

Information and knowledge on risk assessment methodologies for soil contamination

Support for implementing the EU Soil
Strategy for 2030 – Task 1.6

Written by Maria Paola Calasso, Gema Andrea Victoria, Kristina Flexman
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Final report for the European Commission

Support for implementing the EU Soil Strategy for 2030

Task 1.6 Information and knowledge on risk assessment
methodologies for soil contamination



Report for

European Commission
DG Environment

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Executive summary

Purpose of the report

The purpose of this report is to facilitate a dialogue and knowledge exchange on the risk assessment methodologies for soil contamination and to identify best practices, which is an action from the EU Soil Strategy for 2030. This document provides a non-exhaustive overview of the existing methodologies and tools for the risk assessment of contaminated sites.

The report reviews existing policy guidance and initiatives at EU and international level, the legislative framework, the national frameworks used in selected Member States and third countries, and existing tools that support risk assessment.

This document is not a guidance adopted by the European Commission and does not aim to steer the implementation of Directive 2025/2360 on Soil Monitoring and Resilience or to interpret the content of this Directive. This report should not be considered to pre-empt Commission activities to develop supporting documents and scientific tools with regard to Article 24 of the Soil Monitoring Law nor future implementation of site-specific risk assessments at Member State level.

Context

Soils in Europe face many pressures, which results in about 60 – 70% of soils in the EU being unhealthy. This report focuses on the pressure from contaminated sites, i.e. delineated areas with confirmed soil contamination due to point-source release of contaminants associated with anthropogenic activities. The full extent of contaminated sites and the scale of risks to human health and the environment are unknown. Previous estimates have suggested that there may be around 2.8 million potentially contaminated sites in Europe. Member States have varied approaches to risk assessment, using different tools to characterise risks, with different parameters and assumptions built into each tool (e.g. the chemicals, exposure routes and modelling parameters included, and receptors considered).

Findings on risk assessment methodologies for soil contamination

In the context of this report, environmental risk assessment is defined as the examination of risks associated with threatened ecosystems, animals and people.

The importance of effective management of contaminated sites has inspired the creation of various frameworks for the assessment of risks from soil contamination, with a tiered and stepwise approach being crucial and commonly applied within the frameworks. The risk assessment process typically involves progressively more detailed steps as the level and type of site contamination is characterised. For example:

1. **Initial risk screening:** used to determine sites where contamination is suspected/most likely but not confirmed.
2. **Preliminary risk assessment:** conducted to determine whether further investigation is necessary to confirm a suspected/most likely contamination.
3. **Site-specific risk assessment:** applied to sites with confirmed contamination, assessing the nature and extent of the risks.

A typical risk assessment procedure considers the “source-pathway-receptor” paradigm. This means:

1. Identifying the source(s) of contamination, that is at the origin or release points of contaminants to the environment;
2. Evaluating the pathway(s) through which contaminants are being transported from the source to the potential receptors; and
3. Assessing the receptor(s), i.e. the human population or environment, organisms and ecosystems that would be exposed and adversely affected by the contaminants.

Several types of environmental risk assessments have been identified, which may be used depending on what target receptor(s) are selected. These include:

- **Human health risk assessment**, which estimates the nature and probability of adverse health effects in humans who may be exposed to contaminants through different possible pathways (e.g. ingestion, inhalation, food, drinking water, etc.). It usually sets a substance-specific threshold for tolerable exposure (as a reference dose or tolerable daily intake), below which no significant risk to human health is expected.
- **Ecological risk assessment**, which estimates the effects of contamination on ecosystems. In order to derive indices of ecological risk and ecologically based soil quality standards, species sensitivity distributions are used, as they represent the statistical distributions of toxicity values for different biological species.
- Other relevant risk assessments methods include **water quality-based methods** looking for instance at leaching of contaminants to groundwater, as well as at the risk of exceedance of environmental quality standards (EQS) (i.e. concentration limits in water for particular chemicals or groups of chemicals, derived under the EQS Directive to protect human health and the environment).

International and EU-wide standards and other initiatives may inform, and can be used as a starting point for, the development or adaptation of risk assessment methodologies. Among the international initiatives, a series of International Organization for Standardization (ISO) standards have been developed internationally in the context of risk assessment of contaminated soil¹. The Minamata Convention on Mercury contains provisions associated with the identification, assessment and management of sites contaminated with mercury. Finally, the Secretariat of the Stockholm Convention on Persistent Organic Pollutants (POPs), a global agreement to protect human and ecosystem health from POPs, has published a comprehensive guidance document on best environmental practices and best available techniques for the management of POPs contaminated sites.

EU level policies relevant to risk assessment of contaminated land include: the Soil Monitoring Law, the EU Soil Strategy for 2030, the Commission 'One substance, one assessment' package, the Environmental Liability Directive, and the Water Framework Directive and its daughter directives. Other resources from EU authorities and agencies include the European Environment Agency indicator "Progress in the management of contaminated site in Europe", the European Chemicals Agency guidance on information requirements and chemical safety assessment, the Commission technical guidance document on risk assessment, and the European Food Safety Authority guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals.

Current contaminated site risk assessment and management practices vary between, and within, countries. Most countries have developed their own (specific) contaminated site management systems, including the regulation of inventories of (potentially) contaminated sites, provisions for public access to these inventories, risk assessment methods, guidance documents,

¹ ISO 18400-100 to ISO 18400-301, ISO 19204 , ISO 15799 , ISO 17616 , ISO 21365, ISO 16133, ISO 15800, ISO 15175, ISO 19258

investigation procedures, prioritisation formats, remediation structures, and funding mechanisms. Common aspects of the legal frameworks analysed include the following:

- Legal frameworks in some of the countries analysed include **funding mechanisms**.
- Some countries set **threshold values** for significant contamination.
- Some countries set **criteria to assess the risk** of contaminated sites.
- Some countries impose **remediation measures** following a completed risk assessment profile.
- Some national frameworks are based on the **polluter pays principle**.
- Some countries provide a **definition of contaminated sites** in their legal text.

In terms of the methodological framework, all countries follow a step-wise approach. However, the terminology associated with the steps varies among the countries. The landscape of the risk assessment methods could be used for inspiration in developing new risk assessment methodologies or in adapting existing methods.

Different tools exist to assess the risks associated with contaminated sites, such as S-RISK®, ENVIRISK, JAGG, GrundRisk, MODULER'S, Risk Based Corrective Action, UK Contaminated Land Exposure Assessment, Risk-integrated Software for Clean-ups 5. There are differences between the user-friendliness of each tool and differences in the parameters and assumptions built into each tool.

Various EU sources host data that could be used in contaminated site risk assessments, including data on soil properties and on contaminants in soils. The methodologies to collect the data could be more harmonised in order to improve data comparability. A comprehensive and sound approach is needed in order to take informed risk management decisions in the context of site-specific risk assessment. This requires comparable and accurate soil indicators, including soil screening values, threshold values, as well as data on the available fraction and bioaccumulation for each pollutant within a specific soil site. In addition, harmonisation should be defined in terms of using the same laboratory methods to obtain comparable soil fractions of pollutants. However, whilst site-specific risk assessment could benefit from some degree of standardisation, it is by definition site-specific, and therefore input parameters might need to vary.

Considerations for future EU guidance

The Soil Monitoring Law establishes that the Commission should, in cooperation with the Member States, draw up documents and develop scientific tools that may be used by Member States to facilitate them to lay down the specific methodology for assessing the site-specific risks of contaminated sites, taking into account common practices, methodologies and toxicological data.

This report recommends that:

- An EU level guidance could include a manual providing guidance on the **different inputs** to be used when assessing the risks of contaminated sites, such as a list of contaminants alongside information on environmental fate parameters, exposure pathways, toxicological threshold values and other parameters, with examples that are location-specific.
- The guidance could set out a **step-wise/tiered framework** for site-specific risk assessment processes for human health and the environment, as well as guidance on each step.
- Setting up **toxicology thresholds at EU level** would help in the view of having a harmonised framework.

- The guidance could recommend steps for **quality assurance/accreditation** of risk assessment processes.
- Guidance and clarifications could be provided on a series of **optional tools** that could support the risk assessment practice, as well as on boundary conditions for the applicability of different tools and methods.
- **Global coordination** would be beneficial.
- Mobilising resources to **train people** and ensure capacity building in the EU would be beneficial.

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List of abbreviations

Abbreviation	Meaning
ALSAG	The Contaminated Sites Remediation Act, Austria
ARAGORN	Achieving Remediation and Governing Restoration of Contaminated Soils Now
ARPA	The Regional Environmental Protection Agencies, Italy
CLEA	Contaminated Land Exposure Assessment
COPC	Contaminants of Potential Concern
CrcCARE	Cooperative Research Centre for Contamination Assessment and Remediation of the Environment
CSM	Conceptual Site Model
EAA	Environment Agency Austria
ECHA	European Chemicals Agency
EEA	European Environment Agency
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
EQS	Environmental Quality Standards
ESDAC	European Soil Data Centre
EU	European Union
EU PARC	EU Partnership for the Assessment of Risks from Chemicals
EUSO	EU Soil Observatory
FAO	Food and Agriculture Organisation
GIS	Geographical Information System
GrundRisk	Groundwater risk assessment tool, Danish
HERACLES	Human Health and Ecological Risk Assessment for Contaminated Land in EU Member States
HQ	Hazard Quotient
ISLANDR	Information-based Strategies for Land Remediation

Abbreviation	Meaning
ISO	International Organization for Standardization
ISPRA	Istituto Superiore per la Protezione e la Ricerca Ambientale, Italy
JAGG	Jord, Afdampning, Gas, Grundvand (Soil, Evaporation, Gas, Groundwater in Danish)
JRC	Joint Research Centre
LNE	Laboratoire National de Métrologie et D'essais, France
LUCAS	Land Use/Cover Area frame Survey
MAC	Maximum Allowable Concentration
MPC	Maximum Permissible Concentration
NF	Norme Française (standards in France)
NICOLE	Network for Industrially Co-ordinated Sustainable Land Management in Europe
NORMAN	Network of reference laboratories, research centres and related organisations for monitoring of emerging environmental substances
OVAM	Public Waste Agency in the region of Flanders
PAHs	Polycyclic aromatic hydrocarbons
PCBs	Polychlorinated biphenyls
PFAS	Per- and polyfluoroalkyl substances
PEL	Permissible Exposure Limit
PQRA	Preliminary Quantitative Risk Assessment
QA	Quality Assurance
QC	Quality Control
RBCA	Risk-based Corrective Action
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RISC 5	Risk-integrated Software for Clean-ups
ROCKS	Risk Ordering for Contamination Key Sites
RRI	Risk Ranking Index
RTM	Remedial Targets Methodology
SPR	Source-Pathway-Receptor

Abbreviation	Meaning
SSV	Soil Screening Value
TLV	Threshold Limit Value
TRV	Toxicological Reference Values
UFG	Environmental Subsidies Act, Austria
UK	United Kingdom
US/USA	United States/United States of America
VITO	Flemish Institute for Technological Research
WHO	World Health Organisation

PART A – Task background and methodology

1. Introduction

1.1 Purpose of this report

This report is the final report on Task 1.6 of the project 'Support for implementing the EU Soil Strategy for 2030' Contract 09.0201/2022/877182/SER/D.1. This covers the action of the Soil Strategy to facilitate a dialogue and knowledge exchange on risk assessment methodologies for soil contamination and to identify best practices. This task is led by WSP E&IS GmbH ('WSP') with the assistance of the Environment Agency Austria (EAA).

The importance of effective management of contaminated sites has inspired the creation of various frameworks for the assessment of the risks from contaminated sites, with a tiered and stepwise approach being crucial and commonly applied. Within Member States, different approaches, legal frameworks, and terminologies are used to assess potentially contaminated sites and associated risks.

The purpose of this report is to provide a non-exhaustive overview of existing methodologies and tools for the risk assessment of contaminated sites. The report reviews existing policy guidance and initiatives at EU and international level, the legal background and the national frameworks used in selected Member States and third countries, and existing tools that support risk assessment. The report highlights the importance of knowledge exchange between stakeholders, including scholars, the industry, Member States and third countries, and the Commission.

Given the complex nature of risk assessment frameworks and the limited scope of this task that was tendered before the proposal for the Soil Monitoring Law in the context of the implementation of the Soil Strategy, this report should not be considered as pre-empting any activities to develop supporting documents and scientific tools with regard to Article 24 of the Soil Monitoring Law², nor future implementation of site-specific risk assessments at Member State level.

1.2 Structure of this report

This report is structured as follows:

- Part A sets out the task background and methodology. This provides background information on the work delivered and contents of this report (the context and approach to task delivery).
- Part B sets out an overview of the key information identified in this task (i.e. the findings on risk assessment methodologies, policies, frameworks, models, and tools).
- Part C sets out conclusions on the state of risk assessment across the EU, including considerations for potential future support from the Commission to Member States.

² OJ L, 2025/2360, 26.11.2025.

2. Methodology

2.1 Method overview

The sections below outline the steps taken to deliver this task, including how the information sources were analysed and the limitations of the task.

This task has been split in three parts:

- Literature review of selected scientific papers, policy documents, technical reports and national frameworks;
- Consultation with selected stakeholders, including a number of targeted interviews and a workshop on risk assessment to discuss with stakeholders the preliminary findings; and
- Drafting of a final report summarising the findings of the work, including a feedback exchange exercise with stakeholders on the final results.

2.2 Literature review

The aim of the literature review was to explore current approaches to contaminated land risk assessment applied in selected Member States and third countries, in order to highlight similarities and differences among the methods, including the legal basis of the methods. The efforts were directed to identifying government guidance on methods and recommendations from academic and position papers on which methods/techniques are effective.

The sources reviewed included the following:

- Existing legal frameworks in selected Member States and third countries;
- National risk assessment methodologies in selected countries;
- Scientific papers;
- Policy reports;
- Grey literature (e.g., industry association briefings, consultancy reports); and
- Proceedings of conferences, symposia and meetings.

The sources were selected using different approaches, including:

- Web search, using Google/Scholar searches with specific keywords and search terms;
- Targeted interviews with stakeholders;
- Feedback from the workshop participants.

The literature search focused on overarching national frameworks for risk assessment methods and specific methods relevant to site-specific risk assessment. In addition, the research targeted sources drafted in languages fluently spoken by the project team, including English, Italian, French, German and Spanish. Therefore, the preliminary research focused on national legislations and methodologies from Austria, Belgium, Italy, Germany, Spain, the United Kingdom (UK), the United States (US), Canada, Australia and Switzerland. Feedback on methods used in other countries (Denmark, the Netherlands, Luxembourg, Sweden) was sought during the stakeholder workshop (see section 2.3.2 below) and additional sources were reviewed.

A total of 83 sources were reviewed and the full list can be found in the reference list at the end of this report.

The literature sources were reviewed in detail, extracting information on the risk assessment methods used, the stages of the risk assessment that were covered, the countries where each method is applied, and the strengths and weaknesses of each method. Additional relevant information, such as definitions, context, and considerations for deciding on risk assessment methods, was also extracted and used for drafting this report.

2.3 Consultation

As part of the consultation strategy five interviews were conducted and one workshop was organised. In addition, the project team presented the preliminary findings of the task at the Commission Soil Expert Group meeting of 24 June 2025.

2.3.1 Targeted interviews

The interviews aimed to gather initial views from experts to help shape the direction of this task, including any recommendations on sources to review, elements of risk assessment to focus on, and stakeholder views on best practices in defining and implementing risk assessment methods. Stakeholders were also asked about ongoing work that could help progress risk assessment methods (now or in the future).

A list of interviewees to be contacted was compiled based on suggestions from the Commission and suggestions from experts in the project team.

Interviews were held with representatives from two EU-funded research projects, one Member State competent authority, one representative of a research network, and one representative of an industry association. A description of the targeted interviews is presented below:

- **ARAGORN project** – The ARAGORN project (Aragorn, 2025) is an EU funded project that aims to identify contaminated sites and to guide restorative remediation strategies, in line with the EU Soil Strategy. During the interview the following topics were discussed: the possible support from the Commission to Member States, the coherence of the Soil Monitoring Law with other relevant pieces of EU legislation, ARAGORN's commitment to co-creation, ensuring that remediation strategies are developed collaboratively with stakeholders, and the different priorities and protection goals of Member States.
- **TerraCHEM** – TerraCHEM (TerraChem, 2025) is a three-year (2023-2026) project funded by the EU and the Swiss Federation with the aim to investigate chemical pollution in terrestrial wildlife in Europe. The project develops tools and guidance to optimise environmental risk assessment, leveraging the NORMAN Database System. TerraCHEM is also a hub for data exchange, while the NORMAN network enhances the exchange of information on emerging substances and encourages the validation and harmonisation of common measurement methods and monitoring tools. A database collating toxicity thresholds for 95,000 chemicals has been established, as well as models for assessing toxicity at individual and population levels as part of the NORMAN activities. During the interview with the Slovak Environment Institute, a partner of the TerraCHEM project, the following topics were discussed: the possibility of knowledge development and sharing on soil risk assessment methods and the necessary data, important sources to review for this task, and aspects to cover in this report.
- **OVAM Public Waste Agency in the region of Flanders (Belgium)** – OVAM is the Public Waste Agency in Flanders (Belgium). Among other things, OVAM has developed policies on the prevention of soil pollution and on the restoration of soil services. The interviewee has over 30 years of experience working on the harmonisation of risk assessment methods.

During the interview the following topics were discussed: the issue of harmonisation of risk assessment methods and the S-RISK® model (Spaquet, 2025), a site-specific risk assessment tool developed in Flanders, by VITO (the Flemish Institute for Technological Research), and co-owned by all Belgian regions (Flanders, Wallonia, Brussels-Capital Region) and Luxembourg.

- **Cooperative Research Centre for Contamination Assessment and Remediation of the Environment (CrcCARE)** – The Cooperative Research Centre for Contamination Assessment and Remediation of the Environment (CrcCARE) is a partnership of organisations working on methods to deal with and prevent soil contamination (in addition to water and air contamination). The CrcCARE is an initiative of the Australian government, but its expertise is recognised globally. The interviewee is an expert in risk assessment of soil contamination, part of the Global Soil Partnership, who has been working on a global threshold value database and on the methods to derive the threshold values. During the interview the following topics were discussed: the quality assurance system used in Australia for risk assessment, the concept of bioavailability to assess the risk of contamination, insights on what other regions in the world do with respect to the harmonisation of threshold values and their possible use in site-specific risk assessments.
- **Concawe** (represented by Exxon Mobil) – Concawe is a pan-European organisation of fuel manufacturing companies, which carries out research on environmental, health, and safety issues relevant for its activities. Differently from the previous interviews, this meeting occurred after the soil expert group meeting and had the aim to discuss the preliminary findings of this task, next steps, and how the industry could be involved in this knowledge exchange.

2.3.2 Workshop

On 15 May 2025 a workshop was held with the objective to facilitate an information exchange on best practices in risk assessment methodologies. In addition, it aimed to collect feedback from participants on the key practices that ensure that risk assessment methods applied across the EU are effective, efficient, and harmonised where possible.

Prior to the workshop, the preliminary evidence gathered in the literature review and the targeted interviews was summarised in a workshop concept note. and provided to the workshop participants.

The workshop was hosted by the Common Forum on Contaminated Land in Europe as part of their Spring meeting. The Common Forum is a network of experts, regulators, policy makers, and advisors from the environment authorities across Europe (Common Forum, 2025). The Common Forum has regular exchange and meetings to discuss and develop strategies for managing and remediating contaminated sites (Common Forum, 2025). 35 participants attended the workshop, including:

- Representatives of national environment agencies and ministries of Austria, Belgium, Cyprus, Denmark, Estonia, Finland, France, Germany, Luxembourg, Portugal, Spain, Sweden;
- Representatives of environment institutes and public organisations of Belgium, France, and Finland;
- Representatives from the industry including the NICOLE network for industrially co-ordinated sustainable land management in Europe (NICOLE, 2025) and Shell; and
- A representative from the European Commission, Directorate-General for Environment.

Following a brief welcome and introduction by the European Commission and the Common Forum, the task scope and preliminary findings were presented to the participants, which were succeeded by a short discussion to collect the feedback from the audience. Keynote speakers then delivered four presentations, each followed by a Q&A:

- **Environment Agency Austria** – *Embedding prioritisation for investigation (preliminary assessment) into policy frameworks*. The Austrian and Italian legal frameworks on contaminated sites and risk assessment criteria were presented.
- **OVAM** – *Risk assessment of contaminated land: the Flemish approach and the use of the S-RISK® model*. The Flemish legal framework on soil protection was presented, followed by a presentation of the concept of risk assessment in the descriptive soil investigation and the basic principles of human health risk assessment of contaminated sites. The S-RISK® model was then presented, which serves for the calculation of 1) generic human health-based soil remediation values; 2) site-specific human health risks; and 3) site-specific remediation objectives.
- **NICOLE** – *Risk assessment from the NICOLE network perspective*. A representative of the NICOLE network highlighted the importance of cooperation between the industry, Member States competent authorities, and the Commission, and the willingness of the members of the NICOLE network to be involved in this initiative.
- **EU PARC** – *A partnership for developing a next-generation chemical risk assessment*. EU PARC is a public-public partnership to develop and implement research and innovation activities in relation to the assessment of risk of chemicals. The outputs, projects, and innovations developed through EU PARC were presented.

In between the presentations two breakout group discussions were held. Participants were split into three groups in order to allow a more detailed discussion. The two sessions regarded:

- **Best practices** focusing on the practices or guidelines to be considered when defining risk assessment frameworks, the legislative and practical approaches to risk assessment in Member States, and any relevant research project outputs to inform risk assessment methods.
- **Gaps and opportunities** focusing on the necessary support that the European Commission could provide to help further developing risk assessment methods, the gaps to be addressed to improve risk assessment methods, and the potential for harmonisation.

The outcomes of the breakout group discussions were then reported back to the plenary.

Following the workshop, participants provided additional suggestions for information sources for risk assessment methods that were then integrated in this final report.

2.3.3 Written feedback from stakeholders

The draft final report was shared with the interviewees, workshop participants (members of the Common Forum), and Soil Expert Group to invite written feedback.

2.4 Analysis and reporting

Several iterations of this report have been prepared, allowing for multiple rounds of feedback / input from the Commission and stakeholders:

- **Draft 1** – The first draft report was based on findings from the literature review and stakeholder interviews.
- **Draft 2** – The second draft incorporated feedback from the Commission.

- Draft 3 – The third draft incorporated findings from the workshop.
- Final report – This version of the report incorporates written feedback provided by stakeholders and the Commission.

2.5 Limitations

This task aimed to facilitate discussion between stakeholders and gather information on examples of risk assessment methods. Due to the nature of the literature review (focusing on certain geographies) and different levels of engagement from different stakeholders, approaches of some countries are described in more detail compared to others.

It is important to note the breadth and depth of risk assessment methodologies, as demonstrated by Swartjes, F., (2011) in the text book '*Dealing with Contaminated Sites*'. This project therefore covers some key information on risk assessment methods. However, further research could be done to achieve a comprehensive review of existing risk assessment methodologies, to focus on specific aspects and definitions, and on operational constraints, including cost and data requirements.

