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Soil quality — Procedure for site-specific ecological risk assessment of soil contamination (soil quality TRIAD approach)

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National foreword

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 190, *Soil quality*, Subcommittee SC 7, *Soil and site assessment*.

Introduction

This document is set up to ensure the quality of the site-specific ecological risk assessment of soil contamination. This process was described previously in a report by the Dutch PGBO (Integrated Soil Research Programme Agency), continued in the current SKB (Foundation for Soil Knowledge Development and Transfer)[69]. The present document is based on these Dutch reports but has been shortened in order to increase its general applicability. In addition, parts of the ecological risk assessment framework for contaminants in soil prepared by the British Environment Agency[21][22][23][24][25][26][27] were considered (this tiered framework does use the same three Lines of Evidence (LoE) as the TRIAD but not in parallel but consecutively). Experiences from various other sources[29][30][68], in particular, a summary of a Danish study performed as part of the EU FP6 project Liberation[36], as well as a Danish report[35], were added.

The term TRIAD relates to the following three LoE's: chemistry, toxicology and ecology[10]. Originally, it was described as Sediment Quality TRIAD by Long and Chapman[38]. The TRIAD does not particularly consist of three lines of evidence (up to five have been proposed[11]) but in specific situations, two might be sufficient. Descriptions of the soil quality TRIAD approach in the context of soil contamination are given, for example, in References [36], [40], [55], [59], [60], [63], [69], [71] and [73]. It should be mentioned that the soil quality TRIAD is not only used in Central Europe but also in other regions of the world, for example, in Portugal[1], Italy[67] or Brazil[44]. These publications can be used as case studies for the application of the soil quality TRIAD.

NOTE Recently, the ecological risk assessment procedures in The Netherlands, Norway, Sweden and the United Kingdom were compared[35]. The basic ideas of the TRIAD approach [e.g. a tiered approach and the combination of information from different disciplines (chemistry, ecotoxicology, and ecology)] have been accepted in these countries. However, only in the United Kingdom[21][22][23][24][25][26][27] and The Netherlands[40][43][53][58][60][61][63] have detailed frameworks been developed. The overall structure of this document combines and modifies both national frameworks in order to provide guidance independently from the country or region where the site to be assessed is located. The terminology of this document does follow the approach described in the EU project Liberation[36].

Soil quality — Procedure for site-specific ecological risk assessment of soil contamination (soil quality TRIAD approach)

1 Scope

This document describes in a general way the application of the soil quality TRIAD approach for the site-specific ecological risk assessment of contaminated soils. In detail, it presents in a transparent way three lines of evidence (chemistry, ecotoxicology and ecology) which together allow an efficient, ecologically robust but also practical risk assessment of contaminated soils. This procedure can also be applicable to other stress factors, such as acidification, soil compaction, salinization, loss of soil organic substance, and erosion. However, so far, no experience has been gained with these other applications. Therefore, this document focuses on soils contaminated by chemicals.

NOTE 1 This document focuses on ecological risk assessment. Thus, it does not cover human health end points.

In view of the nature of this document, the investigation procedure is described on a general level. It does not contain details of technical procedures for the actual assessment. However, this document includes references relating to technical standards (e.g. ISO 15799, ISO 17616) which are useful for the actual performance of the three lines of evidence.

In ecological risk assessment, the effects of soil contamination on the ecosystem are related to the intended land use and the requirements that this use sets for properly functioning soil. This document describes the basic steps relating to a coherent tool for a site-specific risk assessment with opportunities to work out site-specific details.

This document can also be used for the evaluation of clean-up operations, remediation processes or management measures (i.e. for the evaluation of the environmental quality after having performed such actions).

NOTE 2 This document starts when it has already been decided that an ecological risk assessment at a given site needs to be performed. In other words, the practical performance of the soil quality TRIAD and the evaluation of the individual test results will be described. Thus, nothing will be said about decisions whether (and if yes, how) the results of the assessment are included in soil management measures or not.

NOTE 3 The TRIAD approach can be used for different parts of the environment, but this document focuses mostly on the soil compartment. Comparable documents for other environmental compartments are intended to be prepared in addition (e.g. the terrestrial aboveground compartment) in order to perform a complete site assessment, based on the same principles and processes.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

3.1
stakeholder
person or party with an interest in the *soil quality* (3.21) of a potentially contaminated site

Note 1 to entry: The composition of the stakeholder group depends on the specific local conditions.

3.2
assessment criteria
criteria set up to decide if a site requires further investigation or other action (e.g. remediation)

Note 1 to entry: They can be drawn up by the *competent authority* (3.3), the *stakeholders* (3.1) and the investigators for the interpretation of the results of the soil quality TRIAD study before the investigation is carried out. Two criteria could be distinguished, namely:

a) threshold that marks the boundary between adequate and inadequate removal of uncertainties in the assessment;

b) threshold that marks the boundary between an effect that is considered acceptable and one that is not considered acceptable, based on a reference or a limit value.

Note 2 to entry: Assessment criteria are necessary for every collection of ecological conditions (for example, all species in a generic system, a key species or a protected species).

3.3
competent authority
part of the authorities that is responsible for the implementation of the soil clean-up operation

Note 1 to entry: Depending on the site and the country, the competent authority could be very different. The competent authority assesses investigation results and takes decisions via decrees about the severity and urgency of the soil contamination found. The competent authority also assesses the clean-up plans of the clean-up teams on their own initiative (for example, companies).

3.4
soil management
all the anthropogenic activities that influence the soil system at the site to be assessed

Note 1 to entry: This can include choices in *land use* (3.5) (e.g. groundwater level management, nature management, park management, loading with soil-contaminated substances).

3.5
land use
using the *ecosystem services* (3.8) that the soil provides

3.6
land user
person or group of people who uses the *ecosystem services* (3.8) of the soil, whereby in the role allocation, the larger spatial scales are generally represented by organizations, societal parties and authorities

3.7
ecological effect
change to an aspect of the ecosystem caused by anthropogenic *stress factors* (3.15)

Note 1 to entry: Changes [see also *assessment criteria* (3.2)] to an ecosystem as a result of the presence of contaminants are regarded as negative changes regardless of the direction. In this document, the three lines of evidence (LoE) in accordance with the soil quality TRIAD approach are required for the effect to be determined. In addition, the variation in space, time and parameters is also important. See also *type 1 error* (3.17).

3.8
ecosystem service
service that is (directly or indirectly) provided by an ecosystem

Note 1 to entry: The Ecosystem Service Approach is becoming more and more the theoretical basis for the definition of protection goals in the context of the risks of chemicals in the environment (e.g. EFSA 2012), including the risk assessment of contaminated soils (e.g. [2], [41], and [74]).

Note 2 to entry: Examples of ecosystem services that the soil provides to people are agricultural products, clean surface water, groundwater and drinking water, and a healthy environment in which to live. The provision of many of these services depends in many cases on the activity of diverse organism communities, e.g. degradation of contaminants in soil by microbes, meaning that groundwater is kept clean[75].

