wider spatial scale, e.g., as can be observed for the regional or global distribution of acidifying, ozone depleting or climate changing air pollutants. In the assessment of risks of existing chemicals, the distribution from diffuse sources is also evaluated. This is part of the so-called generic Risk Assessment studies which are the objectives of EU directive 793/93.

Indicators / Outputs / Units	-> this refers to what the method is actually meant for. Units are an important part but that is most of the time not sufficient to express the meaning. For example, **the indicators used in LCA express the cradle-to-grave environmental impacts of a product or service**. This can be expressed in kg CO_2-equivalent. But also in €. Or in millipoints. Or in m^2year land use. -> for foresight methods the outputs are products or processes

ERA indicators include the emissions, the environmental concentrations, the intake of the substance, and no-effect levels or acceptable levels of environmental concentrations or intake. To derive no-effect levels, all quantitative toxicity assessments are based on the dose-response concept, which is first of all based on laboratory tests using test organisms. Epidemiological data may also be used, however, such data are most often not available.

Treatment of uncertainty, verification, validation	-> evaluation of the uncertainty related to this method, how it can be calculated/estimated

Limitations:

The techniques quite often take only one chemical at a certain time into account, focusing on one location, but also considering one up- or downstream process. In addition, generic risk assessment studies are also being perfomed for a whole region,

taking all emission sources into account. It should be noted that risk ERA, although focusing at the local level, is a modelling approach still quite far removed from the prediction of actual environmental impact.

Handling of uncertainties:

Uncertainties are both related to the availability of data and to the uncertainty of the data themselves. In the exposure assessment, uncertainties arise because it is difficult to model the amount of a pollutant in the environment over time, and to assess how much is taken in by individuals. In the effect assessment, uncertainties arise from variability in biological experiments and observations as well as when the findings are extrapolated from animals to humans, or from test organisms to ecosystems. For ecological risk assessment the uncertainties deal with the extrapolation of data for a small number of species to effects on bio-diversity in total. For this purpose different extrapolation methods are available. Uncertainties connected to lack of knowledge and indeterminacies intrinsic to the effects description or the uncontrolled or accidental dissemination of chemicals is generally not included in risk characterisation and assessment procedures.

Main publications / references	-> e.g. , ILCD handbook on LCA, standards (e.g. , ISO) -> can include reference to websites/pages

ECHA, 2016. European Chemicals Agency https://echa.europa.eu/home

European Commission, 2006. REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410

EEA - European Environmental Agency (1998): Environmental Risk Assessment; Approaches, Experiences and Information Sources. Authors R. Fairman, C.D. Mead and W.P. Williams, MARC, King's college London; EEA, Copenhagen. https://www.eea.europa.eu/publications/GH-07-97-595-EN-C2/riskindex.html

Helpdesk REACH&CLP, 2016. http://www.reach.lu/mmp/online/website/menu_hori/homepage/index_EN.html

OECD, 2016. OECD Environmental Risk Assessment Toolkit http://envriskassessmenttoolkit.oecd.org/Default.aspx?idExec=0c54ab24-ec8a-4f76-93fc-2b297cb1c932

Wrisberg, N., H.A.Udo de Haes, U.Triebswetter, P.Eder, R. Clift (2002) Analytical Tools for Environmental Design and Management in a Systems Perspective. The Combined Use of Analytical Tools Kluwer Academic Publishers, Dordrecht

Related methods	-> List of comparable methods, their particularities… (or a link to one or several other fact sheet(s))

Risk Assessment (RA) is a broader method of estimating and managing health risks. The approach calculates the chance of some hazardous event and multiplies that with the number of potential casualties if such an event would happen. The result is a theoretical number of casualties per annum, which is then subjected to a comparison with some sort of agreed on acceptable level. RA is relevant for the release of toxic substances into the environment, but is used for incidents rather than prolongued exposure as a result of continuous emissions. It is also used for other disastrous events such as explosions, floods or traffic accidents.

Life Cycle Assessment uses information of ERA to populate its toxicity related impact categories in Life Cycle Impact Assessment.

ERA can be linked to Substance Flow Analysis when the SFA contains an analysis of environmental flows as well as flows through society.

Some examples of operational tools (CAUTION, this list is not exhaustive)	-> e.g., software… Only give a listing and a reference (publication, website/page…) -> **should be provided only if ALL main actors are properly cited**

Software availability:

A variety of risk assessment software models are available. In general the models are divided into transport/fate/exposure models, effect models and risk management models. There are well over 500 such models in existence for different applications.

In the OECD Environmental Risk Assessment Toolkit a summary table is given of tools and models developed and used in OECD member countries for environmental risk assessment. http://www.oecd.org/chemicalsafety/risk-assessment/summarytableofavailabletoolsforriskassessment.htm

Also the REACH website gives a short overview of the tools needed or helpful to fulfill obligations under REACH (Registration, Evaluation, Authorisation and restriction of Chemicals)and CLP (Classification Labelling Packaging).
http://www.reach.lu/mmp/online/website/menu_vert/outils/624/index_EN.html

Key relevant contacts	-> list of relevant **types** of organisations that could provide further expertise and help with the methods described above.

Formal status:

Guidelines for risk assessment have been developed by OECD, the EU and US EPA. A number of academic societies such as SETAC, ECETOC, SRA are dealing with HRA and/or ERA. Until now ERA has not been formally standardised by ISO. In the REACH program of the EU, a high level of standardization has been obtained.

Glossary of acronyms /abbreviations used	-> Definition