PART B – Findings on risk assessment methodologies for soil contamination

3. Review of risk assessment methods for soil contamination

3.1 Overview

The sections below provide an overview of the main risk assessment methods reviewed as part of this work. In the context of this report, environmental risk assessment is defined as the examination of risks associated with threatened ecosystems, animals and people. Hence, environmental risk assessment is understood as an overarching term typically including human health risk assessment, ecological risk assessment, and other methods relevant for specific applications (European Environment Agency, 1998; United States Environmental Protection Agency, 2025).

3.2 Context

It is estimated that, directly or indirectly, soils are at the base of 95% of the food we eat, as they supply essential nutrients, water, and oxygen (Food and Agriculture Organization, 2015) and they support life above and below ground (Food and Agriculture Organization, 2020). In addition, more than 25% of global biodiversity is contained in the soil (Food and Agriculture Organization, 2020).

Soils in Europe face many pressures, from urban development and land take to unsustainable agricultural practices, contamination with toxic chemicals, and others (European Environment Agency, 2019). As a result of these pressures, an estimated 60 – 70% of soils in the EU are unhealthy³ (European Commission, 2020). This report focuses on the pressure from contaminated sites, which presents a widespread issue in Europe. Contaminated sites are delineated areas with confirmed soil contamination due to point-source release of contaminants associated with anthropogenic activities (Directive (EU) 2025/2360). The causes of point-source contamination in soil may include industrial and mining activities, leakages and spills, and leaching of chemicals from landfill sites (European Environmental Agency, 2022). Furthermore, many toxic chemicals are mobile in the environment with potential for long range transport and can be deposited in soil after being transported in the air, e.g. from industrial emissions of chemicals. Billions of tonnes of chemicals are released into the environment through air, water, and waste streams each year (Naidu, et al., 2021).

The full extent of contamination and the scale of risks to human health and the environment are unknown. Previous estimates have suggested that there may be around 2.8 million potentially contaminated sites⁴ in Europe (Joint Research Centre, 2018). Almost two-thirds of point-source pollution in Europe is estimated to be caused by industrial and commercial activities and waste management and disposal (FAO & UNEP, 2021). The main contaminants found in soils associated with these activities are mineral oils, trace elements (e.g. arsenic, cadmium and zinc) and organic contaminants (e.g. halogenated and non-halogenated solvents, polychlorinated biphenyls (PCBs) and polycyclic aromatic hydrocarbons (PAHs)) (FAO & UNEP, 2021). Extensive contamination of per- and polyfluoroalkyl substances (PFAS) has also been observed in the EU, with maps showing contaminated sites scattered across Member States (The forever pollution project, 2025). This raises alarm given that certain types of PFAS have been proved to cause effects on human health,

³ 'Soil health' is the physical, chemical and biological condition of soil, determining its capacity to function as a vital living system and to provide ecosystem services. Directive (EU) 2025/2360, OJ L, 2025/2360.

⁴ Potentially contaminated sites are delineated areas where soil contamination or contamination of bedrock or parent material caused by anthropogenic point-source activities is suspected based on relevant evidence (Directive (EU) 2025/2360).

including cancer, liver damage, decreased fertility, low birth weight, and immune system effects (Goldenman, et al., 2019). Other chemicals such as metals, microplastics, phthalates, polycyclic aromatic hydrocarbons (PAHs), and pharmaceuticals also pose risks to the environment, which in combination, can lead to additive risks to health and the environment. There is consequently an urgent need to ensure that risks from contaminated sites across the EU are sufficiently investigated, assessed, and prioritised so that appropriate risk reduction measures and remediation can be undertaken to protect humans and the environment.

The Soil Monitoring Law⁵ is anticipated to improve the rates of contaminated site risk assessment in the EU. To effectively protect human health and the environment, scientifically robust risk assessment methods must be implemented. Current approaches differ substantially between Member States due to various reasons (e.g. geological background, protection principles, etc.), covering different contaminants, with different thresholds for acceptable levels of risk, and different protection goals. Therefore, identification of best practices is important to enhance the level of protection and level playing field across the EU.

The Soil Monitoring Law highlights the importance to follow a risk-based and stepwise approach to identify and investigate potentially contaminated sites which might pose a risk to human health and the environment. Member States will be required to identify potentially contaminated sites systematically and according to their potential to cause soil contamination based on scientific evidence (Article 14), investigate them (Article 15), and assess and manage the site-specific risks of contaminated sites for human health and the environment (Article 16). The law also provides that risk assessments should take into account the natural and anthropogenic background levels. In addition, the law requires the Commission to provide Member States with the necessary support to facilitate them to lay down the methodology for site-specific risk assessment of contaminated sites and other obligations of the Directive. This should be done in cooperation with competent authorities through documents and scientific tools, as well as through regular exchange of information, experience, and best practices (Article 24).

3.3 Considerations for defining and selecting risk assessment methods

This section provides an overview of selected risk assessment frameworks, what they typically include, and what should be taken into account when selecting a method.

The importance of effective management of contaminated sites has inspired the creation of various frameworks for the assessment of risks from soil contamination, with a tiered and stepwise approach being crucial and commonly applied within the frameworks.

Risk assessment methods and tools follow similar structures, models and principles, often based on protection goals or considering long-term/short-term risks. They provide the basis for determining an appropriate management response in each management step to reduce the number of sites with potential or identified risks in an appropriate timeframe. The assessment process involves progressively more detailed steps as the level and type of site contamination is characterised. For example:

1. **Initial risk screening:** used to determine sites where contamination is suspected/most likely but not confirmed.
2. **Preliminary risk assessment:** conducted to determine whether further investigation is necessary to confirm a suspected/most likely contamination.
3. **Site-specific risk assessment:** applied to sites with confirmed contamination, assessing the nature and extent of the risks.

⁵ OJ L, 2025/2360, 26.11.2025.

Generally, the process to build a framework for defining unacceptable risks to human health and the environment starts from legally defined objectives or standards. A tiered approach involves several steps from qualitative risk assessment and expert judgement, based on available information, towards a sound quantitative modelling and exposure analysis. Such an approach requires further specification in defining a clear risk assessment objective (receptor), that is an explicit environmental or health variable to be protected. For the environment, this could include an ecological entity and its attributes (Swartjes, F., 2011).

A typical risk assessment procedure considers the “source-pathway-receptor” paradigm. This means:

1. Identifying the source(s) of contamination, that is at the origin or release points of contaminants to the environment;
2. Evaluating the pathway(s) through which contaminants are being transported from the source to the potential receptors; and
3. Assessing the receptor(s), that is the human population or the environment, organisms and natural ecosystems that would be exposed and adversely affected by the contaminants.

The literature has highlighted that in this process, a crucial step is to provide a clear definition of “receptors”. Perspectives vary in terms of environmental (or ecological) risks, which might involve either selected target organisms or overall risks to an ecological system.

It is also crucial to consider the characteristics of the soil and hydrogeological conditions in, and in proximity to, the contaminated sites. Aspects such as the interaction of the contaminants with soil parameters (e.g. pH) or the soil type (e.g. clay, loamy) influence the behaviour of the contaminants in the soil matrix and external parameters (e.g. rainfall) will accelerate or slow down biochemical and physical processes.⁶

Several types of environmental risk assessments have been identified, which may be used depending on what target receptor(s) are selected. These include:

- **Human health risk assessment**, which estimates the nature and probability of adverse health effects in humans who may be exposed to contaminants through different possible pathways (e.g. ingestion, inhalation, food, drinking water, etc.). It usually sets a substance-specific threshold for tolerable exposure (as a reference dose or tolerable daily intake), below which no significant risk to human health is expected.
- **Ecological risk assessment**, which estimates the effects of contamination on ecosystems. In order to derive indices of ecological risk and ecologically based soil quality standards, species sensitivity distributions are used, as they represent the statistical distributions of toxicity values for different biological species.
- Other **relevant risk assessments methods**⁷ include **water quality-based methods** looking for instance at leaching of contaminants to groundwater and/or surface water, as well as at the risk of exceedance of environmental quality standards (EQS) (i.e. concentration limits in water for particular chemicals or groups of chemicals, derived under the EQS Directive to protect human health and the environment).

⁶ Additional feedback provided by stakeholders.

⁷ The list of risk assessment methods does not aim to be exhaustive and focuses on the most relevant methodologies in the context of soil contamination. Other potentially relevant methodologies include, for instance, spreading-based risk assessment and chemical-specific risk assessments.

3.4 Human health risk assessment

Human exposure to contaminated sites can have diverse health impacts, ranging from acute to chronic effects. Human exposure may result from direct contact with soil or through exposure to contact media, for example, through consuming water, vegetables⁸, animal products⁹, inhaling indoor air and dust¹⁰ or oral soil ingestion¹¹ (Swartjes & Cornelis, 2011).¹²

When doing the assessment, the receptor under consideration varies depending on the land use. The most sensitive land use scenarios include residential use, due to young children being included as one of the most vulnerable receptors or homegrown produce being included as an exposure pathway. Comparatively, in the industrial land use scenario, the receptor is an adult human with shorter exposure due to working patterns.¹³

Different parameters can be taken into account in a human health risk assessment. This includes the predicted dose of harmful substances compared to the maximum acceptable dose; background levels in drinking water, food, air, and soil (if an integrated approach is used); and concentration limits e.g. in drinking water, agricultural products, air, and soil.¹⁴

Additionally, human health risk assessments (as well as ecological risk assessments discussed below) might take into account the bioavailable fraction of the contaminants, i.e. the biologically absorbable elements present in the soil. This is required for an accurate assessment, for example, in the case of potential human health risks through vegetable consumption. The available soil fraction could be defined in terms of mobility, solubility, absorption, as soil parameters defining persistence and/or leaching.¹⁵ However, quantifying the bioavailability fraction remains a difficult task for some pollutants¹⁶ (Chen et al., 2023).

In general, the steps to follow in a human health risk assessment are as follows (Swartjes & Cornelis, 2011):

1. **Problem definition:** the scope of the risk assessment needs to be defined, possibly following legal objectives. Regulators often impact the performance of risk assessments (both at their initiation and implementation) and define boundary conditions (e.g. targeted population groups to protect). It is also important to involve various stakeholders and to have communication between the scientists and regulators from early stages of the process. This step might involve the development of a Conceptual Site Model (CSM).¹⁷
2. **Exposure assessment:** this step provides a quantitative evaluation of human exposure to contaminants in soil and includes information on intensity, frequency and duration of exposure, route of exposure, rates, and the amount of internal and external exposure. Exposure assessments are based on exposure scenarios describing the site, soil, and human behaviour at the site. As part of the exposure assessment, the estimated exposure of humans to the contaminants is calculated through modelling or

⁸ Contaminants in soil can be taken up by plants through their roots or deposited on leaves and surfaces.

⁹ Animal products (i.e. eggs, meat or milk) can be potentially contaminated through: i) the animal's soil intake while feeding outdoors or due to deposition of soil on forage; and ii) intake of contaminated feed crops.

¹⁰ For sites with buildings, intrusion of vapours, infiltration of outdoor air or dust carried into closed areas might result in exposure in indoor spaces.

¹¹ For example, by playing children.

¹² Feedback from stakeholder workshop.

¹³ Additional feedback from stakeholders.

¹⁴ Feedback from stakeholder workshop and additional feedback from stakeholders.

¹⁵ Additional feedback provided by stakeholders.

¹⁶ For soil contamination derived from metals, studies are available assessing bioavailability. For example see the following paper: [https://d1wqtxs1xzle7.cloudfront.net/121310211/08-592.120250212-1-q9pg07-libre.pdf?1739351138=&response-content-](https://d1wqtxs1xzle7.cloudfront.net/121310211/08-592.120250212-1-q9pg07-libre.pdf?1739351138=&response-content-disposition=inline%3B+filename%3DToxicity%20of%20Trace%20Metals%20in%20Soil%20as%20Affected%20by%20Soil%20Contamination.pdf&Expires=1764610947&Signature=ZqS79Sw~bMGr-9Dgo9WKUqR2qGr18ghgX)

[disposition=inline%3B+filename%3DToxicity of Trace Metals in Soil as Affected by Soil Contamination.pdf&Expires=1764610947&Signature=ZqS79Sw~bMGr-9Dgo9WKUqR2qGr18ghgX](https://d1wqtxs1xzle7.cloudfront.net/121310211/08-592.120250212-1-q9pg07-libre.pdf?1739351138=&response-content-disposition=inline%3B+filename%3DToxicity%20of%20Trace%20Metals%20in%20Soil%20as%20Affected%20by%20Soil%20Contamination.pdf&Expires=1764610947&Signature=ZqS79Sw~bMGr-9Dgo9WKUqR2qGr18ghgX)).

¹⁷ Feedback from stakeholder workshop and additional feedback from stakeholders.

measuring. A direct way to assess exposure is through human biomonitoring, i.e. by sampling and measuring body fluids or body tissue. However, due to its limitations, biomonitoring is not routinely used, and when used, it is only in the higher tiers of risk assessment. Its limitations include difficulties in sampling or in determining the share of contamination due to soil as opposed to other sources¹⁸, and its high costs. Alternative approaches include environmental monitoring of contaminant concentrations in the soil and estimating the extent to which humans may be exposed. Additionally, monitoring other media, such as drinking water, vegetables, or fish, could be useful in the assessment of exposure.¹⁹

3. **Hazard assessment:** this step aims to determine the degree contaminants are able to cause adverse effects in the human body (i.e. the toxicity). This requires hazard identification, which defines the type and nature of adverse effects of the contaminants, and hazard characterisation, which quantifies the adverse effects. Hazard characterisation ideally results in a dose-response assessment, from which critical exposure values (e.g. predicted no-effect concentrations or maximum tolerable concentrations) are derived. Critical exposure values act as a threshold to determine if contamination likely poses a risk of adverse effects on human health. Assessment factors are often applied to account for uncertainties, e.g. to extrapolate non-human toxicity data to humans, to take into account variability in the human population, or to extrapolate the duration of exposure (The Interdepartmental Group on Health Risks, 2003).
4. **Risk characterisation:** this step combines the results of steps 2 and 3, i.e. comparing estimated exposure with critical exposure, to conclude on whether exposure levels exceed toxicity effect levels. This step results in a conclusion on the contamination status with respect to the risk for human health.

3.4.1 Site-specific human health risk assessment

Based on publicly available case studies, a common approach for a site-specific risk assessment can involve multiple tiers. As the level of tiers increases, the specificity of the elements covered by the assessment also rises, increasing the representativeness and accuracy of the risk assessment. Higher tier assessments are more complex, time-consuming, and costly (Swartjes & Cornelis, 2011), but can be essential for the identification of appropriate risk management measures and subsequent reduction/avoidance of human health impacts.

Generally, the first tier is a generic assessment including the steps described above, comparing measured values of soil contamination at site level with generic soil quality standards²⁰. Including further tiers in the assessment implies the use of information on the site context. Hence, a key difference between general and site-specific human health risk assessments with several tiers is that in the latter, actual exposure scenarios are estimated (as opposed to potential exposure scenarios based on standardised conditions in terms of geographical conditions and human behaviour). Actual exposure scenarios should include as many details as possible on the specific characteristics of the site, human behaviour, and the soil under investigation (Swartjes & Cornelis, 2011).

Risk characterisation in higher tiers of a site-specific assessment (e.g. tier 2 and 3 of the example below) compares actual exposure on site with critical exposure to conclude on the level of risk. The risk is acceptable when actual exposure does not exceed critical exposure, while it is unacceptable when actual exposure exceeds critical exposure. Alternatively, a risk index might be estimated to express the results of site-specific assessments. A risk index allows to qualify different levels of

¹⁸ Additional feedback from stakeholders.

¹⁹ Additional feedback from stakeholders.

²⁰ These are generic soil quality standards which might be derived based on a standardised conceptual site model and exposure assumptions (additional feedback from stakeholders).

risks through a risk scale (e.g. including categories such as “very high human health risk”), providing useful guidance for priority setting in decision-making (Swartjes & Cornelis, 2011). Additional stakeholder feedback suggested that the risk index approach is lower tier (simpler) rather than higher tier assessments.

An example of a site-specific human health risk assessment using a multi-tier approach is provided by the Netherlands. It is used to assess contamination associated with volatile compounds in soil and consists of the following steps (Bakker, Lijzen, & Wijnen, 2008):

1. **Preselection:** this step includes the definition of the risk assessment’s goal and establishes what measured concentrations or other conditions need to be met in the site to continue the assessment (e.g. level of contaminant concentration in soil, depth of contaminant, etc.).
2. **Tier 1 – simple assessment:** this step determines the relevant exposure pathways on site and compares, through a generic assessment, if contaminant concentration levels in soil exceed thresholds below which there is no risk to human health.
3. **Tier 2 – scenario risk assessment:** this step incorporates site-specific exposure information and measured concentrations using site-specific data.
4. **Tier 3 – detailed risk assessment:** when further analysis is necessary, e.g. due to uncertainties around the level of risk, this step requires the collection of additional site-specific data. Depending on the nature of the risk, additional measurements in contact media might be taken, for instance, including concentrations in air, plants, drinking water or fish.

3.5 Ecological risk assessment

Compared to human health risk assessment, which focuses on one species (humans), ecological risk assessment focuses on the impacts of soil contamination on the overall ecosystem (i.e. terrestrial and aquatic when relevant), which involves many different species (e.g. including plants, animals and microorganisms). Protecting the soil is important for environmental protection and protection of ecosystem services²¹. In order to protect such services, the organisms responsible for them in the soil ecosystem need to be protected, by considering the ecosystem as a whole system of mutually dependent organisms (Swartjes, Breure, & Beaulieu, 2011). Stakeholders have different interests in soil ecosystem functions and there is not an ideal state for the soil ecosystem, which then becomes a responsibility of the regulators to define. From the literature it is clear that the worldwide use of different ecological risk assessment tools has called for the need to improve the international consistency of the technical parts of the ecological risk assessment procedures, in order to reach some degree of harmonisation (Swartjes, Breure, & Beaulieu, 2011).

In general, the steps to follow in an ecological risk assessment are as follows (Swartjes, Breure, & Beaulieu, 2011):

1. **Problem definition:** Firstly, the receptors must be properly defined²², i.e. soil-dwelling organisms (plants, animals and microorganisms), vertebrates via secondary poisoning, etc. Next, the protection target needs to be defined. The decision makers have the responsibility to define the soil protection level, for example in terms of soil quality standards, that is the acceptable fraction of the organisms or of the ecosystem services that can be potentially affected by contaminants. A 95% target for species

²¹ Ecosystem services are defined as the benefits that an ecosystem supplies on which humans depend. Examples include the provision of food and water, climate regulation, the provision of cultural services, and supporting services like pollination and nutrient cycling (European Union, 2025).

²² This is also not harmonised across regulatory schemes (additional feedback provided by stakeholders).

protection goal is common in chemical risk assessment (Carlton, D'Alessandro, & Swartjes, 2007).

2. **Exposure and hazard assessments:** This step analyses the exposure and potential damage caused by pollutants in soil. Differently from the human health risk assessment, the exposure assessment and hazard assessment steps are often combined in the ecological risk assessment. For example, experiments may be undertaken to expose earthworms to contaminated soil and directly measure the effects on the population.²³ This combination of the two steps results in more reliable estimates of the relationship between contaminant concentration in soil and ecotoxicological effects.
3. **Risk characterisation:** Based on the results from the previous step, the risk is estimated, and a conclusion is reached on the contamination status in relation to the risk for the ecosystem. When assessing the risks, for example, for plants or for wildlife dermal exposure, the bioavailable concentration of contaminants might be considered, that is, a specific fraction of contaminants in soil that is potentially available to be taken up by organisms.

An accurate assessment of risk could include the quantification of the bioavailable fraction of the contaminants (which is defined in the section above). Bioavailability modelling is currently being developed in Australia to make generic thresholds applicable to certain soil types²⁴. Specifically for the contamination of soil caused by metals, a bioavailability modelling tool exists: the Soil Threshold Calculator. This is a risk assessment tool which allows for determining ecotoxicological thresholds for different protection objectives and for different metals, leveraging available bioavailability models to derive soil quality standards (Arche Consulting, 2020).²⁵

3.5.1 Site-specific ecological risk assessment

Site-specific ecological risk assessment is a structured process used to support decision-making for managing contaminated sites. It helps guide land-use planning, adaptive management, and the setting of remediation goals by estimating ecological risks based on site-specific data (Swartjes, Rutgers, & Jensen, 2011).

The ecological risk assessment process involves collecting, organising, and analysing environmental data to assess potential harm to the whole relevant ecosystem. The complexity of an ecological risk assessment can vary from straightforward assessments to more advanced evaluations requiring input from multiple experts and stakeholders (Swartjes, Rutgers, & Jensen, 2011).

Regardless of complexity, all ecological risk assessments aim to identify and address potential adverse ecological effects. The process typically begins with a first-tier (screening-level) risk assessment, using conservative benchmarks such as national soil quality standards, adjusted for local conditions (Swartjes, Rutgers, & Jensen, 2011).

Key steps in a site-specific ecological risk assessment include (Swartjes, Rutgers, & Jensen, 2011):

1. **Initial screening:** Determine whether ecological concerns exist at the site.

²³ One stakeholder highlighted that these experiments are usually not done during the risk assessment of a contaminated site. Instead, they are needed when threshold values for pollutants are assessed.

²⁴ Feedback from targeted interview.

²⁵ Additional feedback provided by stakeholders.

2. **Stakeholder and expert involvement:** Establish a steering committee and risk assessment team, involving to the extent possible regulators, landowners, site managers, academics, and consultants.
3. **Conceptual Site Model (CSM) development:** Ensure early agreement on ecosystem targets, land use, and protection goals.
4. **Land-use determination:** The steering committee and assessors define the intended land use, which guides risk assessment parameters.
5. **Risk assessment implementation:**
 - 5a. **Identify ecological requirements** and associated protection levels (as derived from step 3) relevant to the selected land use;
 - 5b. **Define and agree on assessment endpoints** (e.g., biodiversity, nutrient cycling) and select appropriate tools and bioassays for evaluating risks to those endpoints.

The goal of selecting assessment tools (step 5b) in ecological risk assessment is to reduce uncertainty and provide clear, quantifiable insights into ecological effects. Each tool measures a specific aspect of ecosystem health and translates it into a standardised, one-dimensional value on a uniform ecological effect scale (Swartjes, Rutgers, & Jensen, 2011).

Tools to support the assessment can range from simple screening methods (e.g. basic bioassays or toxicity thresholds based on concentration and literature data), to advanced, site-specific techniques (e.g. Biotic Ligand Model outputs, nematode maturity index, or food web stability indices) (Swartjes, Rutgers, & Jensen, 2011).

In lower-tier assessments, tools should be standardised, cost-effective, reliable, and sensitive enough to detect effects under realistic field conditions. It is recommended that tools should integrate some effects like the ageing-leaching effect due to historical contamination, as well as physical soil characteristics like soil texture.²⁶ In higher tiers, more complex and tailored tools are used to increase precision and site-specific relevance (Swartjes, Rutgers, & Jensen, 2011).

Each assessment tier should include three types of tools, each offering a different line of evidence. A balanced integration of these lines is needed when the tools offer comparable levels of insight (Swartjes, Rutgers, & Jensen, 2011):

- Chemical analysis (e.g. contaminant concentrations),
- Toxicity testing (e.g. bioassays), and
- Ecological observations (e.g. field surveys).

Tools must align with the ecological endpoints being assessed (e.g. biodiversity, nutrient cycling). Since many endpoints cannot be directly measured, models or surrogate indicators are often used, with support from literature or track records (Swartjes, Rutgers, & Jensen, 2011).