Note 3 to entry: Some soil functions (organic substance composition and degradation, natural self-cleaning ability of the soil and soil structure for a good rooting of vegetation and crops) are counted as ecosystem services in this context. In detail, four basic soil services are distinguished, namely, soil fertility, resistance to stress and adaptation, the soil as a buffer and reactor, and biodiversity. The Millennium Ecosystem Assessment[41] distinguishes at ecosystem level regulating services (regulation of ecosystem processes), provisioning services (products), cultural services (non-material benefits) and support services (for the provision of all the other ecosystem services).

3.9
generic assessment
assessment of a site using a general investigation method that is not geared to the properties of the site

3.10
site-specific assessment
assessment of a site using an investigation method that is partially geared to the properties of the site

Note 1 to entry: The assessment consists of a combination of generally applicable and possibly specifically developed (tailor-made) parts. The interpretation of the results of the investigation is site-specific and can be generalized only to a limited extent [see also *generic assessment* (3.9)].

3.11
site-specific model
description of the local ecosystem and of the intended *land use* (3.5) in terms of ecological conditions for this use, and of the nature and spread of the contamination

Note 1 to entry: This model makes it clear which exposure routes are relevant for aspects of the ecosystem that are needed for the *land use* (3.5). Suitable parameters can then be selected for the soil quality TRIAD study with optimum *weight of evidence* (3.20) and support[70].

3.12
uncertainty
degree of doubt about the assumptions or investigation results, to be broken down in the case of the assessment of the ecological risks of soil contamination into: communications uncertainty, model uncertainty (epistemic uncertainty), uncertainty because of variation and uncertainty in decision-making

Note 1 to entry: For the different types of uncertainty, see also Clause 5.

3.13
reference
part of a site, of a sample or of a group of literature data that acts as a benchmark for the effect scale (the baseline, measure or standard)

Note 1 to entry: It is a description of the condition of the soil in quantitative and qualitative terms that can be used as part of the measure for the *soil quality* (3.21) to be assessed. The ideal reference is identical to the site (or the sample) to be assessed, the only difference being that the *stress factor* (3.15) to be assessed is missing. Chemical, physical and biological aspects form partial aspects of the reference. For a site-specific application, site-specific details are needed to obtain an accurate reference. A reference is preferably chosen at the investigation site; measurements are then preferably taken at the same time as the samples/measurements to be assessed. If no comparable clean reference is available, the least contaminated sample can also be chosen (for example, in a gradient), on condition that the sample is regarded as being sufficiently representative to be used as a reference. A reference can also be based on samples of a comparable site elsewhere or on literature data (= virtual reference).

3.14
scaling
process in which measurement or model data are interpreted using a measure intended for this purpose

Note 1 to entry: When applying the *soil quality TRIAD* (3.16), assessment data are generated to ascertain an effect on the level of the ecosystem as quantitatively as possible. A practical, standardized scale runs from 0 to 1 or from 0 % to 100 %. 0 or 0 % represents no effect and 1 or 100 % represent the maximum theoretical effect at a high concentration of the contaminating substances. Sometimes, only a low level of quantitative scaling is possible, such as on an ordinary scale or on a 2 or 3 point scale (yes/no or yes/maybe/no). These low quantitative scaling methods can be used in a *weight-of-evidence (WOE)* (3.20) approach. Examples of scaling are given in, e.g. Reference [40].

3.15
stress factor
outcome of an anthropogenic activity that has a possible negative effect on the ecosystem, such as chemical soil contamination, overfertilization, desiccation or soil compaction

3.16
soil quality TRIAD
procedure for a site-specific ecological risk assessment, whereby the *weight of evidence (WOE)* (3.20) is made up of three independent lines of evidence (LoE):

1) a line of evidence based on environmental chemistry with data about concentrations of toxic substances being converted into the expected effect on the ecosystem,

2) a line of evidence based on measurements of the ecotoxicity in samples of the site with tests, and

3) a line of evidence based on observations of the ecosystem at the site that focus on demonstrating the effects caused by the contamination

Note 1 to entry: The total of these elements is more than the sum of the separate parts because the burden of proof is partly based on consistency between the elements.

Note 2 to entry: Descriptions of the approach of the soil quality TRIAD study applied to soil contamination are given in References [36], [40], [59], [60] and [63], among other places. For the choice of tests, see also ISO 17616.

3.17
type 1 error
judgment that unjustly concludes that there is an unacceptable effect

Note 1 to entry: The term comes from statistics. If there is a type 1 error, the assessment is based not on an actual unacceptable effect but on chance or a model error. The risk of a type 1 error occurring can be reduced by making more observations or by improving the model with the ecological aspects and indicators. This latter option can be achieved by choosing improved conditions and investigation parameters.

3.18
type 2 error
judgment that unjustly concludes that there is no unacceptable effect

Note 1 to entry: The term comes from statistics. If there is a type 2 error, there is actually an unacceptable effect, but this effect has not been demonstrated because of insufficient or incorrect investigation efforts (too few observations, unsuitable reference(s) or model errors).

3.19
weighting
rating various investigation results transparently, with equal or different weight being given to the information concerned

Note 1 to entry: A simple starting position is to give equal weight to the results of the various assessment parameters. This can be deviated from to devote attention to specific ecological conditions [protected species, key species, processes, *ecosystem services* (3.8)], to relatively reliable parameters, or to special test results (giving weight to observations that show a great effect or giving extra weight to measurements of bioavailable concentrations).

3.20
weight of evidence
WOE
weight of evidence of the soil quality TRIAD study which can be used as the basis for taking decisions responsibly

Note 1 to entry: In this document, WOE is meant above all in the methodological sense, with all available data obtained from various lines of evidence-taking being involved in the final conclusion, possibly on the basis of quantitative weighting. Background information about *scaling* (3.14), *weighting* (3.19) and WOE can be found in References [12], [16], [40], [53], [67], and [72].

Note 2 to entry: With a set budget for the soil quality TRIAD study, the WOE needs to be optimized across investigation parameters and sample intensity. The *assessment criteria* (3.2) per parameter and the acceptable statistical error margin [*type 1 error* (3.17)] is chosen such that the WOE and acceptance of possible results of the investigation by the *stakeholders* (3.1) are maximized.

3.21
soil quality
all current positive or negative properties with regard to soil utilization and soil functions

Note 1 to entry: This definition includes all anthropogenic as well as natural properties, including services provided by organisms.

3.22
screening value
soil value which, if exceeded, indicates an assumed potential effect on soil biological structure and function

3.23
retention function
ability of soils/soil materials to adsorb pollutants in such a way that they cannot be mobilized via the water pathway and translocated into the food chain

Note 1 to entry: The habitat and retention functions include the following soil functions according to ISO 11074:

— control of substance and energy cycles as components of ecosystems;

— basis for the life of plants, animals and man;

— carrier of genetic reservoir;

— basis for the production of agricultural products;

— buffer inhibiting movement of water, contaminants or other agents into the groundwater.

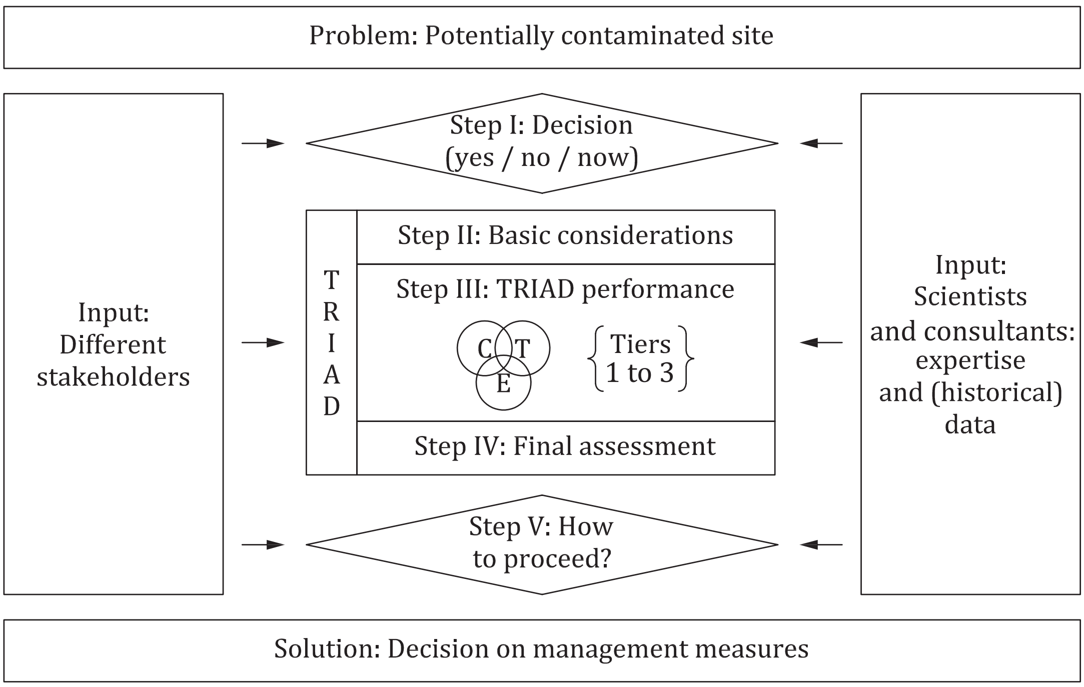
4 Process overview

The main five steps of performing a soil quality TRIAD according to this document are summarized in Figure 1. Only the performance of the soil quality TRIAD itself (= execution phase in Reference [43]) is described.

The method is based on the decision whether and how soil quality shall be assessed at a specific site (Step I) (also called the phase of the development of a Conceptual Site Model (CSM)[21][22]. In case this decision is positive, the three lines of evidence, here abbreviated as chemistry, ecotoxicology and ecology, will be performed (Steps II to IV). Based on an integrative assessment of the results of the investigation, a decision, e.g. regarding soil remediation, can be made (Step V). This document refers primarily to Steps I to IV (Step V is not covered in detail in this document). Note that the extent of the input from stakeholders (left side in Figure 1) and risk assessors (right side in Figure 1) differ in the different steps — but in any step, input from both sides is required.

NOTE 1 The description of the performance of the soil quality TRIAD as described in this overview can be considered as the “ideal” version (e.g. the steps and tiers are performed one after another). However, in reality, depending on the contamination and site properties, the different steps might be performed in a more flexible way. In addition, as soon as a decision on the ecological risk of a specific site is possible, the process can be stopped.

NOTE 2 Annex A describes the use of bioaccumulation data as an additional tool for site-specific ecological risk assessment.



Key

C chemistry

T ecotoxicology

E ecology

NOTE For details of the central (technical) part of the TRIAD approach, see also Figure 2.

Figure 1 — Diagram of the five steps to be carried out for site-specific ecological risk assessment (soil quality TRIAD) of soil contamination supporting decision-making with regard to soil quality

5 Uncertainty and weight of evidence

Uncertainty is a key factor in the assessment of ecological risks.

An assessment of ecological risks has various uncertainties[65].

— Communication uncertainty. This form of uncertainty may occur if experts communicate with land users about ecological risks.

  EXAMPLE Translation of a question from a stakeholder (e.g. Is there an ecological risk and how great is it?) into a scientific question, and communication about the results of the assessment. This uncertainty can be reduced by good coordination between stakeholders and experts.

— Model uncertainty. Models are used in risk assessment to simplify the local ecosystem (also called site-specific models). The assessment is based on indicators that are used to describe this simplified system in quantitative or qualitative terms. The model uncertainty is then linked to the obvious incompleteness of the model, partly as a result of conscious choice, partly as a result of ignorance.

  EXAMPLE A certain plant can be chosen as a model for all the plants in the ecosystem. The chosen plant is not always an averagely sensitive plant or a sufficiently exposed type of plant and is therefore sometimes not representative. The model organism does not exclude effects on other species.

— Uncertainty as a result of variability. Uncertainty that results from variations at the sites in time and space, and from variations and errors in the measurements.

  EXAMPLE An investigation is a snapshot in time, whereas ecosystems change over seasons and years.

The soil quality TRIAD advocated in this document, as the content-based and technical framework for the risk assessment, is based on an optimized weight-of-evidence (WOE) approach. It is made transparent and quantifiable in the integration of the three independent lines of evidence. If the three independent lines of evidence point in roughly the same direction (e.g. quantified on a scale from 0 to 1), this is a strong indication that the model uncertainty is slight and the investigation can be completed. If the three independent lines of evidence do not point in the same direction, the model uncertainty is still great and a new stage needs to be gone through to reduce the model uncertainties sufficiently. The model uncertainty can, for example, be quantified using a deviation factor[40].

The soil quality TRIAD is not intended to reduce communication uncertainties, although it can be used for this. In theory, the results of the soil quality TRIAD are easy to communicate and to summarize in ecological terms as the biological characteristics of the ecosystem are also involved in the assessment at the site itself. In practice, the results of the individual lines of evidence shall be communicated too in order to achieve full understanding of the final results.

6 Soil quality TRIAD performance

6.1 First step: Objective of the investigation (formulating the problem and decision regarding the need of a site-specific risk assessment)

6.1.1 General approach

The decision whether a TRIAD has to be performed or not for a certain potentially contaminated site is part of an ecological risk assessment (ERA). Details of such an ERA differ on the national level, but this decision is based on information compiled in a document often entitled as Conceptual Site Model (CSM). This term has been introduced in the United Kingdom for the first step of an ecological risk assessment framework for contaminants in soil[21][22][23][24][25][26][27]. All available relevant information about the site to be assessed, e.g. the intended (current and/or future) soil management, the soil ambitions of local government (including the future use of the land), and the possible ecosystem stress that may be caused by the soil contamination, is used in this desk study. This step also contains the identification of sources of contamination, ecological receptors of concern and the potential pathways of exposure. If available, the results of the more detailed soil investigation provide the scope and the spatial distribution of the soil contamination. If a soil quality map (e.g. a map of the occurrence of contaminants) is available, this can be an important source of additional information with regard to the soil quality in the area.