All tool outputs must be translated onto a unified ecological effect scale (e.g. growth inhibition, reduced reproduction). This scaling ensures consistent interpretation across tools and enhances integration into transparent decision-making frameworks such as decision matrices (Swartjes, Rutgers, & Jensen, 2011) (Swartjes & Cornelis, 2011).

3.6 Water quality-based methods

Water quality-based methods look at the risk of chemicals leaching to groundwater and/or surface water from contaminated sites. This example looks at an approach for groundwater.

²⁶ Additional feedback provided by stakeholders.

Groundwater might contain natural contaminants, and, in certain cases, anthropogenic contaminants might reach those water bodies if not well protected. From a risk assessment perspective, groundwater is analysed both as a protection target, being a source of drinking water, and as a means of transport for contaminants (Swartjes & Grima, 2011). The potential risks derived from the human consumption of drinking water associated with (potentially) contaminated sites are commonly assessed within human health risk assessments. In many countries, a tiered approach is used to assess site-specific human health risk assessments related to the transport of contaminants in groundwater. Usually, the complexity of the assessment increases with the site-specificity in each tier. This typically involves (Swartjes & Grima, 2011):

- Tier 0: The initial characterisation of the contaminated groundwater body, which is based on criteria reflecting local conditions;
- Tier 1: A simple generic calculation of the contaminant transport;
- Tier 2: A site-specific calculation of the contaminant transport;
- Tier 3: Monitoring.

Many contaminants reach the subsurface either by being intentionally applied to soil or unintentionally leaking from industrial and municipal waste disposal sites. Mathematical models can be used for the higher tiers of groundwater-related risk assessments. They can help predicting site-specific contaminant transport in subsurface water, as well as supporting the development of sound strategies for resource management, remediation of contaminated sites, and prevention (Mallants, Van Genuchten, Simunek, Jacques, & Seetharam, 2011).

Example approaches looking at surface water risks are described in subsequent sections of the report, e.g. Denmark and Sweden set protection goals for surface waters (see section 6.2 and 6.4).

4. Review of existing policy guidance and enabling initiatives

4.1 Overview

This section describes international and EU-wide standards, as well as an overview of relevant ongoing initiatives in relation to risk assessment of soil contamination. The section provides context and useful inputs (e.g. new risk assessment methods under development) which may inform and can be used as a starting point for the development or adaptation of risk assessment methodologies.

4.2 International standards and policies

This section introduces international efforts related to risk assessment of contaminated land.

4.2.1 WHO

During the 6th Ministerial Conference on Environment and Health in 2017, the World Health Organization (WHO) set up a priority for action to address the challenge related to contaminated sites and health. From this commitment, the WHO European Centre for Environment and Health (WHO ECEH) was established with the objective to establish an evidence base on the health impacts of contaminated sites and to support countries in their efforts to assess and mitigate the associated risks. As part of a capacity building exercise, WHO ECEH published a series of briefings to review the evidence on the health impacts of contaminated sites and provide technical advice on redevelopment of contaminated sites (World Health Organisation European Centre for Environment and Health, 2021a), (World Health Organisation European Centre for Environment and Health, 2021b).

4.2.2 ISO standards

The International Organization for Standardization (ISO) standards²⁷ are a set of internationally agreed standards that ensure that products and services are safe and reliable, and that sustainable and ethical business practices are globally adopted (International Organization for Standardization, 2025a). Relevant ISO standards in the context of risk assessment of contaminated soil include:

- **ISO 18400-100 to ISO 18400-301** (soil quality – sampling) are a series of standards referring to site investigation strategies and soil sampling. The standards under this series cover guidance in relation to sampling stands, plans, techniques and strategies, among other aspects of the soil sampling process. **ISO 18400-203** (soil quality – sampling Part 203: investigation of potentially contaminated sites) provides details to inform the investigation of potentially contaminated sites, consisting of various phases including preliminary, exploratory and detailed site investigations. It contains information regarding, for instance, data collection for the development of risk assessments and remedial action plans (International Organization for Standardization, 2018a).

²⁷ Feedback from the stakeholders workshop have highlighted the relevance of ISO standards in the context of contaminated sites.

- **ISO 19204** (soil quality – procedure for site-specific ecological risk assessment of soil contamination) provides a procedure for site-specific ecological risk assessment of contaminated soils, defined as the soil quality Triad approach. The Triad approach assesses three components, which allow an efficient and robust risk assessment of contaminated soils (International Organization for Standardization, 2017), (Kim, D. et al., 2023):
 - ▶ **The chemical assessment** quantifies the contaminants concentration in the site;
 - ▶ **The ecotoxicological assessment** evaluates the soil ecotoxicity, either on-site or in the laboratory;
 - ▶ **The ecological assessment** uses ecological surveys to quantify changes in the biological community on-site.

It is a tiered process consisting of three tiers, as the tier levels increase, more complex and expensive analysis is needed. This standard describes the process at a general level and refers to other technical standards (e.g. ISO 15799 (soil quality – guidance on the ecotoxicological characterisation of soils and soil materials), ISO 17616 (soil quality – guidance on the choice and evaluation of bioassays for ecotoxicological characterisation of soils and soil materials) which are useful for the risk assessment.

- **ISO 21365** (soil quality – conceptual site models for potentially contaminated sites) provides details of the phases to develop and apply a conceptual site model for potentially contaminated sites. It includes guidance, for instance, to carry out preliminary assessments, detailed investigations and feasibility studies, as well as to establish the baseline for human health and environmental risk assessments. ISO 21365 also provides guidance on the use of conceptual site models in remediation processes and any associated construction or engineering work (International Organization for Standardization, 2019a).
- **ISO 16133** (soil quality – guidance on the establishment and maintenance of monitoring programmes) provides general guidance to establish and maintain long-term monitoring programmes for soil quality. It includes general considerations for monitoring programmes, their various elements, as well as instructions to carry out sampling and measurement (International Organization for Standardization, 2018b).
- **ISO 15800** (soil quality – characterisation of soil with respect to human exposure) provides details of soil and site characterisation to evaluate human exposure to contaminants, informing the development of human health risk assessments. It provides background on the potential human receptors and exposure pathways, and details the approach for sampling for soil characterisation and the analytical strategy to follow to characterise contamination (International Organization for Standardization, 2019b).
- **ISO 15175** (soil quality – characterisation of contaminated soil related to groundwater protection) relates to groundwater contamination, including guiding principles and methods for evaluating sites, soils, and soil materials, as well as their functions in retaining, releasing, and transforming contaminants. The document establishes the procedures for assessing direct and indirect inputs to groundwater and provides a three-tier approach to evaluate, for instance, potential leaching risk, substance concentration in soil water, and degradation of organic contaminants (International Organization for Standardization, 2018c).
- **ISO 19258** (soil quality – guidance on the determination of background values) provides guidelines to support the determination of background values for inorganic and organic substances in soils at a local and regional scale. The guidelines define methods for the sampling and data processing strategies (International Organization for Standardization, 2018d).

4.2.3 Minamata Convention on Mercury

The Minamata Convention on Mercury, adopted in 2013, contains provisions associated with the identification, assessment and management of sites contaminated with mercury. To inform the parties in this context, the Secretariat developed a guidance document addressing the main elements for the identification and management of contaminated sites. The guidance document provides an overview of general considerations when identifying and characterising a contaminated site, as well as for developing inventories and carrying out human health and ecological risk assessments. The document incorporates best environmental practices and best available techniques (Minamata Convention on Mercury, 2019).

4.2.4 Stockholm Convention on Persistent Organic Pollutants (POPs)

The Stockholm Convention, adopted in 2001, is a global agreement to protect human and ecosystem health from persistent organic pollutants. Parties of the Convention agree to take action to eliminate or reduce the release of these pollutants into the environment. Recently, the Secretariat has published a comprehensive guidance document on best environmental practices and best available techniques for the management of POPs contaminated sites, including insightful chapters related to site investigation, assessment and CSM, as well as tiered ecological risk assessment (chapters 3 and 4) (Stockholm Convention on Persistent Organic Pollutants, 2025).

4.3 EU-wide standards and policies

This section introduces the EU level policies and standards related to risk assessment of contaminated land. Some of these were discussed more in detail in section 3.2.

- **The Soil Monitoring Law²⁸** has the objective to set up a framework to continuously improve soil health in the EU, maintain soils in healthy condition, and tackle all aspects of soil degradation, with the view to achieve healthy soils by 2050. It includes provisions for the risk assessment and management of contaminated sites.
- **The EU Soil Strategy for 2030²⁹** aims that by 2050 all EU soils are healthy and more resilient, soil pollution is reduced to levels that are considered healthy for human health and the environment, and promotes sustainable management practices.
- **The Commission 'One substance, one assessment' package**, adopted in November 2025, includes three legislative acts to make the assessments of chemicals more efficient, coherent and transparent across EU legislation (European Parliament Research Services, 2025; Council of the EU, 2025). As stated in the EU Soil Strategy³⁰, the EU aims to improve and harmonise the consideration of soil quality in risk assessments for chemicals, under the 'One substance, one assessment' initiative.
- **The Commission technical guidance document on risk assessment** (European Commission, 2003) is one of the main methodological references used by Member States to derive soil screening values (Carlton, D'Alessandro, & Swartjes, 2007). Soil screening values are generic quality standards that are used to regulate land contamination and can help setting long-term objectives or enforce remedial action (Carlton, D'Alessandro, & Swartjes, 2007).
- **The Environmental Liability Directive³¹** establishes a framework for environmental liability based on the polluter pays principle, to prevent and remedy environmental damage.

²⁸ OJ L, 2025/2360, 26.11.2025.

²⁹ COM (2021) 699 final.

³⁰ COM (2021) 699 final.

³¹ OJ L 143, 30.4.2004, pp. 56–75.

It includes remedial action for contaminated and provides guidelines for risk assessments and remediation.

- **The Water Framework Directive³²** establishes a framework for the protection of inland surface waters, transitional waters, coastal waters and groundwater. The Water Framework Directive is supported by **the Groundwater Directive³³**, which establishes measures in order to prevent and control groundwater pollution, and by the Environmental Quality Standards Directive³⁴ provides environmental quality standards for priority substances and certain other pollutants with the aim of achieving good surface water chemical status. Such directives are relevant considering the direct link between soil health and water quality, and specifically the leaching of contaminants from soil to groundwater and to surface water through runoff.
- **The European Environment Agency (EEA) and the Joint Research Centre (JRC) indicator “Progress in the management of contaminated site in Europe”** is based on national initiatives and data from national inventories of contaminated sites and helps quantifying contaminated sites in the EU and progressing towards remediation (European Environment Agency, 2025c).
- **The European Chemicals Agency (ECHA) guidance on information requirements and chemical safety assessment** serves to inform economic operators placing substances on the market to fulfil their obligations under the REACH Regulation. The guidance focuses on regulatory risk assessment; it is therefore not directly applicable to the focus of this report. Nevertheless, the guidance contains useful information to inform the development of contaminated site risk assessment in terms of hazard assessment (e.g. related to information gathering and hazard characterisation) and risk characterisation (e.g. on the development of risk characterisation ratio and other methods for quantitative and qualitative risk characterisation) (ECHA, 2011).
- **The European Food Safety Authority (EFSA) guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals** provides a flexible overarching framework to harmonise the approach for carrying out risk assessments in the case of contamination by multiple chemicals. The framework follows the general approach to human health risk assessment as described in section 3.4 and provides guidance to apply a multiple-tier approach. The guidance includes differentiated methods to assess risks following a whole mixture approach or a component-based approach (EFSA, 2019).

4.4 Enabling initiatives

4.4.1 EU PARC

Among ongoing initiatives that could result in the development of new risk assessment methods, EU PARC is a public-public partnership under Horizon Europe for developing a next-generation chemical risk assessment (European Partnership for the Assessment of Risks from Chemicals, 2025). EU PARC started in 2022 and has an estimated duration of 7 years, receiving support from 24 Member States, 5 additional countries and 3 European agencies (EEA, EFSA and ECHA) (Moeller, 2025).

The initiative’s overarching goal is to minimise negative impacts of chemicals on the human population and the environment, progressing towards a toxic-free environment. To pursue such a goal, EU PARC involves a number of stakeholders including the European Union, Member States

³² OJ L 327, 22.12.2000, pp. 1–73.

³³ OJ L 372, 27.12.2006, pp. 19–31.

³⁴ OJ L 348, 24.12.2008, pp. 84–97.

and third countries, and public partners (such as EU and national risk agencies, universities, public research organisations) (Moeller, 2025). The aim is to jointly support the development and implementation of a programme of research and innovation activities in relation with the assessment of risk of chemicals (EU PARC, 2025a).

The initiative supports the Chemical Strategy for Sustainability (COM/2020/667 final) and the Zero Pollution Action Plan (COM/2021/400 final) and addresses regulatory concerns, while anticipating new regulations. EU PARC aims to harmonise risk assessment methodologies by providing European-wide exposure data and integrated monitoring, as well as health-based guidance values and hazard assessment. For instance, the PARC Integrative Model Network is a compilation of interconnected models and modelling tools aiming at assessing chemical impacts on human health and the environment. The network contributes to streamlining integrative risk assessments based on practical methods and international guidance, creating an inventory of tools, enhancing interoperability between those tools, and informing decision-making (EU PARC, 2025b).

EU PARC is developing several projects relevant in the context of risk assessments of contaminated sites, some examples include:

- “Beyond food: organic contaminants in daily environments”. This project aims to improve understanding of human exposure to harmful chemicals via indoor air, dust, soil and drinking water. For this purpose, the project links contaminant levels in human samples with environmental data collected from the individuals’ houses and their surrounding environment. The project’s outcomes inform the development of more complete and integrated human exposure assessments, which can contribute to human health risk assessments (EU PARC, 2024).
- “Developing a sustainable European human biomonitoring framework”. The project aims at developing a human biomonitoring framework for assessing chemical exposure in Europe to ensure harmonised data collection across Member States (EU PARC, 2022a).
- “Enhancing the reusability of human biomonitoring data for improved health risk assessment”. The project aims at ensuring that human biomonitoring datasets, which track chemicals and their impact on human health, are easy to find, accessible, and interoperate, and that data can be reused (EU PARC, 2022b).
- “Environmental and multisource monitoring: Pilot study on PFAS and endocrine disruptors”. The pilot study is part of PARC’s efforts to address chemical risk assessment of environmental ecosystems and human exposure by establishing and validating environmental monitoring structures for PFAS and endocrine disruptors (EU PARC, 2022c).

4.4.2 HERACLES

HERACLES (human health and ecological risk assessment for contaminated land in EU Member States) was an international network that aimed at increasing consistency of risk assessment tools and promoting the development of common references for risk assessment across the EU for the appraisal of contaminated sites. The initiative was launched in the context of the thematic Strategy for Soil Protection and the announcement of the proposal for a European Soil Framework Directive in 2005 (Swartjes, et al., 2009) (Carlon, D’Alessandro, & Swartjes, 2007).

HERACLES aimed at creating a repository for compiling information on available risk assessment tools and their evaluation. Once evaluated, the harmonised tool would be moved to the toolbox, which consolidates a list of risk assessment tools to apply for developing human health and ecological risk assessments (Swartjes, et al., 2009). No recent references to the HERACLES network, or outputs from the initiative, were found through the research carried out for the present report.

4.4.3 ISLANDR

ISLANDR is an EU-funded project that aims to reduce soil pollution and enhance restoration. Among other things, it provides a series of tools and methods to support the risk assessment. As part of the second work package, it considers well-established risk assessment methodologies for contaminated soil with enhanced insight into the source-pathway-receptor approach. The objective is to prioritise contaminants of emerging concern in soil, upscale existing risk-based approaches, and develop a risk-based soil health assessment (ISLANDR, 2023).

4.4.4 EDAPHOS

EDAPHOS is a project funded Horizon Europe which aims to implement innovative technologies to monitor polluted soils and implement nature-based solutions to accelerate their restoration. Among other things, it aims to improve the monitoring of contaminated soils by remote sensing and the ecological risk assessment methods for the survey of contaminated soils using the triad approach (EDAPHOS, 2025).

4.4.5 ARAGORN

ARAGORN is a project funded by Horizon Europe which aims to unite three frameworks for addressing polluted soils: Risk Assessment, Socioeconomic Assessment and Resilience Assessment. The frameworks are based on a comparison of the status quo of current risk, socio-economic and resilience aspects, compared to how this could change through remediation interventions. Key to the approach developed by ARAGORN is the active involvement of relevant stakeholders throughout the design, implementation and evaluation of remediation interventions for the restoration of polluted soils, fostering shared ownership and enhancing the relevance and sustainability of outcomes. The guidance for evaluation of risks and “risks of remediation”, focus on soil ecotoxicity, human health, and spreading to water recipients. This evaluation is captured by a transparent Excel-based model, which can be used at two different tier levels, and which includes a “risk of remediation” add on, to help screen for possible remediation pathways and inform socioeconomic and resilience assessments.³⁵

³⁵ Additional feedback provided by stakeholders.

5. Legal background and methodological frameworks in selected countries

5.1 Overview

This section provides an overview of the legislative frameworks to provide further context on currently available approaches, as well as of the methodological frameworks used for the risk assessment of contaminated sites in selected countries, in both EU Member States and third countries.

5.2 Member States

Current contaminated site risk assessment and management practices vary between, and within, Member States. Most Member States have developed their own (specific) contaminated site management systems, including the regulation of inventories of (potentially) contaminated sites, the provisions for public access to these inventories, risk assessment methods, guidance documents, investigation procedures, prioritisation formats, remediation structures, and funding mechanisms.

5.2.1 Austria

Legal background

The Contaminated Sites Remediation Act (ALSAG, implemented 1 September 1989) (BGBl. Nr. 299/1989) and the Environmental Subsidies Act (UFG) (BGBl. Nr. 185/1993) follow the polluter pays principle and build the basis for the structured survey, assessment and subsidised remediation of contaminated sites in Austria.

ALSAG provides the legislative basis for registering and managing contaminated sites and regulates a waste taxation system to finance a national program on historically (i.e. before 1st July 1989) contaminated sites, which included investigation and remediation measures.³⁶ According to ALSAG, possible contaminating activities are commercial or industrial activities that have stored or handled significant amounts of harmful substances as well as old landfills, which occurred before 1st July 1989. These historical activities are reported and recorded in a central database.

On 1 January 2025, a comprehensive amendment of the ALSAG (BGBl. I Nr. 30/2024) came into force, introducing independent substantive and procedural provisions, which included land use- and site-specific risk assessment and remedial design. The revision had a series of goals³⁷:

- **Improving effectiveness and efficiency:** A new legal and technical framework was established as a prerequisite for managing historically contaminated sites until 2050. Site-specific remediation target values were established.
- **Accelerating progress in site remediation:** An initial assessment process was established to identify whether significant contamination or significant risk is to be expected,

³⁶ Feedback from the stakeholder workshop.

³⁷ Feedback from the stakeholder workshop.

so that sites that do not need to be investigated can be ruled out. The commissioning of investigation by private individuals or companies and the imposition of specific deadlines in the investigation were also implemented to accelerate the progress.

- **Ensuring more transparency and providing public data:** Requirements for contaminated sites to be designated as independently defined polygons in Geographical Information System (GIS)-based online maps were introduced. In addition, the initial assessment and the evaluation of contaminated sites were made publicly available and different user groups were granted access to a central information point (Federal Ministry of Agriculture, Forestry, Climate and Environmental Protection, Regions and Water Management, 2025a).

The Contaminated Sites Assessment Ordinance defines threshold values for significant contamination or criteria for significant risks at historically contaminated sites, criteria for risk assessment, and generic target values (such as remediation target values and control values).³⁸

As per the Contaminated Sites Remediation Act, the national list of historically contaminated sites is publicly available. The sites with detailed information can be viewed on a GIS map (Altlasten-GIS) (Federal Ministry of Agriculture, Forestry, Climate and Environmental Protection, Regions and Water Management, 2025b). Furthermore, the following information can be accessed via the website altlasten.gv.at:

- Historical activities (landfills and industrial sites) where significant contamination or a significant risk is to be expected following a preliminary assessment;
- Historical landfills and sites that have undergone an assessment (after investigations); and
- Historically contaminated sites.

According to the legislation the obligation to take remediation measures regards³⁹:

- Anyone whose behaviour (action, tolerance, omission) has caused a contaminated site;
- Site-specific contaminants of concern that can be attributed to available records on site activities (e.g. oil tanks, degreasing, laundry);
- Joint liability in case several parties are involved;
- Voluntary remediation is possible for state authorities.

Methodological framework

According to the Austrian legislation, contaminated sites are defined as historical commercial and industrial activities or landfills that are significantly contaminated or cause significant risks to human health or the environment.

In Austria a staged investigation and risk assessment procedure aims to determine whether there is significant contamination or risk (BGBl. Nr. 299/1989).

In the first phase (initial assessment), the potential risk is evaluated based on available data, corresponding to a preliminary assessment/survey (desk study), which then determines whether future investigations are necessary.

In the second phase, significant contamination or significant risk are assessed based on preliminary site-specific investigations like groundwater, soil or soil vapour analysis. According to the results, sites are either formally categorised as a “contaminated site” or delisted.

³⁸ Feedback from the stakeholder workshop.

³⁹ Feedback from the stakeholder workshop.

The assessment procedure is completed by a third phase (site-specific risk assessment), which involves assessing the significance of risks at the site (and urgency to finance remediation measures).

Following the risk assessment procedure, sites can be categorised as not significantly contaminated, significantly contaminated or risk evident (ending up in the national list of contaminated sites), or remediated. This information is publicly available.⁴⁰

More specifically, according to the ALSAG Amendment 2024 (BGBl. I Nr. 30/2024), the assessment of whether an abandoned landfill or a contaminated site is significantly contaminated investigates the following criteria:

1. Types of pollutants detected;
2. Intensity and extent of contamination; and
3. Pollutant loads in a body of water.

The legal ordinance specifies a set of trigger values (either those values are pre-established or otherwise derived on a case-by-case) for different pollutant groups to determine the intensity and extent of contamination and establish whether there is “significant contamination”.

When assessing whether historically contaminated sites cause significant risk to human health or the environment, the following criteria must be taken into account:

1. **Fate and transport of pollutants**, which includes assessing:
 - ▶ Fate and transport of suffocating or flammable gas mixtures, which accounts for the probability of dispersion, the composition of the gas mixtures and the possible extent of the contamination;
 - ▶ Fate and transport (dispersion) of contaminants in groundwater, which takes into account the contaminant mass flow in the immediate groundwater downstream of the contaminated area, the extent of the contamination in the groundwater and the future development.
2. **Impacts of pollutants on soil and water resources**, which includes assessing:
 - ▶ The impacts on soil functions;
 - ▶ The extent of the contamination of water resources;
 - ▶ The current and authorised future use of the site and the surrounding area;
 - ▶ In soils used for agriculture, the possibility of producing and using products as feed or food in the long term;
 - ▶ The risk from suffocating or flammable gas mixtures;
 - ▶ The risk of possible effects of contaminants on human health;
 - ▶ The risks of increased future mobilisation of contaminants and greater dispersion.
3. **Pollutant exposure of legitimate land users**, which includes assessing:
 - ▶ Relevant human activities;
 - ▶ The possible uptake pathways for pollutants;
 - ▶ The route of uptake (oral, inhalation, dermal).

⁴⁰ Feedback from stakeholder workshop.

The risk assessment integrates the source-pathway-receptor-paradigm through a scoring system. The source criterion assesses the environmental impact potential according to size/volume, activity/industrial sector and operation time. The pathway criterion assesses the proximity to sensitive receptors (such as drinking water wells or residential buildings). The receptor criterion assesses the land use and ecological (natural resource) value.

Possible measures that can be taken on contaminated sites include⁴¹:

- **Remediation** through decontamination (i.e. removal of the contamination and its source) or isolation (i.e. permanently preventing the spreading of pollutants). A contaminated site is considered decontaminated if, following the implementation of remediation measures, the threshold values for the intensity of contamination are not exceeded, neither on-site nor in the surrounding area, and there is no significant risk to human health. A contaminated site is considered safe if, following the implementation of remediation measures, the threshold values of are not exceeded in the surrounding area and there is no significant risk to human health.
- **Monitoring and documentation** of the emissions and land use of a contaminated site. Monitoring can be an acceptable measure, when it has been demonstrated that there will be no significant change of the environmental conditions in the vicinity of the contaminated site if the threshold values are not exceeded and there is no sustained upward trend in the concentrations of relevant pollutants in the vicinity of the contaminated site.

5.2.2 Belgium

Legal background

In Flanders, legislation on soil protection has existed since 1995 with the Decree on Soil Remediation, which was updated in 2008 to become the Decree on Soil Remediation and Soil Protection. It aims to prevent new soil contamination and to identify and remediate historically contaminated sites (where historically is defined as a 40-year period). The Decree is based on the polluter pays principle and aims at protecting entities purchasing contaminated land and soil as a resource.⁴² In Flanders (Belgium), a system is in place to finance the recovery of contaminated sites. This consists of a budget for brownfields and wastelands (managed by the governing authorities), and subsidies for soil investigation under certain conditions.⁴³

In the Brussels Capital Region, the Ordinance on the management and remediation of polluted soils (Ordonnance 2009031120) regulates and defines the obligations regarding the treatment and management of (potentially) contaminated sites. This Ordinance introduced a step-wise procedure which must be carried out by an approved soil pollution expert to determine whether soil and/or groundwater are polluted, the extent and type of pollution and, where appropriate, to define a clean-up strategy or to assess the risks to human health and the environment and, where appropriate, to manage these risks.

In Wallonia, the Decree on Soil Management was first adopted in 2008 and updated in 2018 to become the Decree on Soil Management and Remediation (M.B. Nr. 2018070014).⁴⁴ The Decree aims to preserve and improve soil quality, prevent soil degradation and the occurrence of soil pollution, identify potential sources of pollution, organise investigations to establish the existence of pollution (based on comparison with threshold values) and determine the methods for remediating polluted soils. The definition of contaminated sites is associated with the exceedance of screening values after a preliminary investigation.⁴⁵ Based on the polluter pays principles and on a hierarchy

⁴¹ Feedback from stakeholder workshop.

⁴² Feedback from the stakeholder workshop.

⁴³ Additional feedback provided by stakeholders.

⁴⁴ Additional feedback provided by stakeholders.

⁴⁵ Additional feedback provided by stakeholders.

of responsible parties, the Decree also establishes the triggers for soil investigations (i.e. building permits delivery on sites registered in the inventory of (potentially) contaminated sites, closure of a risk activity/installation, environmental damage and decision of the competent authority), which rely on accredited experts, laboratories and samplers. The inventory of (potentially) contaminated sites (“Banque de Données de l’Etat du Sol - BDES”) is a centralised geodatabase of information on the administrative status of cadastral parcels as defined by the Decree. The inventory has to be consulted, for instance, when transferring land.⁴⁶ Belgium has in place a system of certification and quality assurance of practitioners dealing with risk assessment.⁴⁷

Methodological framework

In Belgium, contaminated land risk assessments are conducted within the frameworks established by its three regions. They are regulated by the Public Waste Agency of Flanders (OVAM) in Flanders, the Soil and Waste Department of the Public Service of Wallonia Agriculture, Natural Resources and Environment (DSD within SPW ARNE) in Wallonia and Brussels Environment in the Brussels-Capital Region. Common features are highlighted in the first section below, followed by regional specifications (non-exhaustive).

Common aspects to all regions

Detailed risk assessments across all three regions generally cover four steps (according to Belgian authorities) (OVAM, 2016):⁴⁸

1. **Hazard identification:** information is gathered about the intrinsic hazard of a substance. This step examines the adverse effects the substance can cause (e.g. lethality, effects on reproduction, carcinogenicity) and the conditions under which it is exposed.
2. **Determination of dose-effect relationship:** the relationship between the dose to which the target organism is exposed and the severity of the effects. This information is used to derive values to which the exposure will be compared.
3. **Exposure assessment:** the relationship between the concentration in a specific environmental compartment and the exposure of the receptor (humans). It consists of two elements: a) determination of the distribution of the substance and b) determination of the exposure of the receptor(s) to the substance.
4. **Risk assessment:** the final part of the risk evaluation, in which the information from the dose-effect relationships is combined with the information from the exposure assessment to make a statement about the expected risks.

The evaluation of human toxicological risk assessment includes the following steps (OVAM, 2016):

1. **Preparation of a CSM:** a framework that outlines all essential elements required for human toxicological risk assessment, including information about the contamination in the soil and groundwater, the polluting substance, the receptors, the routes of exposure and associated risks to human, planned or expected future development.

⁴⁶ Additional feedback provided by stakeholders.

⁴⁷ Additional feedback provided by stakeholders.

⁴⁸ While the steps listed here cover the detailed risk assessment process, it should be noted that one industry stakeholder provided information on the approach (including risk assessment preparation) they specifically take as practitioners in Belgium. They suggested that practitioners undertake: desk-based studies to identify potential spills, contaminants of concern, and land use; initial investigations to compare exposure levels to screening values defined in the Soil Decree; and prioritisation of impacts. Where contamination from new/recent pollution exceeds values in the Soil Decree, a remediation strategy is needed. Where contamination from historic pollution exceeds values, risk-based discussions are used.

2. **Performing the human toxicological risk assessment:** this involves a further quantification of the conceptual model, ranging from determining the concentrations to be used, the exposure parameters, substance data, the choice of the calculation model (e.g. S-RISK[®] used in all regions), the input of the data into the calculation model, the generation of the results and the interpretation of these results. When performing the risk assessment, a step-by-step approach is used, whereby at the end of each step it is checked whether there is a need to perform additional, more complex steps.
3. **Interpretation of the risk assessment results:** this step is based on the assessment of intake/absorption against toxicological reference values. Concentrations are assessed against legal standards, toxicological or policy reference values.

The risk assessment in the descriptive soil investigation involves the evaluation of risks for actual and potential situations of exposure of people or ecosystems to contamination, or of spreading of contamination to groundwater and surface water. This assesses whether it is necessary to remediate historical contamination, to implement safety and/or precautionary measures to safeguard against new pollution. It also supports the development of recommendations (e.g. on land use) and priority-setting for remediation. The investigation requires a series of steps (OVAM, 2016):

- Development of a CSM that implements the source-pathway-receptor paradigm;
- Data collection through site measurements;
- Model calculations; and
- Conclusions on human exposure to actual and potential risks (which is assessed through the S-RISK[®] model as explained in section 6), ecotoxicological actual and potential risk, risk for spreading (assessed through the F-Leach model in Flanders and Brussels regions and Connor model in the Walloon region by looking at the presence of mobile pure product, the effect on receptors, leaching, spreading in groundwater, drift of contaminated soil particles), and policy decisions.⁴⁹

Region-specific aspects

Flanders

In Flanders, a preliminary soil investigation is required for land with risk activities in case of transfer of land (including changes in ownership, right of usufruct, leasehold or concession agreements (Decree on Soil Remediation and Soil Protection 2006)), periodically (e.g. every 10 or 20 years), before the start for certain risk activities, and after closure of risk activities. The legislation provides a list of risk activities.⁵⁰

Wallonia

In Wallonia, obligations in case of land transfer are limited to both parties being informed of the status of the transferred parcels as stated in the inventory of (potentially) contaminated sites (BDES).⁵¹ Thus, soil investigations are not mandatorily triggered by land transfer but can be done on a voluntary basis. A preliminary soil investigation is required periodically for land with risk activities and after closure of risk activities. The legislation includes a list of what are considered

⁴⁹ Additional feedback provided by stakeholders.

⁵⁰ Feedback from stakeholder workshop.

⁵¹ Additional feedback provided by stakeholders.

risk activities/installations. A preliminary soil investigation is also required in case of a permit request for land registered as potentially polluted in the inventory (BDES).⁵²

In Wallonia, the reference guide for risk studies comprises five parts: the general application methodology for risk studies, the human health risk assessment methodology, the groundwater risk assessment methodology, the methodology for assessing risks to ecosystems, and the guidelines for drafting the risk assessment report (Service Publique de Wallonie, 2025).

The methodology for assessing risks to ecosystems, groundwater, and human health was developed to meet the needs of the Soil Decree and is based on the principles and procedures adopted by other countries and organisations. The general objective of the methodology is to determine whether or not a biological stress is present in the ecosystem, for one or more of the ecological receptors considered, due to the presence of pollutants in the soil. Biological stress is defined as an adverse change in the general functioning of the ecosystem or at least one niche of this ecosystem. The methodology has two levels of evaluation (Service Publique de Wallonie, 2018):

- **Simplified ecosystem risk assessment** evaluates whether there is an indication or a potential (generic or projected situation) of biological stress for the ecosystem, in a specific context, based on conservative scenarios. It also helps to highlight pollutants that may warrant further investigation.
- **Detailed ecosystem risk assessment** also makes it possible to characterise and quantify the existence or potential of biological stress. This detailed assessment focuses on the receptors, their exposure conditions and the sources of stress (chemical substances) of the site considered.

Brussels Capital Region

In the Brussels Capital Region, the legislation concerning the management and remediation of polluted soils establishes procedures for the identification and treatment of contaminated sites in accordance with the codes of good practice in force in the Region, or failing that, in accordance with the codes of good practice in force in the Flemish or Walloon Regions. If soil pollution is addressed through risk management, a risk assessment must first be conducted (Bruxelles Environnement, 2025).

The methodology assesses the risk of exposure of people, the risk of damage to ecosystems and the risk of spreading of pollutants. The risk study formulates conclusions on the tolerable or unacceptable nature of the risks generated by pollution, the urgency of risk management, the need (or not) to carry out a risk management project or possibly a remediation project, and the deadline for notifying the competent authority of such projects. The presence of a risk requires the concurrence of three elements: the (sources of) pollutants in the soil or groundwater, targets threatened or affected by this pollution, transfer pathways between pollutants and targets. As long as one of these elements is absent, the pollution is considered not to present a risk (Bruxelles Environnement, 2024).

The risk values are defined as concentrations of pollutants in soil or groundwater, calculated by a risk study, beyond which the risks of exposure to people and/or the environment are considered unacceptable and risk management, monitoring and/or emergency measures are required. Risk values can integrate the different types of targets (based on the most restrictive value) or be distinguished according to the type of target (people, ecosystems, groundwater) (Bruxelles Environnement, 2024).

The methodology uses a CSM and the essential elements of the source-pathway-receptor paradigm. This representation presents the state of the pollution and its evolution, highlights

⁵² Additional feedback provided by stakeholders.

significant uncertainties and makes it possible to identify the actions to be taken in terms of pollution management. The general approach is iterative, thus ensuring consistency between the degree of depth of the risk study and the importance of the foreseeable impacts of pollution, and fully complies with the principle of proportionality (Bruxelles Environnement, 2024). The approach covers the step mentioned at the beginning of this section.

5.2.3 Denmark

Legal background

In Denmark the 1999 Statutory Order on Contaminated Soil (LOV nr 370 af 02/06/1999) aims to prevent, eliminate or limit soil contamination and prevent harmful effects from soil pollution on nature, the environment and human health. The law has undergone several revisions since its introduction. The legislation has the objective to manage and remediate contaminated sites. The protection of groundwater resources marks a particular priority. The drinking water supply is entirely groundwater-based and 40% of the country's area is designated as of special groundwater interest. Contamination resulting from agricultural spreading of sludge, fertiliser and pesticides is excluded from the law.⁵³

During the 1990s, case law established that only polluters guilty of gross negligence could be made liable of remediation according to the Environmental Protection Law for site contamination. The Soil Contamination Act of 1999 improved the enforcement of the polluter pay principle by introducing an objective responsibility for polluters as of January 1st, 2000. However, case law has since then established that it must be proved with a high degree of probability that the majority of contamination happened after the year 2000, which is challenging in many cases. Additionally, when several parties are identified as responsible, but their legal entities no longer exist, the remaining parties cannot be made to assume their share. In 2013, the implementation of the Industrial Emissions Directive⁵⁴ introduced the concept of objective landowner responsibility, but only for the industries targeted by the directive, and only with effect from 2013. For the above reasons, the orphan site program in Denmark is of considerable size. The orphan site program is managed by the five regional councils. In parallel, a mega-site program came into existence in 2020, which is state-financed but administered by the regions.⁵⁵

Contaminated sites might be redeveloped for residential use but require a permit. The developer must ensure the resulting land use is not affected by the contamination. Also, the development must not adversely affect a future orphan site program targeting, for instance, groundwater. However, in acquiring and developing the property, the developer does not assume responsibility for contamination in itself. This mechanism has ensured that the reuse of contaminated land is not an issue to the same extent as in other countries.⁵⁶

When a polluter can be made liable, the remediation objective is to return a site to its original state, though the principle of proportionality must be taken into account. By contrast, the remediation criteria of the orphan sites program are risk-based. The same goes for the demands made on voluntary remediation resulting from property development on contaminated sites.⁵⁷

In addition to the orphan sites program, the regions undertake a systematic mapping and registration of (potentially) contaminated sites. This registration feeds into the orphan sites program, helps identify liable polluters, secures safe redevelopment and prevents uncontrolled transport of contaminated soil.⁵⁸ All sites registered as potentially contaminated and contaminated are entered in a real-time database, accessible to the public. The database is used, for instance, in

⁵³ Additional feedback provided by stakeholders.

⁵⁴ OJ L 334, 17.12.2010, pp. 17–119

⁵⁵ Additional feedback provided by stakeholders.

⁵⁶ Additional feedback provided by stakeholders.

⁵⁷ Additional feedback provided by stakeholders.

⁵⁸ Additional feedback provided by stakeholders.

property transactions to document the site's contamination status. Similarly, all chemical analyses resulting from the orphan site investigations are transferred from the laboratory to the national geological database. The content of this database is also publicly available online. However, there is no similar obligation in the case of private site investigations.⁵⁹

Methodological framework

A tiered and risk-based methodology is applied to private and orphan sites investigation, assessment and remediation. The methodology is based on CSM and involves the implementation of the source-pathway-receptor paradigm. Unless contamination is revealed by chance, the first step is a study of the site history, i.e. what activities took place and what substances were used. A list and characterisation of the type of industries which might have caused pollution and the chemical substances most frequently used by those industries are available to inform the study. This due diligence may be sufficient to acquit the site of further investigation or, conversely, to register it as potentially contaminated. Depending on this risk assessment relative to site use, it is determined if/when the site should be prioritised for further investigations.⁶⁰

If subsequent investigations are carried out, they include sampling from the relevant media (soil, groundwater, soil vapour) and analysing these samples for relevant substances depending on the site's historical activities. A comparison between the concentrations of certain substances in the samples and the threshold values (issued by the Danish Environmental Protection Agency) determines if a site is registered as contaminated or not.⁶¹

If/when the site is prioritised for a main investigation, the sampling results and additional concentration results from sampling are fed into a risk assessment tool, such as JAGG (acronym for Soil, Evaporation, Gas, Groundwater in Danish) for vapour intrusion or GrundRisk for groundwater. Site-specific data such as geology, groundwater and geotechnical parameters are also input into these tools. For vapour intrusion, the construction design may be included if applicable. Recent developments highlight a preference for using flux-based risk assessment for groundwater, given their better performance when incorporating multiple sources into the assessment, compared with a merely concentration-based approach. Geophysical investigations may supplement borehole data. For larger projects, a numeric groundwater model may be developed.⁶² For risk evaluation of surface water bodies, a screening tool is used. Selected results undergo a more site-specific evaluation.⁶³ The Danish regions use the metric contaminant mass discharge in the risk assessment of contaminant sites threatening groundwater, and some regions have developed specific tools incorporating this as well as semi-quantitative assessment of uncertainty.⁶⁴

Finally, the remediation target is developed, based on which source reduction is needed to eliminate the risk to the recipient. Based on long-term cost considerations, remediation may be replaced by or supplemented with a monitoring and/or operational solution, whereby the contamination is either observed and/or actively managed.⁶⁵

⁵⁹ Additional feedback provided by stakeholders.

⁶⁰ Additional feedback provided by stakeholders.

⁶¹ Additional feedback provided by stakeholders.

⁶² Additional feedback provided by stakeholders.

⁶³ Feedback from the stakeholder workshop.

⁶⁴ Additional feedback provided by stakeholders.

⁶⁵ Additional feedback provided by stakeholders.

5.2.4 France

Legal background

In France the national policy for the management of contaminated sites and soils is based on a risk management approach linked to current and future land use, as set in the Environmental Code (Code de l'environnement 2021). The legislation requires the person responsible for the pollution to define appropriate methods for treating pollution sources and eliminating concentrated pollution on a case-by-case basis, taking into account available techniques and their economic costs. Authorities then validate the remediation goals.⁶⁶ The Environmental Code defines registers for both contaminated sites (SIS) and potentially contaminated sites (CASIAs), with public access to GIS mapping⁶⁷. If projects are to be developed on those sites, the project developer has to undertake a risk assessment to confirm that the state of the environment is compatible with the project regarding exposure to pollution.⁶⁸

Methodological framework

The French methodology for assessing and managing polluted sites and soils concerns all sites potentially presenting problems of pollution of their soils and/or their groundwater. It offers tools for managing polluted sites and soils to support decision-making within the framework of the applicable regulations (Direction Générale de la Prévention des Risques, 2017)⁶⁹.

The methodology is based on a CSM and involves the implementation of the source-pathway-receptor paradigm.⁷⁰ The methodology suggests a series of considerations that should be taken into account when managing contaminated sites⁷¹:

- Identify the need of the operator and the context of the study (e.g. closure of a facility, acquiring a site, setting up environmental monitoring, controlling pollution, etc.);
- Identify sites falling under the national methodology (occurrence of potentially polluted activities and bad practices likely to cause pollution);
- Identify polluted areas, differentiating between areas likely to be polluted and those that are not (historic and documentary studies, environmental context and field investigations);
- Acquire knowledge of soil pollution to optimise a rehabilitation project, by identifying pollutants and delimiting polluted areas;
- Carry out human health risk management, taking into account the characteristics of buildings;
- Manage the polluted soil and water on the basis of a BATNE(E)C (Best Available Technology Not Entailing Excessive Costs) approach, and on environmental assessment and sustainable development perspectives;
- Take into account pollution derived from other sources (radioactivity and asbestos are subject to specific laws);
- Communicate with interested parties, such as service providers, authorities, and the population; and

⁶⁶ Additional feedback provided by stakeholders.

⁶⁷ <https://www.georisques.gouv.fr/cartes-interactives#/>.

⁶⁸ Additional feedback provided by stakeholders.

⁶⁹ Feedback from the stakeholder workshop.

⁷⁰ Additional feedback provided by stakeholders.

⁷¹ Additional feedback provided by stakeholders.

- Record and monitor pollution after the implementation of management measures.

To improve the quality of services in the field of polluted sites and soils, the French Ministry of the Environment initiated since 2011 a standard (NF X 31-620), along with a reference framework for certification of services in the field of polluted sites and soils. The work of the standardisation committee and the development of these standards were carried out in consultation with representatives of all stakeholders (Direction Générale de la Prévention des Risques, 2017).

The new version of the NF X31-620 series of standards "Soil quality - Services relating to polluted sites and soils" was published in December 2021 to be in accordance with the updated legislation and the contaminated site methodology. It is divided into five parts:

- **X31-620-1:** General requirements;
- **X31-620-2:** Requirements in the field of studies, assistance and control services;
- **X31-620-3:** Requirements in the field of engineering services of rehabilitation works;
- **X31-620-4:** Requirements in the field of services of execution of rehabilitation works;
- **X31-620-5:** Requirements for the realisation of certificates for the consideration of soil and groundwater pollution management measures in the design of construction or development projects.

The Laboratoire national de métrologie et d'essais (LNE) is in charge of the auditing through the LNE Polluted Sites and Soils (LNE SSP) certification, which is a voluntary process attesting the compliance of the services offered by a service provider with the requirements defined in the reference system and the French NF X-31-620 standards relating to Polluted Sites and Soils. As provided for in the LNE SSP certification framework, these certificates are issued on the basis of an audit examining completed rehabilitation cases to assess their quality. This assessment is supplemented by an audit of a construction site where skills, know-how and compliance with environmental, occupational health and safety regulations are assessed.

Contaminated land management distinguishes two main management types⁷²:

1. In the case of population living on or near a polluted area, the land use is observed and cannot be modified. The approach consists of evaluating the compatibility between the current state of the site's environmental quality and current land use. This approach is called Assessment of the State of Media Quality ("Interprétation de l'état des milieux" approach - IEM). This approach makes it possible to identify exposure media that (Ministère en Charge de l'Environnement, 2007):
 - Do not require any particular action, i.e. thus allowing the free enjoyment of environmental uses without exposing populations to excessive theoretical risk levels;
 - Can be subject to simple management actions to restore compatibility between the state of the exposure environments and their observed uses; and
 - Require the implementation of a management plan.
2. In the case of a site where land use can still be modified and for which remediation is possible (e.g. closure of a facility), the approach consists in a Management Plan. The Management Plan is a tool used to establish different remediation scenarios. This tool is used in site rehabilitation when it is possible to act both on the state of the environment and on future uses. For a Management Plan, experts can use modeling for pollutant transfers to assess future human exposure. However, regarding the

⁷² Additional feedback provided by stakeholders.

Assessment of the State of Media Quality, only environmental measurements in the exposure media are considered valid.

For both approaches, environmental concentrations (both modelled or measured) are compared to different values provided by the methodology, depending on the situations, including (Ministère de l'Environnement, de l'Energie et de la Mer, 2017):

- The state of the neighbouring natural environment;
- The values from a quantitative health risk assessment, which needs to be implemented if the media is degraded and if there is no mandatory value for this media and the concerned pollutant (to be noted that in France mandatory or screening values for the soil do not exist); and
- The current management values established by public authorities, depending on the context, land uses and environments (surface water, groundwater, foodstuffs, etc.).

5.2.5 Germany

Legal background

The Federal Soil Protection Act (BBodSchG) and Federal Soil Protection and Contaminated Sites Ordinance, 1999 (updated 2021) (BBodSchV) (Nr.36, Vom 12, Juli 1999) are the principal regulations governing contaminated site management in Germany. They establish a national framework with contamination threshold values for soil and groundwater and detailed technical criteria for risk assessment procedures for investigating contaminated land.