This whole set of information can be divided into three sources:

a) know-how and information provided by the societal, policy and administrative parties (including the owner of the site);

b) input from experts (e.g. having experience in the specific region, contamination or ecology);

c) data from scientific (field or laboratory) investigations or from the literature.

6.1.2 Decision

The decision about the subject and objective of the investigation should be made as clear as possible and the investigation objective should be “SMART”:

— Specific: accurately described so that all the people concerned recognize the same objective;

— Measurable: quantifiable units are used for the assessment of the ecological risks;

— Achievable: the objective is recognized by all the parties involved;

— Realistic: financial conditions and other, e.g. legal, restrictions are taken into account;

— Time-related: at the start, it is clear when the investigation objective should be achieved and how any exceeding of the deadline should be dealt with.

In any case, the investigation effort has to be related to the size of the contaminated site as well as the severity and complexity of the potential ecological risk. The starting point is that the investigation effort is in real proportion to the size of the problem and the uncertainty that (still) exists.

Note that such a decision depends strongly on national regulations and practices which can be very different in individual countries.

6.1.3 Stakeholders involved in an ecological risk assessment

Parties with an interest in the soil quality at the site (stakeholders) are the following:

— users (local, regional, national and societal);

— responsible bodies (competent authority, government);

— owners (finance).

Other parties (without a direct interest in the soil quality at that specific site) are the following:

— experts (soil experts, ecologists, ecotoxicologists, risk assessors);

— investigators (responsible for the implementation of the investigation);

— consultants (writers, process consultants, mediators, communication employees).

Several of these parties or roles may also be combined in one person.

At a small investigation site (e.g. a small landfill site), the input of the stakeholders and the experts can remain limited. At a major investigation site (e.g. the area of a former chemical production plant or a shooting range), the role of the stakeholders should be broken down into the different interested parties.

NOTE The difference between “small” and “major” investigation sites depends strongly on the specific situation in a region or country.

At all times, a clear, traceable and transparently reported distinction should be drawn between the role of the stakeholders and the input of know-how by investigators and consultants, preferably (and dependent on size) also with tasks being divided among different people. Details of these roles should be fixed in the investigation plan.

The way stakeholders can be involved and have to be involved depends on the national regulations and practice.

6.1.4 Independent quality control

Since the decisions based on the performance of the soil quality TRIAD can have far-reaching consequences both in legal as well as in financial terms for stakeholders involved, the quality of the work and the gained data have to be ensured. Obviously, all reference and validity criteria required by the various technical standards (e.g. analytical methods, ecotoxicological tests, etc.; usually available as ISO publication) shall be fulfilled. In addition, the investigation plan, the implementation of the investigation, the integration of the data from the three lines of evidence, their evaluation and the reporting should be documented according, e.g. to the requirements of ISO/IEC 17025, i.e. ideally the organizations performing a soil quality TRIAD should be accredited. However, details of the implementation of quality assurance cannot be described here because of differences in individual countries.

6.2 Second step: Basic considerations

6.2.1 General approach

In Step II, the initial part of the practical investigation mainly consists of the evaluation of detailed information which is necessary for the individual tests, analyses and investigations within the soil quality TRIAD. These practical steps will then be laid out in a formal investigation plan. It is important that it is clear in advance what the opportunities and restrictions of the investigation are and that there is a consensus in advance about the design of the practical work as well as the interpretation of the results. The information required for the investigation plan focuses mainly on two points [see 1) and 2) below], assuming that all relevant information describing the study site (e.g. maps, climate data, history on usage and contamination) has already been compiled in Step I when making the decision that an ecological risk assessment is necessary:

1) Ecological conditions:

The ecological conditions, which could be at risk because of the contamination, shall be identified. These ecological conditions (including the land use) determine which ecosystem services are provided by the soil at a specific site[7][15], its biodiversity, in particular the occurrence of key or protected species[75], and any objectives specifically mentioned by land users. In addition, it has to be checked whether surrounding areas are specifically protected by law.

2) Critical aspects of ecological conditions:

It shall be decided which aspects of the ecosystem the investigation is to focus on, based on the ecological conditions identified already. These critical aspects depend on the specific vulnerability caused by soil contamination. Existing literature and expertise form the information source for this. Both structures (= biodiversity) and processes (= functions of the soil organism community), including the ecosystem services provided by the organism community, will preferably be used when selecting the individual measurement parameters.

NOTE In the UK framework, this step is described in detail, i.e. the identification of ecological receptors of potential concern [e.g. species of special (protection) interest] or direct/indirect pathways of potential concern[22].

6.2.2 Assessment criteria

Agreements between the competent authority, the stakeholders and the investigators shall be made about the way in which the results of the soil quality TRIAD study will be assessed for all three LoEs (these agreements have to be recorded in the investigation plan). This is about limiting and dealing with uncertainties in the results of the investigation. A focused investigation (e.g. a tiered approach when performing practical studies) will reduce this model uncertainty. An adequate reduction of uncertainty is required for scientific underpinning of the decision-making about soil management or clean-up. The agreements should relate at least to the following:

a) The establishment of a measure using reference data. To this end:

   — a suitable reference should be selected for each investigation parameter either measured or derived (preferably site-specific or area-specific); this reference will act as the 0 % level on the effect scale;

   — a (possibly theoretical) 100 % effect level will be defined for each investigation parameter;

   — for each investigation parameter, it shall be decided how the measurement will be scaled from 0 % to 100 % (for example, a linear relation) or how a stimulation will be interpreted (0 % effect or an effect resulting from a plausible relationship with contamination effects that are assessed negatively). With a WOE approach (see 3.20), the extremes of the measure (the first two of the above dashes) are more important for the assessment than the relationship between the two extremes.

   For an assessment with the soil quality TRIAD, an adequate scaling is essential for the integration of data from three different independent lines of evidence.

b) Design with weighting factors for the various investigation parameters.

   A starting point could be an equal weighting of the assessment parameters to be distinguished within the soil quality TRIAD lines of evidence and an equal weighting of the three soil quality TRIAD lines of evidence.

c) Agreements about reducing uncertainties in the risk assessment.

   They are reduced by a) taking variations into account and b) taking model uncertainties into account. Both uncertainties can be reduced in various ways. For each investigation parameter, the optimum sampling strategy and sample size can be determined in relation to the expected (natural) variation. Model uncertainties could be reduced by selecting more and better parameters. The aim is to limit both type 1 and type 2 errors as much as possible.

d) The derivation of assessment criteria for uncertainty, a reduction of model uncertainties as a result of the WOE approach (soil quality TRIAD) and unacceptable effects. In principle, the assessment should focus on the reduction of uncertainties. Once the uncertainties have been sufficiently reduced, the system can be assessed using the integrated investigation results. As a WOE in the soil quality TRIAD study consists of three lines of evidence, integration is always needed.

When the above work has been completed, the definitive investigation plan is drawn up, which includes the agreements concluded about the investigation design, the assessment criteria and the interpretation of the investigation results. After agreement by the stakeholders, the investigation plan is submitted to the competent authority. Consultation with this authority is recommended but approval of the planned study is not mandatory.