Individual federal states have additional guidelines and risk assessment methodologies based on soil types, industry history and groundwater sensitivity. For example, Baden-Württemberg uses state-specific guideline values beyond those set in the legal Ordinance and prioritises groundwater protection. Lower Saxony strongly focuses on agricultural soil protection and uses land-use-specific contamination values. The German Länder are responsible for the enforcement of the soil protection act. They follow slightly different procedures, but the overall regulation is similar.⁷³

According to the Federal Soil Protection Act (BBodSchG) (Bundesamt für Justiz, 2021a), if the competent authority has indications that harmful soil contamination or a contaminated site exists, it shall take appropriate measures to investigate the facts. If the screening values are exceeded, the competent authority shall take the necessary measures to determine whether harmful soil contamination or a contaminated site exists. The investigation and assessment shall, in particular, take into account the type and concentration of the pollutants, the possibility of their spread into the environment and their uptake by humans, animals, and plants, as well as the use of the property. The property owner and, if known, the person in control of the property, shall be informed in writing of the findings and the results of the assessment upon request. If there is sufficient suspicion of harmful soil contamination or a legacy site based on concrete evidence, the competent authority may order to carry out the necessary investigations for risk assessment. The polluter pays principle applies.⁷⁴

Remediation measures are in place in Germany. Some states make available a funding mechanism for remediation.⁷⁵

Germany has in place a system of certification and quality assurance of practitioners dealing with risk assessment.⁷⁶

⁷³ Additional feedback provided by stakeholders.

⁷⁴ Additional feedback provided by stakeholders.

⁷⁵ Additional feedback provided by stakeholders.

⁷⁶ Additional feedback provided by stakeholders.

In Germany there are registries of contaminated sites; however, these are not publicly available.⁷⁷

Methodological framework

The German Individual Assessment of Contaminated Sites Method is a quantitative model-based approach assessing air, soil, surface- and groundwater at contaminated sites.

The Federal Soil Protection and Contaminated Sites Ordinance (BBodSchV) (Bundesamt für Justiz, 2021b) provides the general methodology for the assessment of contaminated sites.

Indications of the existence of a contaminated site exist in the case of a former industrial site, in particular, if pollutants have been handled on the site for a prolonged period or in significant quantities, and the respective operating, management, or procedural methods, or disruptions to the intended operation, give rise to the suspicion of significant inputs of such substances into the soil.

Indications of the existence of harmful soil changes can also be found in evidence of:

- The introduction of pollutants over a longer period of time or in significant quantities via the air or water, or through the application of significant loads of waste or wastewater to soils;
- A significant release of pollutants from soils with naturally higher levels;
- Elevated levels of pollutants in food or feed plants at the site; or
- The release of water containing significant loads of pollutants from soils or old landfills as well as from findings based on general investigations or empirical data from comparable situations, particularly regarding the spread of pollutants.

The methodology is based on CSM and involves the implementation of the source-pathway-receptor paradigm.⁷⁸

When determining the scope of the investigation, all available information, in particular knowledge or reasonable assumptions about the occurrence of certain pollutants and their distribution, the protection needs, and other local circumstances relevant to the assessment shall be taken into account.⁷⁹

When investigating the soil-human pathway, the following uses must be distinguished: children's play areas, residential areas, parks and leisure facilities, and industrial and commercial properties. When investigating the soil-crop pathway, the following uses must be distinguished: arable land and kitchen gardens, as well as grassland areas.⁸⁰

A reasonable suspicion of harmful soil alteration (or designation as a contaminated site) is generally present if investigations show an exceedance, or expected exceedance, of the screening values set in the legislation.⁸¹

If there are indications of the presence of a contaminated site or a harmful soil alteration, the area suspected of being contaminated or of being a suspected site shall first be subjected to a **preliminary investigation**.⁸²

The aim of the preliminary investigation is to determine, on the basis of the results of a survey and by means of local investigations, whether there is sufficient suspicion of the presence of a contaminated site or of harmful soil alteration. If, during investigations of the soil-groundwater exposure pathway, a screening value is exceeded at the sampling site, a leachate forecast should

⁷⁷ Additional feedback provided by stakeholders.

⁷⁸ Additional feedback provided by stakeholders.

⁷⁹ Additional feedback provided by stakeholders.

⁸⁰ Additional feedback provided by stakeholders.

⁸¹ Additional feedback provided by stakeholders.

⁸² Additional feedback provided by stakeholders.

be used to estimate whether the concentration of this pollutant in the leachate at the assessment site is likely to exceed the screening value.⁸³

If there is sufficient suspicion of harmful soil alteration or a legacy site, a **detailed investigation** shall be carried out.⁸⁴

The objective of the detailed investigation is to enable a conclusive risk assessment by in-depth and further investigations.⁸⁵ It serves in particular to determine the quantity and spatial distribution of pollutants, their mobile or potentially mobile components, their potential for spreading in soil, water and air, and the possibility of their uptake by humans, animals and plants. Detailed investigations shall determine whether spatially limited concentrations of pollutants within a suspected or contaminated site pose a risk and whether and how it is necessary to demarcate uncontaminated areas. As part of the detailed investigation, the relevant exposure conditions for the respective exposure pathways and the significant bioavailable, mobile, or potentially mobile fractions of the pollutant concentrations shall be determined. Bioavailability shall also be determined. If there is sufficient suspicion of harmful soil alteration or contaminated land, the pollutant inputs into the groundwater shall be estimated by means of a more detailed leachate forecast. The competent authority may also require an interference forecast. The detailed investigation may also include the identification of naturally occurring degradation and retention processes, insofar as they are to be taken into account as site conditions in the risk assessment.

5.2.6 Italy

Legal background

The key law governing contaminated sites in Italy is the Legislative Decree No. 152/2006 (Codice dell'Ambiente). It establishes a framework for environmental regulations, including procedures for identifying, assessing, and remediating contaminated sites. The framework defines screening values for soil and groundwater contamination, procedures for site-specific risk assessment, and establishes the roles of regional and national authorities in site management.⁸⁶

The Regional Environmental Protection Agencies (ARPA) provide site-specific risk assessment methodologies and enforcement mechanisms, and the Istituto Superiore per la Protezione e la Ricerca Ambientale (ISPRA) provides technical and monitoring guidelines (Italian Institute for Environmental Protection and Research, 2025).

In Italy 59 National Priority List Sites are under the responsibility of the Ministry of Environment. While other local sites are under the responsibility of Provinces/Regions that may delegate, or may cooperate with ARPA. Site information is publicly available in a national database (MOSAICO) (Andrisani, Vecchio, Arelli, & Araneo, 2022)).

Methodological framework

Italy follows a tiered approach based on the source-pathway-receptor paradigm.

- **Preliminary assessment:** This initial phase involves a desk study to collect existing information about the site, followed by a site visit to identify visible signs of contamination and potential sources.

⁸³ Additional feedback provided by stakeholders.

⁸⁴ Additional feedback provided by stakeholders.

⁸⁵ Additional feedback provided by stakeholders.

⁸⁶ Feedback from the stakeholder workshop.

- **Detailed investigation:** Based on the findings of the preliminary assessment, a more in-depth investigation is conducted, including sampling and laboratory analysis of soils, water, and air to quantify contaminant concentrations.
- **Risk analysis:** Utilising the data obtained, a risk analysis is performed to determine the likelihood of adverse effects on human health and the environment.

According to the Legislative Decree n. 152/06, potentially contaminated sites are defined as sites where the exceedance of screening values in soil and/or groundwater is confirmed after a preliminary investigation when an event of contamination has occurred.⁸⁷ If either soil or groundwater exceed the threshold values then further assessment and or/ remediation is required. Risk assessment values are defined to assess the level of risk and plan remediation measures.

Sites with a suspicion of contamination or sites where polluting activities took place, potentially contaminated sites, and contaminated sites are included in regional remediation plans. The event of contamination could be related to the presence of a polluting activity, to an accident, or simply to discovering (e.g. during an excavation for building a house) a previous soil contamination (including historical). Potentially contaminated sites are ranked considering the degree of contamination, the risk to public health and ecosystems, and the feasibility and cost-effectiveness of remediation. These criteria together with a scoring system are used for the ranking at regional/provincial level. As explained in the following section 6, the Risk Ordering for Contamination Key Sites (ROCKS) model is used for the ordering of contaminated sites.

5.2.7 Luxembourg

Legal background

In Luxembourg the draft law on soil protection and management of polluted sites provides preventive measures against the degradation of soil quality and for the rehabilitation of deteriorated soils. The final text contains two main components: a preventive component focused on soil protection and a remedial component that describes the principles for managing potentially polluted or contaminated sites. The law sets measures to monitor soil quality, develop a national soil protection plan, and provide the means to take into account the soil component as a non-renewable natural resource in decisions (Le Gouvernement du Grand-duche de Luxembourg - Administration de l'environnement, 2018).

Methodological framework

In Luxembourg the methodology for risk assessment foreseen in the draft law on soil protection and management of polluted sites⁸⁸ involves four different steps (Le Gouvernement du Grand-duche de Luxembourg - Administration de l'environnement, 2018):

- **First phase:** diagnostic study. The diagnostic study comprises, firstly, preparatory studies concerning site context, history and the identified pollution risk areas and the development of the CSM; and secondly, the development and execution of an analytical program and a sampling plan based on these studies aiming to confirm or refute the presence of contaminants on the site.
- **Second phase:** advanced study. If a contaminated site is confirmed, the advanced study asks for a detailed delimitation and characterisation of all contaminated sites identified.⁸⁹

⁸⁷ One industry stakeholder added that the Italian framework does not specify one particular model but sets out expectations and references a range of software tools that could be used.

⁸⁸ Luxembourg is currently operating on a "case by case" evaluation based on threshold values with a very limited "risk based" elements in place.

⁸⁹ Additional feedback provided by stakeholders.

The second phase may include a site-specific risk assessment. The aim of the second phase is to evaluate the potential risk of the contaminated sites, and if relevant, to gather the necessary information to prepare a rehabilitation plan (in the third phase) and to define rehabilitation objectives.

- **Third phase:** rehabilitation plan. If an unacceptable risk has been identified, the third phase asks to develop and execute a detailed rehabilitation plan in order to eliminate and/or manage the risks emanating from the contaminated sites.⁹⁰
 - ▶ The primary purpose of the site-specific risk assessment is to verify whether a contaminated site poses an unacceptable risk to human health or the environment. The demarcation of contaminated areas and the exact quantification of the volumes of polluted land or groundwater are the subject of an in-depth study.

5.2.8 Netherlands

Legal background

In the Netherlands the Environmental Activities Decree (Besluit activiteiten leefomgeving, 2025) provides measures regarding preliminary soil investigation, standard remediation approaches, customised soil remediation, and quality assurance.

Prior to soil remediation, a soil investigation needs to be conducted. Remediation entails two possible approaches, or a combination of the two, removing part of the contamination and covering a portion. Quality assurance provisions require that only a certified company can carry out soil remediation.

Following the Soil Covenant, by the end of 2015, urgent locations were identified based on ecological or dispersal risks and a series of remediation measures was prepared (Technische commissie bodem, 2011).

Methodological framework

In the Netherlands, the environmental risk assessment includes the assessment of risks to humans, the risks to the ecosystem, and the risks of the contamination spreading. It consists of three steps (Technische commissie bodem, 2011):

- The first step determines whether there is a case of serious soil contamination;
- The second step is a simple, generally applicable (generic) risk assessment; and
- The third step is a risk assessment tailored to the specific situation at the site.

The results of the risk assessments lead to conclusions about the (un)acceptability of the risks and the urgency of remediation.

According to the ecological risk assessment approach, unacceptable risks to the ecosystem exist if in the current or intended use of the location, biodiversity may be affected, the functioning of natural processes may be disrupted, or bioaccumulation⁹¹ and transfer of poison from one species to another may occur (Technische commissie bodem, 2011).

⁹⁰ Additional feedback provided by stakeholders.

⁹¹ The gradual build-up of chemical substances and metals.

5.2.9 Spain

Legal background

The Royal Decree 9/2005 is the main regulatory framework in Spain for contaminated land management and establishes criteria and standards for determining when land is considered contaminated. Annex V provides Generic Reference Values (GRVs) for contaminants in soil, including heavy metals (lead, mercury, cadmium, arsenic), hydrocarbons (BTEX, PAHs), chlorinated compounds and pesticides.

Methodological framework

The Geological and Mining Institute of Spain, in collaboration with the Ministry of Agriculture, Food and Environment (now called Ministry for the Ecological Transition and the Demographic Challenge), have developed technical guidelines, "Simplified Risk Assessment Guide for Closed or Abandoned Extractive Industry Waste Facilities (Ministerio de Agricultura y Pesca, Alimentación y Medio Ambiente, 2016)", for the assessment of risks in contaminated soils in Andalucía, complementing the legal framework established by the Royal Decree 9/2005. The methodology is based on risk-based corrective action (RBCA) and provides detailed steps on exposure pathways, contaminant fate and transport models, and risk characterisation. This guidance is a specific example applied to mining waste which follows the Royal Decree 9/2005 and that can be adapted to other contaminated sites. Key steps include (Junta de Andalucía, 2019):

1. **Identification of 'risk scenarios'**, which establishes potential sources of contamination and hazards (e.g., water contamination, wind dispersion of particulates) and defines specific risk scenarios using a classification system:
 - ▶ Effluents affecting surface water;
 - ▶ Effluents affecting groundwater;
 - ▶ Wind dispersion of contaminants;
 - ▶ Water erosion and sediment dispersion;
 - ▶ Direct contact with contaminated materials.
2. **Identification of potential receptors**, which assesses human populations, ecosystems, and socio-economic assets that may be affected.
3. **Probability assessment**, which evaluates the likelihood of a risk scenario using Probability Index values, that consider factors such as the nature of the waste, climatic conditions, and proximity to water resources.
4. **Severity assessment**, which determines the severity of impacts on people, the environment, and economic activities using Severity Index values.
5. **Risk classification and prioritisation** with a risk matrix that uses a combination of probability and severity results to classify and prioritise risks, facilitating decision-making on the necessary remediation actions.
6. **Conclusion**. Prioritisation and decision-making generate a ranked list of sites needing intervention and determine if a detailed risk assessment is necessary for complex cases.

5.2.10 Sweden

Legal background

The Swedish Environmental Code (Miljöbalk 1998:808) applies the polluter pays principle and includes provisions regarding contaminated sites and their remediation. Full liability exists for pollution caused by activities after 1969. However, there is limited liability if pollution was caused during the 1960s, and no liability if it was caused before 1960. If there is no responsible party, investigations and measures for the contaminated areas that pose the highest risks can be financed with governmental grants, as regulated by the law.⁹²

To supplement the Environmental Code, the Swedish Parliament has adopted a series of national environmental quality objectives, which should be used as a guide in the decision-making process on environmental issues. For each objective, there are a number of specifications, which clarify the state of the environment that is to be attained. The specification most essential for the work concerning remediation of contaminated sites is related to the objective “A non-toxic environment”, which reads: “Contaminated sites are remediated to such an extent that they do not represent a threat to human health or the environment”.⁹³

To meet the environmental quality goals set by the Swedish Parliament, including those on site remediation, grants to fund the investigation and remediation of orphan sites, as well as national guidance documents have been developed (Swedish Environmental Protection Agency, 2021).

Methodological framework

The Swedish EPA has produced several reports providing guidance on how to deal with contaminated sites, from conducting inventories of potentially contaminated sites and performing risk assessment, to choosing suitable remediation methods.⁹⁴

In the Swedish guidance, a contaminated area is defined as an area where soil, groundwater, surface water, sediment or buildings are so contaminated, by one or more local point sources, that the levels significantly exceed local/regional background levels. Contaminated areas have primarily arisen through emissions, spills and accidents from previous industrial activities. Landfills and fills can also be significant sources of pollution.⁹⁵

Sweden has established an inventory of potentially contaminated sites according to a methodology that consists of a qualitative approach that draws on available information, such as historical records and maps, as well as sample analysis from contaminated sites (Method for Inventories of Contaminated Sites, MIFO). The method has been developed in order to have a uniform assessment of risks and with a reasonable degree of reliability, so that sites could be assessed consistently. Identified contaminated sites are then classified according to risk scale going from 1 (very high risk) to 4 (low risk) (Swedish Environmental Protection Agency, 2002). The method can be used to trigger both more detailed environmental and human health risk assessment (Swedish Environmental Protection Agency, 2021).

The Swedish approach to risk assessment for contaminated sites focuses on four main aspects: hazard assessment of the contamination, the level of contamination (exposure), the potential of contaminant spread/migration, and the sensitivity and protectional value of the environment at or near the site (Swedish Environmental Protection Agency, 2009a).

⁹² Additional feedback provided by stakeholders.

⁹³ Additional feedback provided by stakeholders.

⁹⁴ Additional feedback provided by stakeholders.

⁹⁵ Additional feedback provided by stakeholders.

The Swedish methodology for risk assessment follows most international methodologies and consists of four iterative steps, for which the evaluation of continued investigation is needed: (Swedish Environmental Protection Agency, 2021).

1. **The problem formulation** describes how contaminants can spread from the site and affect human health, the environment and natural resources. Elements to be included in the formulation are:
 - ▶ Establishing the scope and spatial extent;
 - ▶ Describing the sources and properties of the contaminants;
 - ▶ Describing transport and exposure routes and pathways;
 - ▶ Describing the risk objects;
 - ▶ Describing possible future scenarios;
 - ▶ Establishing the conceptual model;
 - ▶ Identifying knowledge gaps that form the basis for supplementary studies and investigations;
2. **The exposure analysis;**
3. **The effect assessment;** and
4. **The risk characterisation.**

The need for a simplified or detailed risk assessment is decided on a case-by-case basis.

Guideline values for contaminated land are one of several tools used in the risk assessment of contaminated sites.⁹⁶ Guideline values, in the context of the remediation of contaminated sites, indicate the contaminant levels which do not pose unacceptable risks to human health, the environment or natural resources. However, contaminant concentrations which exceed guideline values do not necessarily give rise to negative effects. The Swedish generic guideline values are not legally binding values. The Swedish Environmental Protection Agency in collaboration with other experts has developed a model to derive guideline values. The model for calculating guideline values is available for free in the form of an Excel file. The model has been used to derive generic guideline values for a number of different contaminants and for commonly occurring conditions. The model can also be used for calculation of site-specific guideline values (Swedish Environmental Protection Agency, 2002).⁹⁷

Various stakeholders have contributed to the remediation of contaminated sites, including the Swedish Environment Protection Agency, county administrative boards, local municipalities, and other research and non-profit organisations (Naturvardsverket, 2025).

5.3 Third countries

This section explores selected frameworks applied outside of the EU to provide further insights on currently available approaches and select best practices. These are mainly characterised by tiered approaches for an overall risk assessment process from preliminary investigation to site-specific detailed risk assessment characterising the (un)acceptability of risk.

⁹⁶ Additional feedback provided by stakeholders.

⁹⁷ The Swedish Guidelines for contaminated soil provides further guidance and links to relevant reports <https://www.naturvardsverket.se/publikationer/5900/riktvarden-for-fororenad-mark/>.

5.3.1 UK

Legal background

Contaminated site risk assessments in the UK follow a structured process based on the Environmental Protection Act 1990 (part 2A) (1990 c.43)⁹⁸. The UK Environmental Agency's Land Contamination: Risk Assessment (LCRM) (Environment Agency, 2025) provides best practice guidance.

Methodological framework

A tiered approach to risk assessment includes the following (Environment Agency, 2008), (Environment Agency, 2025):

1. **Tier 1: Preliminary risk assessment**, which includes:
 - ▶ A desk-based study and site walkover.
 - ▶ Identification of potential contamination sources, pathways, and receptors (the Source-Pathway-Receptor (SPR) model).
 - ▶ Development of a CSM outlining possible pollutant linkages.
 - ▶ Determination of the need for further investigation and/or assessment.
2. **Tier 2: Generic quantitative risk assessment**, which includes:
 - ▶ Intrusive site investigation (e.g., soil, groundwater, and gas sampling).
 - ▶ Laboratory testing of contaminants against generic screening criteria⁹⁹ such as Category 4 Screening Levels and soil guideline values (human health); CIRIA C665 and INFO-RA2-4 (ground gases and vapours); Drinking Water Standards and Surface Water Environmental Quality standards for controlled waters; soil screening values for assessing ecological risk and INFO-RA2-5 (ecological assessment).
 - ▶ Detailed information on risk assessments to specific receptors is found on the CL:AIRE Water and Land Library, which includes human health, water environment, gases and vapours, ecosystems, buildings, and services.¹⁰⁰
 - ▶ The groundwater spatiotemporal data analysis tool (GWSDT) used to collect and visualise groundwater time series data.¹⁰¹
 - ▶ The CSM.
3. **Tier 3: Detailed quantitative risk assessment**, which:
 - ▶ Is used if contaminants exceed screening criteria in Tier 2.

⁹⁸ Additional relevant pieces of legislation include: The Contaminated Land (England) Regulations 2006, Environmental Damage (Prevention and Remediation) Regulations 2015, Water Resources Act 1991, Groundwater (England and Wales) Regulations 2009, Water Environment (Water Framework Directive) Regulations 2017.

⁹⁹ One stakeholder mentioned that the criteria are commonly derived by individual companies for use on their projects, using published models and guidance.

¹⁰⁰ One stakeholder mentioned that typically, in generic assessments- conservative assumptions are made around depth to groundwater, proximity of receptors etc. Commonly criteria are derived for high and low density residential, commercial and industrial end-use.

¹⁰¹ One industry stakeholder indicated GWSDT is not commonly used in the industry.

- ▶ Employs site-specific risk assessment methods, such as CLEA (Contaminated Land Exposure Assessment), Remedial Targets Methodology (RTM) and ConSim (which uses the Monte Carlo method).
 - ▶ Determines the level of remediation required.¹⁰²
4. **Tier 4: Remediation and management**, under which:
- ▶ A remediation strategy is developed, including mitigation measures such as excavation and removal of contaminated material, soil treatment (e.g. bioremediation, chemical oxidation), and groundwater treatment.
 - ▶ A verification and validation report to regulatory authorities is provided.

The UK also has guidance which aims to help local authorities implement the legal framework for contaminated land management (Department for Environment, Food & Rural Affairs, 2012). This explains terminology, how to deal with uncertainty, and how to ensure a strategic and transparent approach is taken, as well as more managerial aspects, for example emphasising that when specialist consultants are chosen to undertake risk assessment, care should be taken to ensure (as far as possible) that they are appropriately qualified and competent to undertake the work.

5.3.2 US

Legal background

Contaminated land risk assessments are regulated under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (United States Environmental Protection Agency, 2025a) and the Resource Conservation and Recovery Act (RCRA) (United States Environmental Protection Agency, 2025b). The Environmental Protection Agency (EPA) provides guidance on human health risk assessments (United States Environmental Protection Agency, 2025c) and ecological risk assessments (United States Environmental Protection Agency, 2025d).

Methodological framework

The US methodology and legislation is similar to some of the other countries described, with a staged process starting at desk study and moving through increasingly site-specific risk assessment.

Human Health Risk Assessment includes the following steps (United States Environmental Protection Agency, 2025c):

1. **Hazard identification of chemicals of concern.**
2. **Linear and non-linear dose-response assessments**, which determine the relationship between exposure levels and the likelihood of adverse health effects based on toxicological data.
3. **Exposure assessment**, which estimates the magnitude, frequency and duration of human exposure to the contaminant. It considers both the exposure pathway and the exposure route.
4. **Risk characterisation**, which consists of the individual risk characterisations from the previous steps and an integrative analysis.