NOTE Involving the competent authority as early as the initial discussions on the investigation plan can avoid the investigation plan having to be explained again and modified. The role of the competent authorities can differ considerably in different countries.

6.3 Third step: Practical performance of the soil quality TRIAD

6.3.1 General

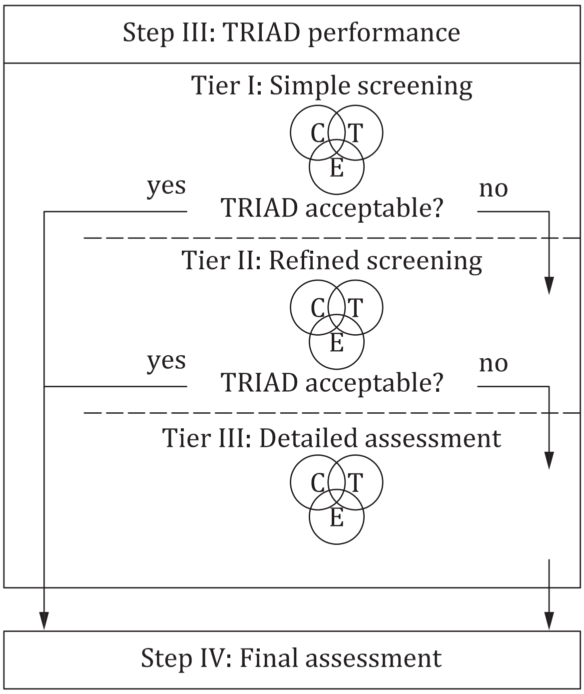
The soil quality TRIAD is a powerful weight-of-evidence approach originally developed in order to evaluate sediment quality[38]. In the terrestrial compartment, less experience is available on the practical use of the soil quality TRIAD (but see Reference [36]). The investigation is performed according to the investigation plan as laid down in 6.2. Reporting of the investigation results should meet the requirements set out in Clause 7. In the following, the overall structure of the soil quality TRIAD (i.e. as a tiered process), the three lines of evidence as part of a WOE approach and appropriate methods for each tier and each line of investigation (so-called tool boxes) are described.

6.3.2 Soil quality TRIAD tiers

The soil quality TRIAD can include different tiers in which each consecutive tier is increasingly fine-tuned to the site-specific situation. In the first tier, the research is simple, broad and generic. In later tiers, more specific and complex tests and analyses may be used. The tiered approach is chosen for several reasons, the most important of which is cost-effectiveness. Each subsequent tier is characterized by an increasing complexity (see Figure 2), i.e. both ecological reality but also efforts and resources needed increase when going from Tier 1 to Tier 3. If amount and quality of data are high (i.e. uncertainty is low) when assessing the results of any given tier of the soil quality TRIAD, then the ecological risk assessment may be finished and actions taken if needed (see Figure 2). If there is still a high level of uncertainty (indicated e.g. by conflicting results from the three lines of evidence) or the result of the assessment is not acceptable, more investigations are desirable in a higher tier. The information from previous tiers can be used in the assessment of the next one. At the end of each tier, an assessment is made. In this assessment, all available results will be used including the results from previous tiers. Data should not be considered when further research has shown that a result is not reliable, e.g. when the validity criteria are not met due to low quality of the test organisms or high temperature fluctuations in a climate chamber.

In any case, work in this tiered approach ends when there are sufficient data for a final assessment to be performed in Step IV.

At each soil quality TRIAD step, different methods from the three lines of evidence can be used. If considered most cost-effective, it is always possible to stop further investigations after each tier and either re-define the land use or if needed take necessary actions to remediate or prevent dispersion of contaminants.



Key

C chemistry

T ecotoxicology

E ecology

Figure 2 — Schematic view of the tiered approach when performing a soil quality TRIAD study

6.3.3 Soil quality TRIAD lines of evidence

The soil quality TRIAD approach consists of three lines of evidence (LoEs) (often called “legs” in the literature), i.e. chemistry, ecotoxicology and ecology (see Figure 3). These LoEs can be defined as follows.

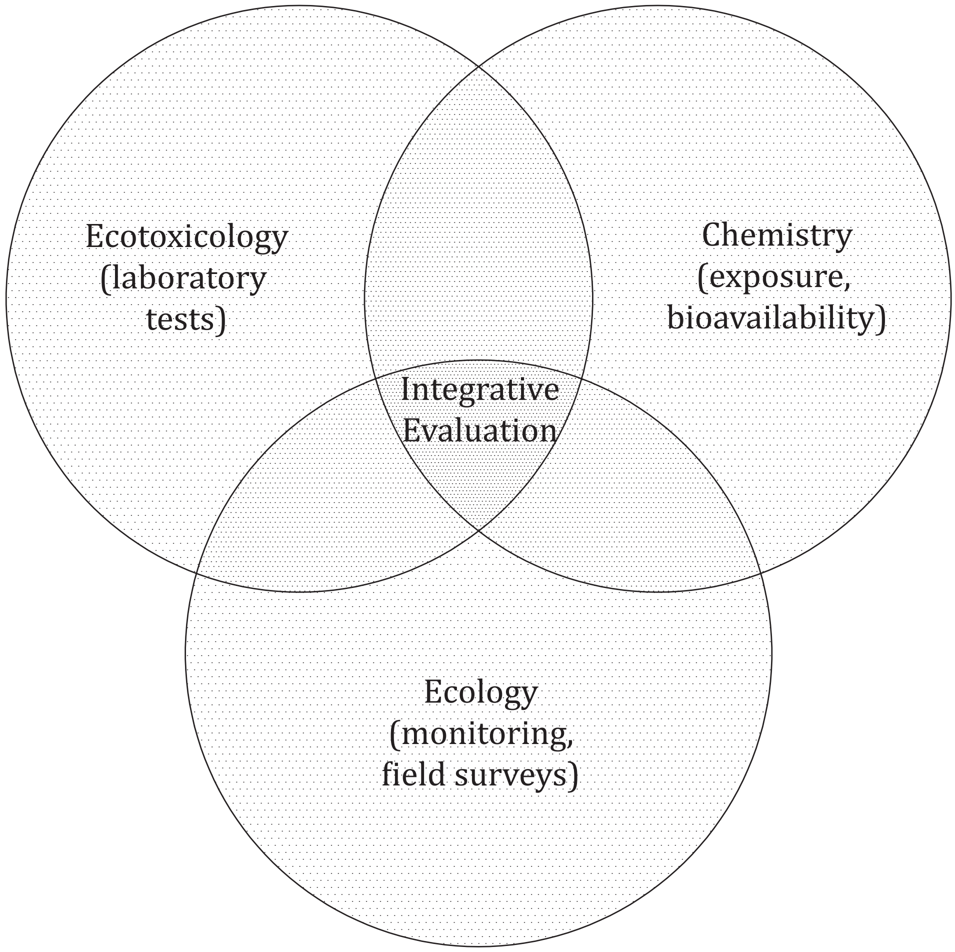


Figure 3 — Schematic view of the three lines of evidence (LoEs) of the soil quality TRIAD (in brackets: rough indication of the main methodological approach)

a) **Chemistry** (also called environmental chemistry or residue analysis)