¹⁰² One industry stakeholder suggested that this tier can involve the consideration of: contaminant properties (including bioavailability); geology and hydrology (including depth to water); type, distance and position of receptors relative to contaminant migration; fate and transport modelling, including degradation/ attenuation of the parameters, including in some cases dilution in receiving waters etc.

Ecological Risk Assessment, which includes the following steps (United States Environmental Protection Agency, 2025d):

1. **Site characterisation and data collection** to review historical site use and identify potential receptors.
2. **Chemical and toxicity screening** to identify contaminants of concern, e.g., following the National Oceanic and Atmospheric Administration sediment quality guidelines and Environmental Protection Agency screening values.
3. **CSM** to map exposure pathways, e.g. through flowcharts and GIS-based maps.
4. **Assessment and measurement of endpoints** which are explicit ecological values at risk (e.g. fish population)
5. **Using exposure assessment methods**, which include media sampling and chemical analysis; bioaccumulation modelling to estimate contaminant transfer in the food web, e.g. bioaccumulation factor (BAF), bioconcentration factor (BFC), and food chain models; and exposure modelling, e.g. environmental fate models (EPA's EXAMS or PRZM models) and species exposure models.
6. **Using effects assessment methods** to measure direct biological effects, e.g. toxicity reference values and benchmarks (ECOTOX); toxicity testing, e.g. acute/chronic toxicity tests (LC50 tests, chronic bioassays); field surveys to assess the ecological impacts, e.g. species counts, reproductive studies.
 - ▶ *Assessment of hazard quotient* to compare exposure to toxicity, e.g. $HQ = \text{Exposure} / \text{Toxicological Reference Values (TRV)}$.
 - ▶ Assessment of species sensitivity distributions to identify species at risk, e.g. using probabilistic modelling.
 - ▶ *Using uncertainty analysis* to evaluate confidence in risk estimates, e.g. sensitivity analysis or Monte Carlo simulations.

5.3.3 Canada

Legal background

Federal, provincial, and territorial regulations govern contaminated land risk assessments in Canada. Guidance is provided in the Federal Contaminated Site Risk Assessment Guidelines (FCSRA) (Government of Canada, 2025).

Methodological framework

Risk assessments follow a tiered approach based on the SPR model, similar to the UK.

Human Health Preliminary Quantitative Risk Assessment (PQRA) is the initial assessment and consists of the following steps and methods (Health Canada, 2021):

1. **Description of the property/site.**
2. **Problem formulation**, which includes:
 - ▶ Screening Contaminants of Potential Concern (COPC) and comparison of the contaminant concentrations (in soil, groundwater, sediment and air) against generic screening values, such as those set in Canadian Environmental Quality Guidelines (Canadian Council of Ministers of the Environment, 2025) and Provincial/Territorial Standards.

- ▶ Identifying receptors (e.g. residents, workers, indigenous populations).
- ▶ Determining exposure pathways.
- 3. **Exposure assessment**, which includes:
 - ▶ Characterisation of potential receptors, exposure frequency and duration, and exposure equations.
 - ▶ Environmental modelling.
- 4. **Hazard assessment**, under which COPC, Toxicological Reference Values (TRV) are compared to estimated site exposure levels.
- 5. **Risk characterisation**, which includes carcinogenic and non-carcinogenic risk evaluation.

Human Health Detailed Quantitative Risk Assessment (DQRA) is required if the PQRA identifies risks. It produces a site-specific risk assessment and involves the following steps (Health Canada, 2012):

1. **Problem formulation**, which includes:
 - ▶ CSM through maps of contaminant transport and human exposure routes.
 - ▶ Screening of selected COPCs.
 - ▶ Determining exposure scenarios based on current and future land use.
2. **Exposure assessment**, which includes:
 - ▶ Direct measurement and environmental sampling in soil, air, groundwater, surface water, and sediment.
 - ▶ Fate and transport modelling to predict contaminant movement and degradation.
 - ▶ Exposure scenario analysis, which considers current and future land use.
 - ▶ Bioavailability assessment, which determines how much contaminant is absorbed in the body.
 - ▶ Advanced modelling tools include fate and transport models, Monte Carlo Simulations, and site-specific bioaccumulation models.
3. **Hazard assessment**, which includes:
 - ▶ Establishing TRVs to determine acceptable exposure values.
 - ▶ Dose-response modelling to evaluate carcinogenic and non-carcinogenic risks.
 - ▶ Establishing Relative Absorption Factors (RAFs) adjusted for dermal, inhalation, and ingestion exposures.
4. **Risk characterisation**, which includes Hazard Quotient (HQ) Calculation, Incremental Lifetime Cancer Risk (ILCR) and exposure to multiple contaminants.

5.3.4 Australia

Legal background

In Australia national environmental protection measures are used to harmonise the assessment of potentially contaminated sites. The legislation in Australia sets threshold values associated with the environmental protection measures from an ecological and human health perspective.¹⁰³

Methodological framework

Representatives from national environmental protection agencies have come together to establish a harmonised approach to risk assessment, which has been subject to a detailed consultation through a policy advisor committee with a chair and industry representatives.¹⁰⁴

After the initial investigation to assess soil contamination, bioavailability is assessed in order to qualitatively estimate risk, noting that once some pollutants come in contact with soil, they would be slowly released, while others would never be released, and others may vaporise immediately. This step covers cadmium, lead, copper, zinc, and arsenic. While, for organic pollutants bioavailability is not assessed. At the preliminary investigation level, 100% bioavailability is assumed independently of the soil type. Then, using software tools a more detailed qualitative risk assessment is performed, looking at the exposure scenarios from both an ecological and human health perspective. In Australia the nature of soil and distribution of pollutants change considerably in different parts of the country. Assessing bioavailability avoids the need to use different threshold values for different soil types.¹⁰⁵

Quality Assurance (QA), Quality Control (QC), accreditation, and auditing of practitioners

The Australian approach includes auditors from environmental protection agencies which ensure the scientific reliability of the methods proposed by practitioners.¹⁰⁶

Australia and New Zealand have implemented a Quality Assurance (QA), Quality Control (QC), and accreditation process to ensure practitioners are suitably qualified and their work monitored to confirm the effectiveness of contaminated land assessment and investigation work.

QA in New Zealand is utilised to ensure planned activities, such as building developments, meet quality requirements (Ministry for the Environment, 2021). QA includes systematic actions, procedures, checks, and decisions to ensure the representativeness and integrity of samples, as well as the accuracy and reliability of analytical results. Within a field context, QA includes:

- Ensuring that qualifications, training, and experience of staff and sub-contractors are appropriate.
- Selecting appropriate sampling and preservation methods, containers, and storage to minimise contamination and analyte losses.
- Implementing decontamination procedures for tools and equipment.
- Accurately recording work, observations, and conditions during sampling.
- Labelling samples with unique identifiers, date, and time.
- Recording sample locations and completing a chain of custody paperwork.

¹⁰³ Feedback from targeted interview.

¹⁰⁴ Feedback from targeted interview.

¹⁰⁵ Feedback from targeted interview.

¹⁰⁶ Feedback from targeted interview.

- Ensuring that samples are delivered to the laboratory in good condition and within required timeframes.
- Verifying receipt and understanding of samples by the laboratory.

QC is the observation of techniques and activities to demonstrate that quality requirements have been met. It involves monitoring and measuring the effectiveness of QA procedures. In a field context, QC includes:

- Monitoring and measuring the effectiveness of QA procedures.
- Checking equipment cleanliness, collecting rinsate blanks, and analysing duplicate samples.
- Documenting the extent of QC based on sampling objectives in the sampling and analysis plan.
- Collecting two samples from a single location, storing them in separate containers, and measuring variability due to soil heterogeneity, laboratory analysis, and field sampling techniques.
- Collecting de-ionised water run through decontaminated sampling equipment to test for residual contamination, indicating potential cross-contamination between samples.

In Australia (Government of Western Australia, 2021), standardised field sampling includes:

- Sample logs (primary samples, trip and field blanks, rinsate samples, replicate samples, decontamination procedures, etc.).
- Bore logs (soil bore, groundwater bore/vapour probe installation logs, documenting fill, lithology, grain size, clay content, odours, staining, etc.).
- Sampling logs (field screening results, depths to water, purging details, observations, etc.).
- Field instrument calibration records.
- Field instrument detection limits.
- Chain of custody form identifying (for each sample) the sampler, media, collection date and time, sample preservation method, analyses to be performed, sender signature and departure date and time.

Accreditation and auditing of practitioners

Auditors are specialised professionals in contaminated land accredited by the Western Australia Environmental Protection Agency (WA EPA) under the Contaminated Sites Act (2003) to conduct audits in Western Australia. An audit report provides an independent review of investigations, assessments, monitoring, and remedial work carried out by environmental consultants.

Accreditation and auditing ensure consistent, high-quality work across the region, allowing for ongoing monitoring and process improvement based on real-time results.

5.3.5 Switzerland

Legal background

In Switzerland, according to environmental protection legislation, the aim of contaminated site remediation is to eliminate harmful or nuisance effects caused by a contaminated site.

The investigation and remediation of contaminated sites is carried out in accordance with the objectives and requirements of the Environmental Protection Act of October 7, 1983, and the Ordinance on the Use of Natural Resources. Based on a preliminary investigation, the authority must assess whether a contaminated site is in need of inspection or remediation. Soils from contaminated sites are to be remediated if a substance contained in them exceeds the concentration values set in the legislation. The remediation measures are intended to reduce the contamination below this threshold. For sites requiring remediation, the party responsible for remediation must conduct a detailed investigation to gather all the information required for a more detailed risk assessment. Based on this information, the authority will determine the objectives and urgency of the remediation. A remediation project must then be developed, which will be assessed by the authority, checking in particular whether the remediation objectives are met. The authority will then specify in the remediation order the definitive objectives, the specific remediation measures, the monitoring requirements, and the deadlines to be met (Federal Office For the Environment, 2022).

In addition to investigations in the contaminated area of the site itself, the assessments usually require sampling of the groundwater. If pollutants are detected, monitoring is required, which is followed by water treatment when concentration values are exceeded.

The Contaminated Sites Ordinance specifies substances concentration values that are used for the assessment of contaminated sites. For substances for which concentration values have not been specified, the local authority determines such values on a case-by-case basis with the approval of the Federal Office for the Environment in accordance with the provisions of Water Protection legislation (Federal Office for the Environment, 2013).

Methodological framework

In Switzerland, in order to avoid endangering people and the environment through contaminated sites and waste, pollution concentration and soil limit values are derived on a risk-based basis. The concentration values of the Contaminated Sites Ordinance are based on basic human toxicological data combined with a defined exposure scenario (absorption of the pollutant by the body via drinking water). The values thus correspond to a (human) toxicologically based drinking water value. The solid limits and guideline values are based on the concentration values of the pollutant combined with the mobility of the pollutant in the waste matrix (Federal Office for the Environment, 2013).

The remediation of contaminated soils under contaminated site legislation aims to protect the people, animals, and plants that interact with the soil. From this perspective, the soil is viewed primarily as a source of impacts. A preliminary investigation is used to determine whether a site is causing or will cause harmful impacts and therefore requires remediation. A detailed investigation is then used to assess the risk potential of a site, the full extent of the pollutant potential, the distribution of the pollutants, and the exact extent of the hazard. The detailed investigation determines the urgency of remediation measures and the objectives of remediation. Since the protected asset is the soil's "users," not the soil itself, the remediation objectives are user-specific. In principle, the highest measured pollutant concentration is used for the assessment (Federal Office For the Environment, 2022).

The remediation objectives can be adjusted in case the measures required to achieve them will fail to improve the overall environmental condition and whether the costs of the measures are disproportionate.

The Contaminated Site Ordinance contains also specific criteria for the investigation and assessment of impacts on groundwater from contaminated sites. In order to assess the impacts of a site, the concentration of the substances originating from it in its immediate vicinity is to be determined. This is done on a case-by-case basis over which area the downstream area immediately adjacent to the site extends. In many cases, sampling in the downstream area alone cannot determine whether the detected substance concentrations originate from the site under

investigation or from another location or whether they are part of the background contamination of the groundwater. In such cases, it is essential that the upstream area is also sampled with the aim of identifying and quantifying the site-originating substances from the difference between the substance concentrations in the upstream and downstream areas (Federal Office for the Environment, 2003).

5.3.6 Norway

Legal background

According to the Norwegian Environment Agency, the goal of cleaning up areas with contaminated soil is to make it safe for people living there and not harm the environment.

The Pollution Control Regulation (Klima- og miljødepartementet, 2004) defines contaminated soil as the soil or bedrock where the concentration of substances hazardous to health or the environment exceeds the established standard values for contaminated soil. Soil where the concentration of inorganic substances hazardous to health or the environment does not exceed the local natural background level in the area where a terrain intervention is planned to be carried out, shall nevertheless not be considered contaminated. Soil that forms acid or other substances that may cause pollution in contact with water and/or air is considered contaminated soil unless otherwise documented.

The Norwegian Environment Agency is aware of many locations where there is soil contamination or suspicion of contamination. A map of contaminated sites is provided to the public (Miljødirektoratet, 2025).

Areas where there has been previous industrial activity may be contaminated due to past emissions from production or acute pollution. When industry closes and land use changes, measures may need to be implemented. Stricter requirements are placed on the soil in areas where people live and children play than in industrial areas, traffic areas, etc. Requirements are also placed to protect the environment and prevent runoff to waterways.

Methodological framework

The Norwegian Environment Agency mentions that the consequences for health and the environment depend on (Miljødirektoratet, 2021a):

- The balance between the pollution that leaks into the ground and what is washed out;
- The extent and distribution of the contamination;
- The type of pollution;
- The type of soil;
- The amount of precipitation;
- Which organisms live in the soil;
- The potential for spread from the soil to humans and nature; and
- The potential of the substances to have harmful effects on human health and the environment.

The overall goal of the risk assessment is to investigate the risks associated with the contaminated area and how much the risk must be reduced so that no negative effects on people and the environment occur in the current situation or in the future. Within the risk assessment of contaminated soil, three main themes are identified (Miljødirektoratet, 2021a):

- **Source** - contaminated soil or groundwater, examples of this are abandoned landfills, contaminated industrial sites and leaks to the ground from oil tanks.
- **Spread** - via soil, water or air, examples of routes of spread are soil (for example, oral ingestion or skin contact) and dust (for example, inhalation), soil gas, groundwater, surface water and erosion.
- **Receiver** - effect on people, ecosystem, society, examples of recipients are humans, animals, plants and drinking water sources.

The exposure must lead to a risk of a negative effect on the recipient. If the risk is considered to be so great that the environmental objectives at the site are not achieved, measures must be considered to reduce the risk so that the environmental objectives are achieved.

All mapped sites with contaminated soil that exceed standard values or natural background levels in the area must undergo some form of risk assessment.

The necessary scope of the risk assessment will, however, vary from case to case, and is governed by, among other things, the level of contamination, land use and environmental objectives for the site. The condition class system also sets upper limits for which pollution levels can be accepted with risk assessment at sites with land use that are covered by this system.

The Norwegian guide proposes a step-by-step procedure, divided into three stages (Miljødirektoratet, 2021b):

- **Step 1: Simplified risk assessment**

A simplified risk assessment determines whether there is a risk by comparing it with standard values for contaminated soil, background values and condition classes for contaminated soil. In a simplified risk assessment, it is assessed whether the soil contamination exceeds or is within the condition classes that are normally accepted for the current land use at the site. It is also considered whether the condition classes are conservative enough for the site's environmental objectives, or whether there are special conditions at the site that indicate the need to be more conservative.

- **Steps 2 and 3 Extended risk assessment**

In step 2, many of the standard values in step 1 are replaced with site-specific data. Information for this is obtained from literature searches, fieldwork, and laboratory experiments.

An extended risk assessment is relevant if:

- ▶ The pollution is extensive, complicated, or covers several different media;
- ▶ Substances hazardous to health and the environment have been identified for which no standard values and/or condition classes have been prepared.
- ▶ The area's land use is not mentioned in the condition class system.
- ▶ There is great uncertainty about the pollution situation and risk, or the pollution is located in or close to vulnerable areas.

Theoretical calculations and modelling are conducted based on information about the location and data from field surveys. Furthermore, risk assessments can be expanded (to step 3) by conducting more measurements in the field, for example gas measurements in buildings or the content of substances harmful to health and the environment in water and/or organisms (biota).

5.4 Conclusion

There is variation between the approaches in the different countries in terms of the legal framework, the quantitative/qualitative nature, the types of risks considered, and the level of risk considered unacceptable to human health and/or the environment.

The common aspects of the legal frameworks analysed are listed below, based on the information gathered in this task (which may not be complete for some countries). Tables 1 and 2 in section 8 provide an overview of the extracted characteristics of the national legal and methodological frameworks analysed.

- Some countries¹⁰⁷ (among those analysed) provide a legislative basis for **the registration of contaminated sites** and some¹⁰⁸ provide public access to a map showing registered potentially contaminated and contaminated sites.¹⁰⁹
- In most of the countries analysed¹¹⁰ the legislation has the objective to **manage and remediate** contaminated sites.
- Legal frameworks in some of the countries analysed¹¹¹ include **funding mechanisms**.
- Some countries¹¹² (among those analysed) set **threshold values** for significant contamination.
- Some countries¹¹³ (among those analysed) set **criteria to assess the risk** of contaminated sites.
- Some countries¹¹⁴ (among those analysed) impose **remediation measures** following a completed risk assessment profile.
- Some national frameworks¹¹⁵ (among those analysed) are based on the **polluter pays principle**.
- Some countries¹¹⁶ (among those analysed) provide a **definition of contaminated sites** in their legal text.

In terms of the methodological framework, all countries follow a step-wise approach, mostly following the principles of risk assessment seen in section 3. However, the terminology associated with the steps varies among the countries.

- **A staged investigation and risk assessment procedure** is used to determine whether there is significant contamination or risk for human health or the environment.

¹⁰⁷ Austria, Belgium, Denmark, France, Germany, the US, Canada and Norway.

¹⁰⁸ Austria, Belgium, France, Denmark and Sweden.

¹⁰⁹ Note that the 2023 study ([linked here](#)) supporting the European Commission's impact assessment for the Soil Health Law (feeding into the Soil Monitoring Law) provides an overview of the status of Member States' contaminated site inventories (Table 7-37 p.180), showing that nearly all Member States had either established, or had planned to establish, national and/or regional inventories, as of 2016.

¹¹⁰ Austria, Belgium, Denmark, France, Germany, Italy, Luxembourg, the Netherlands, Sweden, and Switzerland.

¹¹¹ Austria, Belgium, Denmark (to some extent), Germany (in some states), Sweden (to some extent), and the US. Austria subsidises remediation of contaminated sites, while Denmark and Sweden provide grants to fund investigation and remediation.

¹¹² Austria, Belgium, Denmark, Germany, Italy, Spain, Sweden (indicative and not binding), Australia, Norway, Switzerland, the UK, and the US.

¹¹³ Austria, Belgium, Denmark, and Germany.

¹¹⁴ Austria, Belgium, Denmark, France, and Germany.

¹¹⁵ Austrian, Belgian, Danish (to some extent), German and Swedish.

¹¹⁶ Austria, Belgium, Denmark, Germany, Italy and Sweden. The Austrian definition requires a significant level of contamination or risk, based on threshold values established in the legislation. The Belgian, Danish, German, and Italian definitions are based on the exceedance of screening / background values after a preliminary investigation. The Swedish definition regarding environmental damage relates to land and water areas, buildings and structures that are so polluted that they may cause damage or detriment to human health or the environment.

This procedure includes a preliminary investigation, followed by a detailed investigation, and risk assessment.¹¹⁷

- **A step-wise approach** which includes the exposure assessment, hazard identification, the determination of dose effect relationship is used in some of the countries analysed¹¹⁸, with some differences among the countries with respect to the level of details.
- The use of a **CSM** for the implementation of the source-pathway-receptor paradigm is common to many of the countries analysed¹¹⁹.
- Some of the countries analysed¹²⁰ use a system of **certification, quality assurance and auditing** for practitioners.
- One of the countries analysed¹²¹ uses a **point system** to assess contamination and rank sites.

This overview and landscape of the legal frameworks and principles could be used for inspiration in developing new risk assessment methodologies, or in evaluating and adapting existing methods.

¹¹⁷ Austria, Belgium, Denmark, France, Germany, Italy, the Netherlands, Spain, Sweden, the UK and Switzerland follow this approach, with some differences in the level of detail adopted in various steps by the different countries.

¹¹⁸ Belgium, France, the US and Canada. Luxembourg is planning to use a similar approach.

¹¹⁹ Austria, Belgium, Denmark, France, Germany, Italy, the UK, the US and Canada. Luxembourg is planning to use a similar approach.

¹²⁰ Belgium, France, Germany, the Netherlands and Australia.

¹²¹ Italy.

6. Tools to support the risk assessment of contaminated sites

6.1 Overview

This section highlights selected tools which are currently used to support risk assessment procedures and to map and prioritise contaminated sites. It includes some of the tools mentioned in the academic and grey literature and tools described by stakeholders during interviews, during the workshop, and as part of the review of this report.¹²²

6.2 Tools to assess the risks associated with contaminated sites

The sections below provide an overview of selected tools that are used at national level to assess the risks of contaminated sites.

6.2.1 S-RISK®

S-RISK® (Spaquet, 2025) is a decision-making and user-friendly tool for managing polluted soils, ultimately enabling the determination of the volumes of land to be remediated (Jailler, 2020a). It is a steady-state, mass conservation model designed to calculate human exposure and risk associated with soil and groundwater contaminants. The model allows the calculation of exposure doses by age group.

Three fields of application are possible¹²³:

- Calculation of generic human health-based soil remediation values, which is particularly useful if legal values are proposed in the regulation.
- Calculation of site-specific human health risks within a detailed risk assessment.
- Calculation of site-specific remediation objectives.

S-RISK® is based on and intends to replace the Vlier-Humaan model developed by the Van Hall Institute, which has been used since 1996 within the Flemish (Belgium) Decree on contaminated sites. A major revision by VITO (Flemish Institute for Technological Research), of the formerly used Vlier-Humaan led to the development of S-RISK® in 2013. The revision included making the tool available online, introducing a helpdesk, and introducing maintenance features. In 2018 a major update of the software was required as VITO expressed the wish to stop web hosting and maintenance. Since 2023, SPAQUE (Walloon public company in charge of remediation of orphan sites for the Walloon government) hosts the tool and is in charge of maintenance, IT development, and helpdesk for all users. The update of the model is possible through a scientific committee involving several stakeholders (regulatory, scientific institutes and service providers). S-RISK® ownership is shared between four institutions: Brussels-Environment, OVAM (Flanders), SPW (Wallonia) and Ministry of Grand-Duchy of Luxembourg.¹²⁴

¹²² As mentioned by stakeholders, some of the Horizon projects are currently working on additional risk assessment tools (not included in this report), such as ARAGORN, which will be released in the coming years.

¹²³ Feedback from stakeholder workshop.

¹²⁴ Additional feedback provided by stakeholders.