In this LoE, the presence of contaminants in the environment is measured, most importantly in the soil itself. Both total concentration and environmentally bioavailable fractions can be measured, which could be presented, for example, as mg/kg soil dry mass or as µg/l pore water (the latter is relevant for the assessment of the retention function, i.e. when testing aquatic organisms). In the original TRIAD approach, only total concentrations were measured. Now, methods are available to measure the (bio) available or accessible fractions (e.g. ISO 17402). In combination with soil characteristics (e.g. ISO 18772) and modelling approaches, an improved estimate of the riskful fraction can be made. In addition, concentrations accumulated in biota, or modelled via food-chains, are used for the calculation of risks on the basis of toxicity data from the literature (see Bibliography). The measured concentrations can be compared in a first assessment with soil screening values (SSVs). These SSVs have been derived from results of ecotoxicological tests (mainly performed in the laboratory), independently from each other in various countries (e.g. The Netherlands[69], Denmark[66], Germany[3], or the United States[76]). Their legal status varies from country to country, but often they play an important role as the first measure to assess the quality of a soil. Besides these values, valid for whole countries or regions, site-specific SSV (e.g. for specific soils) could be prepared but in this case, enough test data with these soils have to be generated. SSVs are usually based on (often the same or similar) test data and are derived using the SSD approach (species sensitivity distribution)[9][54], meaning that the values themselves do not differ considerably. However, their use in legislation can clearly differ. In higher tiers, concentrations based on specific extraction procedures (both in soil or biota) could be used. When adopting any chemical method based on the concept of bioavailability, it is necessary that a corresponding reference system based on ecotoxicity test data has been developed (differentiated for each chemical contaminant)[4].

b) **Ecotoxicology** (often called toxicology)

Tests (sometimes called bioassays) with many different groups (mainly microbes) or species (mainly nematodes, oligochaetes, insects, mites or snails but also plants) are carried out in order to measure the actual toxicity present in environmental samples from the test site. In order to do so, standard guidelines [mainly ISO, e.g. ISO 15799, ISO 17616, but in North America also EPA (US Environmental Protection Agency) and EC (Environment Canada) guidelines] are commonly used. Recent compilations of suitable test methods have been published by Environment Agency[27] and Environment Canada[28], which also include guidance for sampling and preparation of soils. Even broader is ISO 17616[24], which provides an overview not only on ISO test guidelines but also strategic issues (e.g. which tests are most useful in which situations) as well as interpreting the results of these tests. The number of tests is still growing but it seems that the increase is slowing down, since most microbial functions as well as many representatives of soil invertebrate groups or plants have already been identified as test organisms. At the same time, tests with acute end points (especially mortality) became less acceptable, primarily due to their low sensitivity. In contrast, chronic tests with their higher sensitivity and also higher ecological relevance are required in newer legislations. However, there are still some gaps in the battery of soil test organisms (e.g. isopods; see e.g. Reference [77]), especially when looking at non-temperate regions of the world. Since most of the test species were selected for the study of the effects of individual chemicals in highly standardized laboratory tests, often using OECD Artificial Soil, there is a lack of knowledge on their behaviour in natural field soils. However, this situation is currently improving (e.g. References [20], [34], [42], and [57]), meaning that today such tests are possible to be performed in the majority of temperate (probably including Mediterranean) soils. In the ecotoxicological risk assessment of contaminated soils, these tests are used directly (i.e. by using soil from the test site) but also indirectly, since results from the same tests have been used to derive the SSVs mentioned above when describing the work performed in the chemistry LoE. Last but not least, it has to be mentioned that biomarkers have often been proposed as possible end points in this context (mainly for screening purposes); so far no individual methods have been internationally validated or standardized [for a critical evaluation of test methods (including biomarkers), see References [20] and[40]].

c) **Ecology**

In this LoE, many different methods can be used, which most often are directly taken over from ecology. Best known are the methods to assess the aboveground vegetation at a test site, often collectively known as plant sociology (first compiled by Braun-Blanquet[6]; e.g. for Central Europe, see also Reference [18]). It is still one of the few methods which can be used by simply walking over the test site, while determining the species composition and growth of plants. In the case of soil organism methods, they are usually known for many years but only very few have been standardized so far. Most notably, a recent compilation from Canada[28] as well as ISO 23611-1 to ISO 23611-6, focusing on the sampling of various soil invertebrates [earthworms, micro-arthropods, enchytraeids, nematodes, soil macrofauna (e.g. diplopods, isopods)] and the design of such studies, have been published. However, ISO 23611-6 is more of a guidance paper, since the design of almost any site-specific monitoring differs, depending on the specific objectives of the investigation and the characteristics of the test site, in particular the ecological conditions in combination with the extent and history of the contamination. Therefore, any standardization will certainly be limited in this area.

Field ecological observations are performed at the contaminated site and the results are compared to some kind of reference (or benchmark). The ideal reference is identical to the test site (or the test soil sample) to be assessed, the only difference being that the stress factor to be assessed is missing. However, this is not always possible. Alternatively, a virtual reference can be defined, which is based on the investigation of a number of uncontaminated sites which in terms of land use, climate, and soil properties are similar to the test site (for an overview on this approach, see Reference [56]). Recent compilations of biological soil monitoring in Europe have been published by Gardi et al.[31], Rutgers et al.[61], and Scheifler et al.[62]. Despite the growing numbers of papers on site-specific monitoring using a wide range of methods, it has to be stated that these methods have rarely been used in a legal context so far (probably most often in The Netherlands).

6.3.4 Measurement parameters

Parameters for the investigation have to be selected on the basis of (among other things) demonstrated sensitivity, cost-effectiveness, representativeness, complementarity, available local data and the possibility of determining these in a standard manner (preferably according to ISO standards). These parameters should be related to the vulnerability of the ecosystem at the test site. In addition, the collection of parameters should be evenly balanced and proportional to the size and complexity of the study site and its contamination so that an adequate complementary cover of relevant ecosystem aspects is obtained in the investigation plan for the soil quality TRIAD. An overview of available parameters is shown in Reference [59] among other places. As already mentioned, for the choice and evaluation of ecotoxicological tests, see ISO 17616.

For each of the LoEs in the soil quality TRIAD, there is a variety of analyses or tests that can be chosen (the so-called tool boxes). Some examples are given below (modified after Reference [36]), differentiated according to the tiers of the soil quality TRIAD (see 6.4.1). It should be noted that, not any method is used in any soil quality TRIAD; for example, there are clear differences in soil quality TRIAD methodology depending on the land use of the test site. It is also clear that this list is not exhaustive. In fact, other methods can be used too (especially at higher tiers), but when using non-standardized methods, reasons for choosing them as well as all details of their performance have to be documented in detail.

NOTE 1 In case of suspected genotoxicity at a given site, appropriate tests could be added to the toolbox [e.g. using bacteria (ISO 13829) or plants (ISO 29200)].

NOTE 2 For the assessment of a site-specific soil, both the habitat function (i.e. testing organisms living in the bulk soil) as well as the retention function (i.e. testing aquatic organisms) are considered. Suitable test methods are provided in ISO 15799 (see also Reference [40]).

NOTE 3 When using chemical extraction methods and in particular models, it is clear that they have been validated using appropriate ecotoxicological data (e.g. References [5] and [32]).

a) Tier I (screening)

Toolbox C-I (Chemistry): Refinement of soil screening levels; calculation of toxic pressure. Data are often already available.

Toolbox T-I (Toxicology): *Arthrobacter* test (ISO 18187); plant screening test (ISO 17126); earthworm avoidance test (ISO 17512-1); Collembola avoidance test (ISO 17512-2); Microtox®[1)] test (ISO 11348-3).

Toolbox E-I (Ecology): Ecological screening by a simple vegetation survey (including a reference to the CORINE habitat classification approach of the EU).

b) Tier II (refined screening)

Toolbox C-II (Chemistry): Bioavailability methods to establish actual and potential availability, depending on the respective chemicals: 0,001 mol/l $CaCl_2$, 0,43 mol/l HNO_3, Tenax®[2)]/Cyclodextrin extraction, solid phase micro extraction (SPME); POM-SME.

Toolbox T-II (Toxicology): Reproduction test on earthworms (ISO 11268-2); reproduction test on Enchytraeidae (ISO 16387); or springtails (ISO 11267); plant growth test with two species (ISO 11269-2).

Toolbox E-II (Ecology): Bait lamina test (ISO 18311); C and N mineralization tests (ISO 14238); soil induced respiration test (ISO 17155), nematode trophic groups.

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1) Microtox® is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

2) Tenax® is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

c) Tier III (detailed assessment)

Toolbox C-III (Chemistry): Use of chemical models, simulation of the chemical situation in columns, or the SOFIE-cell[17]. Advanced chemical methods are not excluded.

Toolbox T-III (Toxicology): Multi-species test system, e.g. with springtails, mites and enchytraeids (e.g. Reference [37]); chronic plant test (ISO 22030) or plant growth test with six species (ISO 11269-2); microbial metabolic diversity tests, e.g. PLFA (ISO/TS 29843-1, ISO/TS 29843-2), or DNA (ISO 11063).

Toolbox E-III (Ecology): Impact on biological activity [e.g. litterbag test, microbial diversity tests, e.g. the quantification of soil microbial phyla as well as functional groups by qPCR assays (ISO 17601), diversity of the plant community and the soil invertebrate community].

NOTE In the UK framework, the cause–effect relationship is an integral part of the ecological risk assessment at a site to be assessed[25]. This step has not been included in this document because it is a possible but not always necessary step of the TRIAD approach.

6.4 Fourth step: Assessments at the different tiers: scaling, weighting and integrating results

6.4.1 General

This subclause gives an insight into some of the important decisions risk assessors have to make when conducting the soil quality TRIAD in practice, e.g. how to scale, weight and integrate the outcome of the various investigations at the individual tiers. It is based on Reference [36].

6.4.2 Quantification of results from terrestrial tests

Essentially, the results from all tests should be funnelled into the risk assessment framework. To be useful for risk assessment, the outcome from all tests in a WOE approach should therefore be made comparable across the various LoEs, e.g. by a uniform scaling method. This should preferably be done without losing quantitative information[8][70]. The primary aim is to maximize the utilization of the results of particular tests as quantitative as possible, and to use results from all tests together in a transparent and integrative scheme, e.g. in a decision matrix. Reference [8] reviewed several possibilities for disseminating final WOE findings and concluded that tabular decision matrices are the most quantitative and transparent ones. In order to derive a quantitative decision matrix for easy evaluation and integration of results from different tests in the soil quality TRIAD, it is proposed to use an effect scale running from 0 to 1, corresponding to no effect up to maximum effect. The results from each parameter (e.g. tests or ecological field survey) should be projected on this effect scale, according to best available knowledge or best professional judgments.

Different tests will obviously require different approaches. For instance, for a growth test, the percentage of inhibition can be used as the unit for effects directly. For ecological field monitoring, the results should be scaled relatively to the ecological state of the reference site (= 0) and a (theoretical) state indicating 100 % effects. Projection of test results on this effect scale requires experience and expertise. Once all results are scaled into a uniform effect value, the overall response of a set of methods, e.g. the chemical LoE, can be calculated.

6.4.3 Scaling in practise

A paramount issue when selecting tools for use in the soil quality TRIAD approach is the ability to scale the outcome of an assay. If the outcome of a method cannot be scaled from 0 to 1, it is not applicable in the context of the soil quality TRIAD approach presented here. However, it should, in principle, be possible to scale any tool, which has ecological relevance and ability to serve as an indicator of toxic stress, from 0 to 1. It may nevertheless sometimes need expert judgment to do so, wherefore basic knowledge of ecological risk assessment is an advantage. Scaling of results is usually not part of the description in standard guidelines. Therefore, some effort shall be given to this before initiating and conducting the studies on a case-by-case basis (detailed examples are given in Reference [36]).

6.4.4 Weighting

Besides the issue of scaling, attention should also be paid to the issue of weighting different tests, tiers and soil quality TRIAD LoEs. Some general principles can be put forward.

— The different LoE in the soil quality TRIAD should be equally weighted in the risk assessment, unless special considerations demand for a differential weight. The soil quality TRIAD is divided into three parts, each part has its own weaknesses and strengths. Together they form a strong starting point for the risk assessment according the principles of a balanced WOE approach.

— Within one LoE, attention should be given to different aspects of the ecosystem. The starting point can be equal weights for all organisms and processes, applying the following statement: “all organisms are unequal, but equally important”. Another possibility is to give important ecological functions or life support functions equal weights. A balanced soil quality TRIAD approach should address all the important functions of a soil ecosystem like production, decomposition and consumption. In specific cases, differential weighting between the different LoEs in the soil quality TRIAD may be needed.

Within an individual LoE of the soil quality TRIAD, differential weighting of tests may be applied for three possible reasons.

a) First, differential weights on the end points can be applied because of ecological considerations. This differential weighting should be defined in the investigation plan and agreed on by all stakeholders. This allows extra attention to specific (functional) groups, key species, and endangered or “charismatic” species.

b) The second reason for applying differential weights is to account for the uncertainty or variability within the end points. Tests with a high level of uncertainty, or with a high variability in results, may be given a smaller weight in the ERA[39].

c) The third reason for differential weight might correct for bias in measured and calculated effects. For instance, the geometric mean of the inverted effect value gives extra weight to those observations giving a positive response. This acknowledges the fact that many ecological field surveys are not able to demonstrate ecological effects, although in reality, these effects are present, for instance, in highly dynamic ecosystems. In such systems, money may be too tight to collect and analyse the necessary number of replicates to demonstrate a significant effect. Reference [13] used differentiated weights in the ERA for aquatic systems following a multi-criteria decision analysis. Effects on e.g. top predators and benthos received a higher weight than parameters such as mentum deformities. This information was used to rank different sites according to their possible risk for ecosystem quality. For the terrestrial system, less experience is available. Based on this discussion[36], weigh the results of each test or measurement equally. However, this decision has to be made on a case-by-case basis by the respective stakeholders.