S-RISK[®] has been used in the Brussels Capital Region and in Wallonia (Belgium) since 2017. Luxembourg has been using S-RISK to develop their own national risk assessment approach and is expecting to use it for site-specific assessment in the future¹²⁵. The model is currently under license, but current co-owners are open to the entry of other countries/regions into the steering and scientific committees, as new co-owners with cost sharing and modification of the ownership agreement.¹²⁶

Based on the S-RISK[®], a dedicated tool for gardeners (SANISOL) has been developed to provide recommendations in a user-friendly manner.¹²⁷ In Wallonia (Belgium), elevated quantities of metals have been traced in the topsoil of urban and industrial areas, posing a health hazard and limiting the development of urban gardening. Based on a health risk assessment model, the web tool provides recommendations concerning the health risks posed by the presence of the metal elements in soil and the products that can be cultivated safely in the vegetable garden (Pereira, B. et al., 2022).

S-RISK[®] provides a complete revision of the original model and updates model concepts, equations, and parameter values, offering flexibility for users. The model's improved equations are based on a review of past risk assessments, ensuring sufficient protection from exposure routes while maintaining consistency with existing regulatory frameworks.

S-RISK[®] follows the standard iterative steps of a risk assessment (i.e. identification of hazards, dose-response relationships, exposure assessment, risk characterisation) (Jailler, 2020a).

The model takes into account background concentrations and calculates risks based on various transfer pathways, including volatilisation, transfer in plants and animals (meat, milk and eggs), soil resuspension, and leaching, among others. The S-RISK[®] calculates all different exposure routes, while other models may focus only on the most critical exposure pathway (such as children or food).¹²⁸ It assesses organic and inorganic contaminants and provides site-specific risk assessments, remediation objectives, and generic human health calculations. The model incorporates detailed equations and parameters, ensuring comprehensive risk characterisation for different exposure routes and health effects through estimating contaminant concentrations in different environmental compartments (indoor and ambient air, tap water, vegetables, meat, milk and eggs) and their subsequent transfer to humans. The model then compares these exposure levels to toxicological reference values to determine potential health risks. It allows to calculate separately the risks for threshold effects (non-carcinogenic or non-genotoxic carcinogenic substances) and for non-threshold effects (genotoxic carcinogenic substances) (Jailler, 2020a).

According to Jailler (2020a), the S-RISK[®] assessment has proved to be a comprehensive and versatile model as it covers a wide range of contaminants and transfer pathways, applies to both generic and site-specific assessments, and can be adjusted to the soil properties and receptors. Specifically, the tool contains specific and flexible databases, which are region/country specific, but it can be customised for other regions. It includes exposure scenarios, about 80 chemicals with physio-chemical parameters, background concentrations (which are optional to include), toxicity reference values, and soil properties. Soil, groundwater, soil air¹²⁹, ambient air, and vegetable monitoring data can be encoded in the tool (Jailler, 2020a).

The downside is that undertaking an assessment through S-RISK[®] is time-consuming and complex, as it requires a detailed data bank for accurate risk characterisation. However, it is not more or less complex than other human health risk assessment tools.¹³⁰ In addition to this, the model relies on “steady state” assumptions, which may not reflect real-world dynamics.

¹²⁵ Feedback from stakeholder workshop.

¹²⁶ Feedback from targeted interview and additional feedback provided by stakeholders.

¹²⁷ Additional feedback provided by stakeholders.

¹²⁸ Feedback from targeted interview.

¹²⁹ Soil air is the air found within the porous spaces in soil.

¹³⁰ Additional feedback provided by stakeholders.

The S-RISK® model has utilised previous successful risk assessment methods and improved on concepts, equations, and parameter values. The tool offers flexibility to its users and provides sufficient protection from exposure routes while maintaining consistency with existing regulatory frameworks.

6.2.2 ENVIRISK

The ENVIRISK tool was developed from 2017 by the Envisol design office (Envisol, 2025) as a web platform, currently hosted on an Envisol server in France. Similarly to S-RISK, the ENVIRISK tool consists of a platform that receives input from the user, performs the calculations on its server, and then returns the output data to the user (Jailler, 2020b).

The tool was developed to implement the health risk assessment methodology used in France. It allows the assessment of risks both based on the contaminant concentration in the soil and water and also considering a remediation objective, called a decontamination threshold, when it is provided for a given risk (Jailler, 2020b).

In ENVIRISK, the user is able to modify the following parameters: the physicochemical properties used to simulate the behaviour of the pollutant in the soil and in water (volatility, solubility); the toxicity data of the pollutants, expressed in the form of dose-response relationships (the Toxicological Reference Values); and the exposure parameters used to weight the exposure doses (such as number of hours spent in a building, daily quantity of vegetables ingested, quantity of earth and dust ingested, etc.) (Jailler, 2020b).

In ENVIRISK, rather than having a default dataset to define a standard scenario, the user is encouraged to create their own scenario based on their CSM. This is a fundamental difference between the French approach and the Belgian and Luxembourg approaches. In France, there are no longer threshold values in soils, nor standard scenarios, as any investigation carried out in soils or waters is subject to a detailed risk study. In Luxembourg and in Belgium, for a large majority of polluted sites, the consultant will compare the results of soil/water analyses with the reference values in soils already established for different standard uses (residential use, commercial use, etc.) (Jailler, 2020b).

The ENVIRISK software has the following advantages (Jailler, 2020b):

- The risk assessment process follows the standard iterative steps (i.e. identification of hazards, dose-response relationships, exposure assessment, risk characterisation);
- It allows encoding of data measured in soil, groundwater, soil air, ambient air and vegetables;
- It allows the calculation of risks and the derivation of remediation targets;
- It allows the user to calculate separately the risks for threshold effects (non-carcinogenic or non-genotoxic carcinogenic substances) and for non-threshold effects (genotoxic carcinogenic substances);
- It includes Toxicological Reference Values in the appropriate and untransformed units;
- The models used for the assessment of soil/air transfer are the most reliable in the literature;
- It contains deterministic and probabilistic models to facilitate a sensitivity analysis on a parameter as part of a detailed risk study;
- It benefits from recent IT developments allowing it to be up-to-date for around ten years.

However, ENVIRISK software also has the following disadvantages (Jailler, 2020b):

- Using commercial software automatically implies a strong dependence on the company marketing it;
- It is not considered intuitive and requires regular practice to be able to use the tool effectively;
- Its applicability in other regions is limited because the used threshold values are associated with the French legal context;
- It does not integrate standard scenarios by default; and
- It does not integrate a soil/plant transfer model.

6.2.3 JAGG

The Danish Environmental Protection Agency has developed the JAGG model (in Danish called Jord, Afdampning, Gas, Grundvand), which is widely used for the risk assessment of contaminated sites. The model simulates the contaminant concentration at a point of compliance based on input source concentrations and geometry and other soil and groundwater parameters (Danish Environmental Protection Agency, 2017).

JAGG can be used to carry out risk assessments of the vaporisation of contaminants to indoor and outdoor air (Danish Environmental Protection Agency, 2025a). The tool uses a spreadsheet, where the physical-chemical data and limit values for soil, groundwater and evaporation to air are presented for numerous pollutants. A graphical presentation of the risk assessment is provided.

Among other things, the program allows to (Miljøstyrelsen, 2017):

- Carry out the risk assessment of diffused soil contamination in relation to land use. The calculations may be used to determine whether a site is suitable for very sensitive land use such as house gardens or playgrounds in kindergartens;
- Assess the migration of contamination in the unsaturated zone; and
- Calculate the probability of locating contaminated soil.

JAGG can also be used to calculate the risk for a groundwater resource, but for use in the orphan sites program it has been replaced by GrundRisk (see below).¹³¹

In addition, in Denmark for risk evaluation of surface water bodies, a screening tool is used to assess whether pollutants leaching from contaminated soil pose a risk of damaging surface water or natural areas. Selected results undergo a more site-specific evaluation (Danish Environmental Protection Agency, 2025b).

6.2.4 GrundRisk

In addition to JAGG, the Danish Environmental Protection Agency has developed the GrundRisk tool (Danmarks Miljøportal, n.d.), which is used as a support tool to enable the systematic and data-based assessment of the risks that contaminated soil poses to groundwater in the orphan-sites programme.

The tool aims to provide realistic estimates by considering the most relevant transport processes and identifying groundwater threatening sources (Danish Environmental Protection Agency, 2017). The tool provides competent authorities and private advisers access to data on mapped sites to assess the threats to groundwater, which can inform the prioritisation of remediation actions. The tool consists of two components:

¹³¹ Additional feedback provided by stakeholders.

- The screening element, which facilitates the development of simple assessments by providing automatic estimations for the area of interest based on standard values and local geology; and
- The risk assessment element, which allows for site-specific detailed assessments if data is available from site contamination studies.

The tool is flux-based and therefore considers not only concentration, but also pollutant mass and the effect it has on a real or hypothetical modelled groundwater abstraction.¹³²

6.2.5 MODUL'ERS

MODUL'ERS (INERIS, 2014) is a software tool for conducting prospective health risk assessments within the framework of health impact assessment and for carrying out residual risk analyses of contaminated sites. It allows to estimate the exposure levels and risks over time. MODUL'ERS has been developed and financed by the French Ministry of the Environment. This software is public and free of charge subject to registration for a training course.¹³³ This tool can be used for cases of different complexity.

MODUL'ERS consists of a modelling and simulation platform and a library. It allows to build adapted multimedia models, by arranging the predefined modules from the library and to conduct deterministic and probabilistic simulations and associated sensitivity analyses.

MODUL'ERS makes a concrete link between the conceptual site model and the prospective assessment of exposure and health risks.

Its flexibility allows to create models adapted to the transfer mechanisms of the pollutants between different environmental media and to the required precision and available information. For each substance, the user chooses:

- The transfer mechanisms to be taken into account when modelling the expected concentration in the media;
- The modelling approach to represent certain transfer mechanisms (e.g. a model for the transfer of pollutants from soil to indoor air);
- Between the use of measured data vs. the use of modelling.

The library includes modules for calculating concentrations in media, such as soil surface, surface waters, groundwater, , indoor and outdoor air (pollutants in gaseous and particulate form, plants, meats and excreted products from animals, aquatic animals).

The tool has the following features:

- Taking into account, within the same scenario analysis, exposures linked to different locations (e.g. consumption of plants grown in different locations);
- Calculation of the risk using different levels of aggregation (e.g. by substance, by exposure vector, by exposure route, by target organ);
- Calculation of the risk without a threshold value, taking into account the evolution of concentrations in the environment and that of exposure parameters on human health over time;
- Calculation of the risks considering the threshold value for different age groups (from 1 to 10 definable groups);

¹³² Additional feedback provided by stakeholders.

¹³³ Additional feedback provided by stakeholders.

- Addition of substances to the predefined list;
- Import of input data from Excel to quickly reconstruct a case based on a standard model or to develop an exposure scheme across multiple geographical locations;
- Results in the form of graphs and tables, that can be exported to Excel for further statistical processing or use in a GIS map or to a study report (in pdf report) with customisable content.

6.2.6 Risk Based Corrective Action (RBCA) Tool Kit

The Risk Based Corrective Action (RBCA) Tool Kit for chemical releases was developed by GSI Environmental Inc and designed to meet the requirements of the ASTM¹³⁴ Standard Guide for Risk-Based Corrective Action (E-2081) for Tier 1 and Tier 2 RBCA evaluations for chemical release sites, in addition to traditional risk assessment calculations. The software combines contaminant transport models and risk assessment tools to calculate baseline risk levels and derive risk-based cleanup standards for soil, groundwater, surface water, and air exposure pathways (GSI Environmental , n.d.).

Features of the RBCA Tool Kit include:

Exposure pathway evaluation, assessing a range of routes including:

- ▶ Groundwater ingestion
- ▶ Surface water use and fish ingestion
- ▶ Combined contact with surface soil (ingestion, dermal contact, vapor inhalation, homegrown produce)
- ▶ Outdoor and indoor air exposure (e.g., vapor intrusion).

Fate and transport models, including:

- ▶ Steady-state air, soil, and groundwater exposure models;
- ▶ Transient groundwater modelling analysis to help estimate not only how high but how soon exposure could occur (GSI Environmental , n.d.).

The RBCA tool kit has been discontinued and is no longer available to purchase.

6.2.7 UK Contaminated Land Exposure Assessment (CLEA) Model

The UK Contaminated Land Exposure Assessment (CLEA) Model is a UK standard tool for assessing human health risks from soil contamination and was developed by the UK Environment Agency to derive soil guideline values. The CLEA model uses generic assumptions about the fate and transport of chemicals in the environment and a generic conceptual model for site conditions and human behaviour to estimate child and adult exposures to soil contaminants for those potentially living, working, and/or playing on contaminated sites over long time periods (Environment Agency, 2009).

The CLEA software is based on the CLEA model, which allows users to obtain assessment criteria, and enter their own chemical, soil, building or land use datasets. The CLEA software can be used to:

- Obtain generic soil assessment criteria using generic assumptions about the characteristics of contaminants and people likely to be present on site;

¹³⁴ American Society for Testing and Materials

- Derive site-specific soil assessment criteria by entering user data on the characteristics of contaminants and people likely to be present on site;
- Assess whether a measured concentration in soil (and where available, measured site concentrations for contaminants within soil air, ambient and indoor air, and fruits and vegetables) would present a potential risk to human health for a particular set of circumstances (Environment Agency, 2015).

The CLEA model is solely focused on chronic health risks from soil, and excludes acute hazards and exposure, ecological effects, and water contamination (Environment Agency, 2009).

Users can download the CLEA software (version 1.071) and handbook from the Environment Agency website.¹³⁵

6.2.8 Risk-integrated Software for Clean-ups (RISC) 5

RISC5 is a software package designed for performing fate and transport modelling and human health risk assessments for contaminated sites. The fate and transport models estimate reception point concentration in both air and ground water. The software is able to perform conventional forward risk calculation in addition to back risk calculations, which computes a cleanup level for an input risk value. (Environmental Software Online, n.d.)

Features of the RISC 5 software include (Environmental Software Online, n.d.):

- Perform calculations for two different human exposure scenarios (with up to seventeen exposure pathways each) simultaneously (e.g. calculations for both residential and industrial scenarios can be performed at the same time);
- Determine cumulative risks from two different exposure scenarios, as might be the case when the user wants to sum the risks for the scenario where a resident is exposed during both childhood and adulthood;
- Estimate exposure point water and air (both indoor and outdoor) concentrations using predictive chemical fate and transport models;
- Allow for additivity of pathways and compounds for either a forward calculation of risk or back calculation of cleanup levels.

6.2.9 Swedish tool to establish guideline values

In Sweden, a model has been developed for establishing risk-based guideline values for contaminated soil.¹³⁶ The model is available as an Excel-based calculation tool.¹³⁷

The methodology used to develop generic guideline values reflects common conditions at contaminated sites in Sweden. These values provide protection against health and environmental impacts in most cases, though they are not suitable for every situation. When the generic guideline values are not appropriate, site-specific values may be developed. This involves considering the local conditions at the site and adjusting the parameters in the calculation tool. A key aspect of this process is the expected land use, since it determines the types of activities taking place, who may be exposed, and the level of protection required for the soil environment. Site-specific guideline values should be calculated using the Excel-based tool. Under deviating conditions, other

¹³⁵ <https://www.gov.uk/government/publications/contaminated-land-exposure-assessment-clea-tool>.

¹³⁶ The structure of the model, as well as the methodology and data used to calculate generic guideline values, is presented in the Swedish Environmental Protection Agency's report 5976 (Swedish Environmental Protection Agency, 2009b).

¹³⁷ Updated versions of the model and the tool are free and available on the Swedish EPA's website (Swedish Environmental Protection Agency, 2026).

exposure pathways or receptors can be included, or other tools and methods can be used (e.g. the triad approach for the soil environment), to supplement the calculations.¹³⁸

The Swedish EPA provides generic guideline values for two categories of land use; sensitive land use and less sensitive land use. These values consider four protection targets: human health; the soil environment; groundwater; and surface water.¹³⁹

Risk assessments incorporate both direct exposure to contaminated soil and indirect exposure through the transfer of contaminants to air, groundwater, and plants. The guideline values also ensure protection of the soil environment within the affected area and safeguard groundwater and surface water from contamination. The human health pathways are integrated into one human health value.¹⁴⁰

The final guideline value is determined by selecting the lowest value derived for human health, soil environment, groundwater or surface water. Further adjustments are made to prevent acute toxic effects, avoid the presence of free-phase organic contaminants, and ensure that values do not fall below natural background levels or concentrations caused by diffuse, large-scale contamination. Only part of the tolerable daily intake is allocated for exposure, since there are normally other sources of exposure.¹⁴¹

It should be noted that at an EU level, methods for deriving soil screening values were reviewed and evaluated by Carlon, D'Alessandro, & Swartjes (2007).

6.2.10 Comparison of tools

Jailler (2020a) compared the S-RISK® tool with other tools, including:

- Risk-based corrective action (RBCA) – used in USA and in France, developed by GSI Env. Inc. and marketed by GroundwaterSoftware.com (GSI Environmental, 2025);
- Contaminated land exposure assessment (CLEA) tool – used in the UK for soil screening values and risk assessment, free access (Environment Agency, 2015)¹⁴²;
- MODUL'ERS – developed by the French National Institute for Industrial Environment and Risks (INERIS), per request from the Environment Ministry (INERIS, 2014);
- Risk-integrated software for clean-ups (RISC 5) – developed by British Petroleum and marketed by GroundwaterSoftware.com (Groundwater software, 2025).

According to Jailler, the four models appear satisfactory from a methodological point of view. RBCA, RISC 5 and CLEA offer the possibility of carrying out risk calculations forwards and backwards, unlike MODUL'ERS. RBCA (now discontinued) had a disadvantage of not being compatible with current versions of Excel, despite all the features it brings (robustness and ease of use). MODUL'ERS and RISC 5 (especially MODUL'ERS) have the advantage of containing deterministic and probabilistic models (taking into account uncertainties at each stage) in order to facilitate sensitivity analysis. While using CLEA is rudimentary (Excel sheet with command buttons), using MODUL'ERS is less user-friendly, according to feedback from experienced risk assessors who have used it. (Jailler, 2020a).

Workshop participants suggested that when comparing tools, the goal should be broadened from identifying the “most reliable and accurate” risk assessment tool to identifying the best tool to¹⁴³:

¹³⁸ Additional feedback provided by stakeholders.

¹³⁹ Additional feedback provided by stakeholders.

¹⁴⁰ Additional feedback provided by stakeholders.

¹⁴¹ Additional feedback provided by stakeholders.

¹⁴² It is noted by a stakeholder that the CLEA model is for human health. For more complex modelling around groundwater migration/ leaching, the RTM or CONSIM models are used.

¹⁴³ Feedback from stakeholder workshop.

- Calculate screening value for a soil legislation (if the country chooses the system of screening values, such as Belgium) and also be able to carry out a site-specific risk assessment (such as France);
- Be a user-friendly tool used by soil experts in service provider companies;
- Be updated if necessary (including IT development and maintenance).

6.3 Tool for prioritising potentially contaminated sites: ROCKS

In addition to the tools above, the Risk Ordering for Contamination Key Sites (ROCKS) software (ISPRA, 2025), has been developed by ISPRA to prioritise potentially contaminated sites within regional development plans, using risk evaluation criteria. The prioritisation criteria were developed through a collaborative process including 15 regions of Italy, one autonomous province, and 14 regional environmental protection agencies to guide the prioritisation of potentially contaminated sites within regional remediation plans (ISPRA, 2024).

ROCKS allows users to enter site information through a guided interface, which helps identify errors and inconsistencies. The sites are then scored based on predefined criteria and ranked accordingly. The ranking is displayed in a user-friendly list with options to filter and navigate through the sites. The assessment is customisable as users can set regional classification criteria, adjusting weights and scores for various fields to reflect local prioritisation.

According to ISPRA (2024), the complexity of ROCKS may be overwhelming for some users, and accurate prioritisation relies on the quality and completeness of the input data and the user. Therefore, users may require initial setup administrative support and ongoing support to ensure quality results. However, overall, ROCKS is considered to be a user-friendly tool that provides guided data entry and prioritisation based on a nationally shared methodology. The assessment criteria can be tailored to local needs and support a wide range of data management functions, including import/export and administrative tools.

In addition to technical manuals, ISPRA provides software applications to assist in calculating risks.

A simplified qualitative procedure is also used for the evaluation of the known or potential contamination risk of a site, called Risk Ranking Index (RRI).¹⁴⁴

- The software creates a database with all the uploaded sites;
- When a site is uploaded/modified, the related RRI score is calculated;
- If not all the parameters are uploaded or if there are inconsistencies to be solved the site is saved as “draft” with “0” RRI score;
- The software (Working environment menu) allows users in regions to modify the scores and weights assigned to administrative parameters considering the specific regional context.

¹⁴⁴ Feedback from stakeholders workshop.

7. Data availability and harmonisation

Various EU sources host data that could be used in contaminated site risk assessments, including data on soil and on pollutants in soils. The methodologies to collect the data could be harmonised in order to improve data comparability and enhance policies to address contaminated sites.

7.1 Soil data availability and collection at EU level

The section below highlights a few datasets with relevant information on soil health at EU level which could provide context or a starting point for risk assessment.

- **The Soil Degradation Dashboard** was launched in 2023 and updated in 2024 and 2025 (Joint Research Centre, 2025). It monitors the state of soil degradation in the EU through a series of indicators, including indicators on heavy metal contamination.
- **The EU Soil Observatory (EUSO)** has been established with the aim to become the principal provider of reference data and knowledge at EU-level for all soil matters (Joint Research Centre, 2021). It supports the EU policies on soil and provides knowledge and data to safeguard and restore soils. The proposed functions for EUSO included the development of an EU Soil Dashboard and to further consolidate the functionality of the European Soil Data Centre (ESDAC). **The EUSO Soil Degradation Dashboard** was launched in 2023 and updated in 2025 (Joint Research Centre, 2025). It monitors the state of soil degradation in the EU through a series of indicators, including indicators on heavy metal contamination.
- Hosted by the JRC, **ESDAC** is one of the main data sources for soil in Europe (Joint Research Centre, 2025). ESDAC covers many soil data and information, mostly at European scale, and when possible, at national or global scale. The main datasets categories include soil properties, soil threats, soil point data, and data from projects (e.g. Land Use/Cover Area frame Survey (LUCAS)). The database has the potential to host comparable and harmonised data related to contaminated sites, along with GIS maps, following data collection at Member State level, as it is done for example in Austria, Belgium, France, Norway.^{145, 146} National geological survey departments have made efforts to map the background levels of some chemicals.¹⁴⁷ National datasets are often based on environmental permits, land-use records, and environmental assessments.¹⁴⁸ However, data at Member State level are often not comparable because they are obtained using different methodologies (Vieira, D. et al, 2024).

Most of the EU-wide data on soil pollution originates from the land use/cover area frame survey (**LUCAS**). The survey is carried out by Eurostat in cooperation with Member States, through direct observations made by surveyors in the field. The LUCAS survey includes the analysis of both extractable and bioavailable fractions of metals and metalloids in EU soils (Vieira, D. et al, 2024). Specifically, the survey allows to prepare maps of heavy metals concentrations (As, Cd, Cr, Cu, Hg, Pb, Mn, Sb, Co and Ni) in European topsoil, which can be used to identify areas presenting a hazard to health or the environment (Toth, G. et al., 2018).

¹⁴⁵ It should be noted that in 2017 EIONET countries were asked to provide information on various variables related to contaminated sites. However, the data collected were not totally comparable.

¹⁴⁶ Additional feedback provided by stakeholders.

¹⁴⁷ Additional feedback provided by stakeholders.

¹⁴⁸ Additional feedback provided by stakeholders.

Among the various functions, the data from the LUCAS survey can be used for soil protection and mapping. The surveys provide microdata on land cover, land use, and associated environmental parameters, point and landscape photos, and estimates on land cover and land use (Eurostat, 2025). Regarding soil properties and contaminants, the samples collected were analysed to assess:

- ▶ Particle size distribution (% clay, silt and sand content);
 - ▶ pH (in CaCl_2 and H_2O);
 - ▶ Organic carbon (g/kg);
 - ▶ Carbonate content (g/kg);
 - ▶ Phosphorous content (mg/kg);
 - ▶ Total nitrogen content (g/kg); and
 - ▶ Extractable potassium content (mg/kg).
- Alternatively, other databases seemed to be able to contribute to point source pollution assessment as a result of the access to the global database on mine sites. The water and planetary health analytics (WAPHA) global metal mines database represents an alternative to assess point source pollution, as it analyses potentially dangerous concentrations of toxic waste derived from past and present metal mining activity (Hudson-Edwards, 2023).
 - Having a common data platform follows one of the objectives of the One Substance One Assessment package, which aims at creating a common platform integrating existing databases for chemical data across different media, including soil. As part of this initiative, **ECHA** will create and manage a database providing alternatives to substances of concern (2023/0453 (COD)).

7.2 Contaminant threshold data availability

In addition to data on soil properties and the extent of contamination, data on chemical hazards and threshold values is necessary to assess the level of risk presented by contaminated sites. Different risk assessment methodologies may involve assessing different types of threshold values, using a range of different terms. Yunta, et al. (2025) set out the following key definitions (among others):

- Soil Quality Guideline: Guideline value for the concentration of a substance in soil considered safe for human health and the environment.
- Soil Screening Value (SSV): Generic quality standards that are used to regulate land contamination on the basis of the risk levels (negligible, intermediate and potentially unacceptable).
- Threshold Limit Value (TLV): Maximum concentration of a substance in soil considered safe for human exposure over a specified period.

Yunta, et al. (2025) also describe the different types of 'Limit Values' that may be used to identify the maximum concentration of a substance in a soil. These include:

- Maximum Allowable Concentration (MAC): Maximum concentration of a substance in soil allowed by regulatory agencies.
- Maximum Permissible Concentration (MPC): Maximum concentration of a substance in soil considered safe for human exposure.

- Permissible Exposure Limit (PEL): Maximum concentration of a substance in soil allowed by regulatory agencies for occupational exposure.

Different types of thresholds have different purposes and meaning in different Member States (Carlön, D'Alessandro, & Swartjes, 2007) (European Environmental Agency, 2022). Many are derived based on (eco)toxicological data, taking into account background levels of contamination which differ between regions.

Some thresholds for soil contamination are set out in EU law. For example, the Sewage Sludge Directive (OJ L 181, 4.7.1986, pp. 6–12) sets limit values for the concentrations of metals (Cd, Cu, Ni, Pb, Zn, Hg, Cr) in soil. However, limits for other substances in soil are not set out at EU level, which differs to the approaches for surface water, groundwater, and air where there are EU-level limits.

An EU level streamlined policy approach, such as the Soil Monitoring Law, might provide room for more harmonisation of the methodologies to identify and set threshold values such as soil screening values. This is also supported by stakeholders. EU guidance on the methodology for deriving the screening values would lead to more harmonised values, while national variations such as dispersal routes due to for example geology could still be accounted for.¹⁴⁹

According to the European Environmental Agency (2022), a more harmonised approach to risk assessment and soil screening and threshold values would ensure a more effective management of soil pollution across Europe.

The ARAGORN project is collecting soil threshold values at European and national levels. The project highlighted the need to collect European soil screening values and suggested to use a tiered risk assessment approach and to consider bioavailability, remediation, and socio-economic analysis. Stakeholder engagement is encouraged at each stage, allowing for the integration of local knowledge and preferences into the development of screening values and remediation strategies, as outlined in the project's co-creation framework.¹⁵⁰

Available tools, such as the Soil Threshold Calculator for metal pollution might support the harmonisation process by deriving soil type-specific ecotoxicological thresholds, which can inform the establishment of harmonised limit values (Arche Consulting, 2020)¹⁵¹.

7.3 Data harmonisation

A comprehensive and sound approach is needed to take informed risk management decisions in the context of site-specific risk assessment. This requires comparable and accurate soil indicators, including soil screening values, threshold values, as well as data on the available fraction and bioaccumulation for each pollutant within a specific soil and site. It can be argued that, whilst site-specific risk assessment needs clear and robust guidance, it is by definition site specific, and therefore input parameters might need to vary, for example based on the CSM.¹⁵²

Attempts were made to differentiate background levels, reference values, and screening values for natural and anthropogenic sources of the soil contamination. Challenges related, among others, to the variation in terminology to define polluting substances. (Vieira, D. et al, 2024).

Some EU projects (e.g. SoilWise, ISLANDR, ARAGORN, EDAPHOS mentioned under section 4) share the common goal of enhancing soil health through the collection and harmonisation of data, and the identification of solutions to monitor and remediate soil pollution.

¹⁴⁹ Additional feedback provided by stakeholders.

¹⁵⁰ Additional feedback provided by stakeholders.

¹⁵² Additional inputs provided by stakeholders.

- **SoilWise** is a project funded by the Horizon Europe program, which has developed a data repository for soil that includes databases and reports on soil contamination (SoilWise, 2025).
- As mentioned under section 4, the **ISLANDR project** aims to reduce hotspot soil pollution in Europe. It does so by collecting and sharing data, mapping contaminated sites, and optimising monitoring methods. It focuses on some soil pollutants; PFAS, organochlorines and organobromine compounds, petroleum and coal compounds, and metal(loid)s (Yunta, et al., 2025).
- The **ARAGORN project** aims to map contaminated sites in Europe and developing a risk assessment framework for stakeholders (Aragorn, 2025). In partnership with the International Network on Soil Pollution and the Common Forum, they are working towards a global database on soil pollutant threshold values in agricultural soils and other land uses. The project aims to understand and describe the differences in the approaches used for derivation of threshold values, and to assist countries to derive their own national/regional threshold values. In addition, ARAGORN's data harmonisation efforts are guided by co-creation principles, leveraging stakeholder perspectives to ensure that data collection protocols and risk assessment frameworks are contextually appropriate and widely accepted. This participatory approach helps to align technical methodologies with local needs and priorities.¹⁵³

Harmonisation requires using the same laboratory methods to obtain comparable soil fractions of pollutants.¹⁵⁴ Harmonising data collection methods would allow to enhance comparability among projects and policies, interoperability, and data sharing (Yunta, et al., 2025). In order to do this, Yunta, et al. (2025) recommend to:

- Encourage projects collecting soil samples to adopt standardised sampling methods to ensure consistency and comparability.
- Develop a harmonised data collection protocol to facilitate data sharing and integration.
- Ensure compatibility of data formats and structures to enable data exchange and analysis.
- Establish a data sharing platform to facilitate access to data and promote collaboration.

The Soil Monitoring Law provides a good basis for harmonisation by requiring measurements through standard protocols and methodologies, prescribing formats for datasharing and reporting, and setting up a digital soil health data portal.

¹⁵³ Additional feedback provided by stakeholders.

¹⁵⁴ Additional inputs provided by stakeholders.

8. Conclusions on risk assessment methods

This report provides a synthesis of selected risk assessment practices for contaminated sites across Member States and selected third countries, through a comparative overview of existing legal frameworks, methodological steps, tools and ongoing initiatives, as well as the identification of the significant heterogeneity in risk assessment approaches across Member States. This diversity is highlighted as a potential barrier to ensuring a level playing field in terms of environmental and human health protection.

8.1 Standards and policies

At global level, the WHO has ambitions to improve global soil health, including through the identification and management of risks from contaminated sites, although specific frameworks for the identification and risk assessment of contaminated sites are not set out by the WHO. Several ISO standards include, among others, procedures for risk assessment, while international conventions such as the Minamata Convention on Mercury and the Stockholm Convention on Persistent Organic Pollutants have developed relevant guidance documents.

At EU level, several EU policies, such as the Soil Monitoring Law and the Environmental Liability Directive provide some guidance in relation to risk assessment. The European Commission's guidelines on chemical risk assessment from 2003 are also used by some stakeholders for the derivation of soil screening values. It should be noted that these guidelines focus on the modelling/calculation steps of risk assessment in all types of environmental compartments (marine water, surface water, sediment, and soil), rather than the specific risk assessment framework for contaminated sites.

8.2 Risk assessment frameworks

Contaminated site risk assessments generally follow a tiered approach in an overarching framework. The number of steps, the way they are executed, and the flexibility of the framework can vary between countries. The key steps taken are: a) problem definition; b) exposure assessment; c) toxicity or hazard characterisation; and d) risk characterisation. These steps are described in section 3 of this report. Some frameworks also include steps for stakeholder and expert involvement, CSM development, land-use determination, and quality assurance processes.

Frameworks vary as they consider different types of receptors (e.g. risks to biological species or risks to water quality) and different types of contaminants (e.g. different groups of chemicals). Some frameworks include multiple stages of risk assessment (e.g. simple/preliminary risk assessments and detailed risk assessments). Some frameworks integrate specific tools/models to assess risks, while others are more flexible.

Some risk assessment procedures are defined under national legislative frameworks, as explored in section 5 of this report.

The sections above highlight that different approaches are used across EU Member States and third countries, leading to potentially different conclusions on the level of risk posed by sites with comparable levels of contamination. A risk assessment method that leads to comparable results among and within Member States should also leave flexibility to take into account site-specific conditions, related to geographic and geological factors.

In addition, differences among Member States include¹⁵⁵:

- Different priorities, for example, methods to take into account soil ecotoxicity can be country specific.
- Different types of protection goals (different routes to exposure of people and different environmental compartments and species);
- Different coverage of short-term and/or long-term risks;
- Different coverage of risks beyond direct household/environmental impacts e.g. resilience for food production; coverage of risk assessment for soil re-use; consideration of climate change measures.

¹⁵⁵ Feedback from targeted interview.

8.3 Risk assessment tools

In Europe, S-RISK, ENVIRISK, JAGG, and GrundRisk have been developed to support contaminated site risk assessment calculations and to prioritise potentially contaminated sites (ROCKS). Jailler et al. (2020) provides an overview of the strengths and weaknesses of S-RISK and ENVIRISK, as well as other tools including RBCA, CLEA, MODUL'ERS, RISC 5. Risk assessment tools facilitate the input of the various types of data and enable (semi-)automated calculations to be undertaken. There are differences between the user-friendliness of each tool and there may be differences in the parameters and assumptions built into each tool (e.g. the chemicals included, exposure routes and modelling parameters included, and environmental receptors considered). This study has not identified a single tool that covers all the desired characteristics.

The tools are described in detail in section 6 of this report and summarised in the table below.

Table 1 Comparison table of identified risk assessment tools for contaminated sites

Tool Name	Main Application	Key Features	Geographic Use / Ownership
S-RISK®	- Human health risk assessment; - Calculation of remediation objectives.	- Steady-state, mass conservation model; - Calculates exposure doses by age group. - Covers multiple exposure routes (soil, water, air, food); - Flexible database; - Supports generic and site-specific assessments.	Belgium Luxembourg; co-owned by regional authorities
SANISOL (based on S-RISK®)	Human health risks assessment from metals in soil	Provides recommendations for safe cultivation in contaminated soils	Wallonia (Belgium)
ENVIRISK	- Human health risk assessment; - Calculation of remediation target.	- Web-based platform; - User can modify parameters; - Supports deterministic and probabilistic models; - Scenario-based.	France
JAGG	Ecological risk assessment of contaminated sites (vaporisation, land use, groundwater)	- Spreadsheet-based; - Simulates contaminant concentrations; - Graphical output; - Supports assessment for sensitive land uses.	Denmark
GrundRisk	Groundwater risk assessment for orphan sites	- Flux-based; - Considers mass and effect on groundwater abstraction; - screening and detailed assessment of components	Denmark

Tool Name	Main Application	Key Features	Geographic Use / Ownership
MODUL'ERS	- Prospective human health risk assessment; - Residual risk analysis.	- Modelling and simulation platform; - Flexible module library - Supports deterministic and probabilistic models; - Supports multiple media and exposure routes.	France
RBCA Tool Kit	Risk-based corrective action for chemical releases	- Combines contaminant transport and risk assessment models; - Calculates baseline risk and cleanup standards for multiple pathways.	USA, France
CLEA Model	Human health risk assessment Derivation of soil guideline value	- Generic and site-specific assessment criteria; - Supports multiple land uses; - Free software.	UK
RISC 5	Human health risk assessment	- Predictive models for air and groundwater; - Supports forward and backward risk calculations; - Multiple exposure scenarios.	UK, USA
ROCKS	Prioritisation of potentially contaminated sites	- Guided interface; - Scoring and ranking; - Customisable criteria; - Supports regional plans.	Italy
Sweden model	Establishment of risk-based guideline values	- Excel-based calculation tool. - Possible to develop both generic and site-specific guideline values; - Both direct exposure and indirect exposure to contaminated soil is considered; - The final guideline value is determined by selecting the lowest value derived for human health, soil environment, groundwater or surface water.	Sweden

8.4 Next steps

The literature review has highlighted that further work could be done to:

- Harmonise the definitions and language associated with risk assessment of contaminated sites;
- Standardise procedures and methodologies to obtain comparable results; and

- Clarify which procedures are most appropriate in certain conditions.

Stakeholders have highlighted the importance of keeping the **choice of risk assessment methods flexible and not prescriptive**, considering that different methods have been used in several Member States historically.

One stakeholder suggested a tiered framework for risk assessment, which allows for flexibility while being prescriptive in some aspects. It consists of:

- Tier 1: a mandatory EU baseline with harmonised toxicological reference values and exposure parameters based on EFSA/ECHA assessments.
- Tier 2: standardised methodologies for deriving national screening values using established models; and
- Tier 3: structured flexibility for Member States to integrate local conditions within clearly defined constraints of Tier 1 and 2.¹⁵⁶

One of the characteristics that can be taken into account when choosing a model regards the **approach** to risk assessment being **deterministic versus probabilistic**. A deterministic approach does not include uncertain variables to characterise exposure, effects, and risk. While a probabilistic approach incorporates uncertainty to estimate the likelihood of exposure and risk. The first tiers of a step-wise approach are usually deterministic.¹⁵⁷ In this regard, one stakeholder highlighted that the assessment of risk should take account of the likelihood of negative effects and typically be based on a balance of probabilities. Predicted impacts at very low confidence intervals (e.g. extreme percentiles of a probability distribution) should not be used as the basis for risk management decisions.¹⁵⁸

Regarding the factors to consider in a risk assessment process, stakeholders highlighted the importance of clarifying the role that **bioavailability of contaminants** should have in decision making across Member States.¹⁵⁹ Using bioavailability can avoid the need to use different threshold values for different soil types, as it is done in Australia where soil and pollutants differ considerably in different parts of the country. Another variable that can be considered in the risk assessment is making a distinction between the effects from **point source versus diffuse source pollution**.¹⁶⁰ **Transparency on all the parameters** and assumptions used in the risk assessment is key, including the receptors considered, the data used and the protection levels.¹⁶¹

In addition, one stakeholder stressed the importance of **defining remediation requirements** and targets on a **site-specific** basis, taking into account local conditions, such as natural background concentrations. This was also confirmed by another stakeholder who suggested to avoid generic remediation target levels. Therefore, remediation actions should not be triggered solely by exceedance of screening values or based on an initial (generic) risk assessment.¹⁶² Stakeholders indicated that remediation ‘targets’ should therefore be the result of a site-specific risk assessment exercise.¹⁶³

¹⁵⁶ Additional feedback provided by stakeholders.

¹⁵⁷ Additional feedback provided by stakeholders.

¹⁵⁸ Additional feedback provided by stakeholders.

¹⁵⁹ Additional feedback provided by stakeholders.

¹⁶⁰ Additional feedback provided by stakeholders.

¹⁶¹ Additional feedback provided by stakeholders.

¹⁶² Additional feedback provided by stakeholders.

¹⁶³ Additional feedback provided by stakeholders. One stakeholder suggested to use consistent criteria to define ‘unacceptable risk’. Such criteria could be a lifetime excess cancer risk (after World Health Organization) and the Hazard Index.

It was suggested to integrate risk assessment results with **socio-economic analysis** frameworks and external considerations (e.g. resilience).¹⁶⁴

During the workshop, some stakeholders suggested to use a general approach to risk assessment using a **tool** that considers all points to be taken into account from surface water to human exposure and at the same time taking into account the site-specific characteristics. However, a broad consensus was not reached on this matter. While a comprehensive tool has not been identified in this study, S-RISK[®] includes many of the desired characteristics.¹⁶⁵ Thresholds with a desired level of precaution could be calculated.¹⁶⁶ Recommendations on different tools that could be used for various purposes could also support stakeholders.¹⁶⁷

Regarding **data harmonisation**, one stakeholder suggested designating a central repository for screening values and background concentrations, requiring standardised metadata, and introducing harmonised reporting templates for contaminated site inventories to enhance comparability across Member States.¹⁶⁸ It is therefore important to clarify how different screening values, trigger values, and threshold values are functioning in the different legal frameworks of different countries.^{169, 170}

¹⁶⁴ Additional feedback provided by stakeholders.

¹⁶⁵ While this study does not aim to suggest a preferred tool, this work has highlighted the importance of harmonisation, in terms of the definitions, data to be collected, methodologies, and obligations. Suggesting a tool that could have most of the desired characteristics for risk assessment allows to have an assessment of currently available tools and data, without implying an obligation for Member States to adopt them.

¹⁶⁶ Feedback from targeted interview.

¹⁶⁷ Additional feedback provided by stakeholders.

¹⁶⁸ Additional feedback provided by stakeholders.

¹⁶⁹ Additional feedback provided by stakeholders.

¹⁷⁰ One stakeholder also raised the need on a future EU guidance to address diffuse heterogenic pollution, highly mobile, persistent substances or cumulative risks, and on the treatment of PFAS and mixture toxicity. However, the right EU framework should be considered to address such issues.

PART C – Considerations for the EU Guidance, challenges, and next steps

9. Considerations for EU guidance and support from the Commission

Current risk assessment and management practices for contaminated sites vary between and within EU Member States. The impact assessment study supporting the Commission's proposal for the Soil Monitoring Law (European Commission, 2023) highlighted that different approaches to assess contaminated sites could lead to an uneven playing field and reduced human health and environmental benefits. The Soil Monitoring Law presents an opportunity to implement a more uniform and consistent contaminated land regime across Europe, which is protective of human health and the environment, while allowing to take into account of local conditions. The implementation of the law aims at improving the level playing field across the EU, providing a minimum level of risk-management for all EU citizens. While flexibility is important to take account of the different soil and site-specific characteristics, certain aspects of risk assessment (e.g. toxicological values) could be more harmonised across Member States.

The Soil Monitoring Law establishes that the Commission should, in cooperation with the Member States, draw up documents and develop scientific tools that may be used by Member States to facilitate them to lay down the specific methodology for assessing the site-specific risks of contaminated sites, taking into account common practices, methodologies and toxicological data. The guidance would address the requirements of Article 16 and Annex V of the Soil Monitoring Law and would be non-binding. Stakeholders have highlighted that it would be useful to provide support to several Member States in defining their risk assessment methods to implement the Soil Monitoring Law. It will be key to provide guidance and options when deciding on risk assessment methods, rather than very detailed information on specific methods.¹⁷¹ As part of this process, engagement of Member States is encouraged at each stage, allowing for the integration of local knowledge and preferences.

An EU level guidance could include a manual providing guidance on the **different inputs** to be used when assessing the risks of contaminated sites, such as information on environmental fate parameters, exposure pathways, toxicological threshold values and other parameters, with examples that are location-specific. It would be valuable if this guidance was regularly updated.¹⁷² The international standards could be a starting point for the guidance.¹⁷³ The guidance could also explain how country- and site-specific considerations might need to be made (e.g. based on geographic conditions, history of land management, national legal provisions).

The guidance could set out a **step-wise/tiered framework** for site-specific risk assessment processes for human health and the environment, as well as guidance on each step, e.g. how to derive soil screening values, how to construct CSMs to also include relevant SPR linkages, how to identify receptors of concern including sensitive species and to establish species sensitivity distributions, how to implement risk assessment tools, how to assess (intended) land use. One stakeholder pointed out that the use of a framework based on a phased and tiered risk assessment would ensure that all parties are protected to a similar risk level.^{174, 175} In addition, it was suggested to not mandate the use of a single model to drive the risk assessment process in order to accurately reflect the CSM at any individual site.¹⁷⁶ This was also supported by another

¹⁷¹ Feedback from targeted interview.

¹⁷² Additional feedback provided by stakeholders.

¹⁷³ Additional feedback provided by stakeholders.

¹⁷⁴ The stakeholder specifically recommended to widely adopt the UK LCRM model, and to adapt it to local conditions.

¹⁷⁵ Additional feedback provided by stakeholders.

¹⁷⁶ Additional feedback provided by stakeholders.

stakeholder who reflected that the CSM is an easy-to-understand graphical representation of the 'contamination', which creating a level playing field within contaminated land management.

Defining **toxicology thresholds** at EU level would increase consistency across Member States.¹⁷⁷

As mentioned earlier in this report, a more harmonised approach to risk assessment and soil screening and threshold values could ensure more effective management of soil pollution across Europe, while national variations due to for example geology could still be accounted for.

Moreover, the guidance could recommend steps for **quality assurance/accreditation** of risk assessment processes.

Guidance could be provided on a series of optional **tools** that could support the risk assessment practice, as well as on boundary conditions for the applicability of different tools and methods. The use of risk assessment tools could remain flexible to account for different frameworks and local considerations, which can be integrated through socio-economic analysis.

It is essential to work towards more **data harmonisation** and standardisation in order to address the challenges of emerging pollutants and to develop effective soil pollution management strategies.

In addition, **global coordination** would be beneficial, for example, guidelines established in Australia, New Zealand, and the US may be useful building blocks for the EU to develop guidance for Member States. There are also ongoing efforts in China to establish soil screening values.¹⁷⁸ Collaboration may be possible through the FAO, e.g. the Global Soil Partnership.

It is suggested to mobilise resources to **train people** and ensure **capacity building** in the EU.¹⁷⁹

Finally, it was mentioned by stakeholders that other EU pieces of legislation (e.g. the Water Framework Directive¹⁸⁰ and the Industrial Emission Directive¹⁸¹) often influence decisions on soil remediation, as land managers must also meet requirements to not pollute surface water, groundwater, food source, etc. Therefore, it was suggested to take into account the **relevant EU pieces of legislation** when concluding on soil screening values and the Soil Monitoring Law more in general.¹⁸²

¹⁷⁷ Feedback from targeted interview and additional feedback provided by stakeholders.

¹⁷⁸ Feedback from targeted interview.

¹⁷⁹ Feedback from targeted interview.

¹⁸⁰ OJ L 327, 22.12.2000, p. 1–73.

¹⁸¹ OJ L 334, 17.12.2010, pp. 17–119.

¹⁸² Feedback from targeted interview.

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