6.4.5 Integration of results

Once the results have been scaled for each test, it is possible to integrate the results of the different tests in each of the lines of evidence (LoE). Finally, the integrated results from all three LoEs are further integrated into one “risk number” of the soil quality TRIAD[36][44]. The first integration process, i.e. within one LoE, aims to get a sufficient and complete set of information for estimating the risk of contamination. Different pieces of information are used together for this evaluation. For instance, the application of SSD adopts the reasoning that all organisms are important although they have a different sensitivity towards the contamination[6]. Furthermore, estimates of effects based on different exposure scenarios may be used together to account for species-specific differences in bioavailability.

In the second integration step, the independent pieces of information from the three LoEs are incorporated into one number of risks. Here, it is also evaluated to what extent the three LoEs indicate the same risk, wherefore a measure of deviation between the three LoE is added. A high deviation between the results of the three LoEs could also trigger further research, as more insight is necessary to draw a final conclusion on the ERA. The major advantage of this integration method is the use of numbers, instead of the more qualitative “+” and “–” symbols used by, for example, Reference [10]. By using risk numbers instead of risk symbols, less information is lost and information about the magnitude of the risk (high effect, small effect) is given. No definite limit for acceptable risk (or deviation of risk) can be given. This may vary according to the land use of the site as well as the decisions made by stakeholders. In case of high deviation, two approaches can be taken. More research is conducted to lower the uncertainty or the high uncertainty is accepted but as a result of this, a less sensitive land use should be chosen.

6.5 Fifth step: Decision on how to proceed

Based on the results of the soil quality TRIAD investigation and the agreed assessment criteria, a decision has to be made which meets the investigation objective. This decision forms the actual result of the investigation process and is therefore set out in writing and then discussed with all the parties involved. Strictly speaking, the result of a soil quality TRIAD would be to indicate whether there is an ecological risk at a given site or not — but not to say how to handle that risk.

NOTE 1 Depending on the investigation objective, this decision can form the basis for soil management measures, e.g. the need for a clean-up of the site or whether or not to take specific measures to reduce ecological risks.

NOTE 2 Details of this step depend highly on the national regulations and practices. So, in any case, decision-making is made in close contact with competent authorities.

7 Reporting

The investigation report includes at least the following:

a) the following passage: “The investigation was carried out in accordance with ISO 19204”. If one or more points in this document has/have been deviated from, this is added to the above passage and the deviations are described explicitly and explained;

b) soil and site details, such as its coordinates, vegetation, land use (also its history), climate, soil properties, contamination, ecological characteristics (e.g. occurrence of protected species);

c) the stakeholder details (as a minimum: the land owner and the competent authority);

d) the investigators’ (if appropriate, also consultants) details;

e) the investigation objective;

f) the results of each step in the assessment (see also Figure 1);

g) the selected assessment parameters with associated agreements about references, scales, weighting and assessment criteria;

h) a description with reasons for the investigation design (for example, by adding the investigation plan in the appendix);

i) a description of the work carried out for the soil quality TRIAD study (sampling method and numbers, chemical analyses, ecotoxicological tests, field observations);

NOTE Sampling details can be found in References [28] and [40], ISO 18400-101, ISO 18400-102, ISO 18400-103, ISO/DIS 18400-104, ISO 18400-105, ISO 18400-107 and ISO/CD 18400-206.

j) possible peculiarities or irregularities that occurred during the implementation of the investigation and an evaluation of the consequences of these for the results and conclusions;

k) results of the soil quality TRIAD study:

— all raw and unscaled investigation results (in transparent tables as much as possible);

— all the scaled results together in a transparent table (example given in Reference [60]). The effect size per soil quality TRIAD line of evidence is included after the weighting of selected parameters;

l) description of the uncertainties and the evaluation of the investigator (or consultants) as to whether the uncertainties have been insufficiently reduced in this investigation to be able to satisfy the subject of the investigation;

m) an overview of the arguments that result in the decision as to whether measures should be recommended to reduce the ecological effects (risk reduction) as part of the soil management.

The minimum requirements set for the reporting also apply to small sites and simple assessments. In the case of these sites, selections of parameters and the choice of assessment criteria are not unique and a reference to a relevant source is sufficient (for example, Reference [40]). In the case of larger or complex cases, additional requirements can be set for the reporting, such as the reasons for certain choices. A unique investigation approach and interpretation should in any case be described and the content should be justified. In the case of a non-unique approach, references to relevant sources are sufficient.

Annex A
(informative)

Bioindicators of effect and accumulation — Additional tools for site-specific ecological risk assessment

Measurements of contaminants in plants, soil invertebrates and/or some vertebrates like small mammals inform on the transfer of contaminants (at least those that are not degraded in organisms) from soil to organisms and are now operational tools of site-specific risk assessment. Reference values that can be used to interpret bioaccumulation data for a site-specific risk assessment exist for plant communities, snails and small mammals (https://ecobiosoil.univ-rennes1.fr/ADEME-Bioindicateur/english/worksheet.php).

Data on bioaccumulation in organisms are also necessary to evaluate the food web transfer of contaminants that can possibly cause secondary poisoning (i.e. transfer and toxic effect of contaminants from first level of food chain to consumers belonging to higher levels[51]; review in Reference [14]). Some models already exist to evaluate the risk of and link to secondary poisoning [for example, Berisp (Breaking Ecotoxicological Restraints In Spatial Planning) or Terrasys (http://sanexen.com/terrasys/quest-ce-que-terrasys/)]. These models need validated data on concentration of contaminants in food items belonging to the basis of food chain (primary producers, soil invertebrates). Concentrations in plants or soil invertebrates can be modelled on the basis of soil contamination. Nevertheless, when considering a particular site, the use of site-specific experimental data may improve the risk assessment and reduce the uncertainty factors that may be included at several steps of the process where using modelled data. Bioaccumulation assessment in the various animals (see review for invertebrates and vertebrates in Reference [14]) can provide important information on the bioavailability of contaminants in soils.

Measurements of bioaccumulation in plants or soil organisms are thus useful to:

— assess the effective bioavailability of contaminants in soil to organisms;

— approach the food chain transfer and the risk of secondary poisoning of consumers.

In some cases, bioaccumulation can be associated with toxic effects but this is not always the case (see ISO 17402). For example, high concentrations in earthworms or snails or plants can be well supported by these organisms but can cause cumulative exposure of and toxicity for their consumers[33][62].

Bioaccumulation assessment can be implemented in Tier II or in Tier II and Tier III (e.g. in plants[52] or snails[46][48][49] or both plants and snails[49] or small mammals (https://ecobiosoil.univ-rennes1.fr/ADEME-Bioindicateur/english/WS/WS16-Micromammals.pdf). Some site-specific studies already demonstrate the interest of using effect and bioaccumulation indicators for a site-specific risk assessment[47][49].

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